Corporate Report
2019

Be passionate challengers

Year ended March 31, 2019

ONO PHARMACEUTICAL CO.,LTD.

Corporate Philosophy

Dedicated to Man's Fight against Disease and Pain

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.

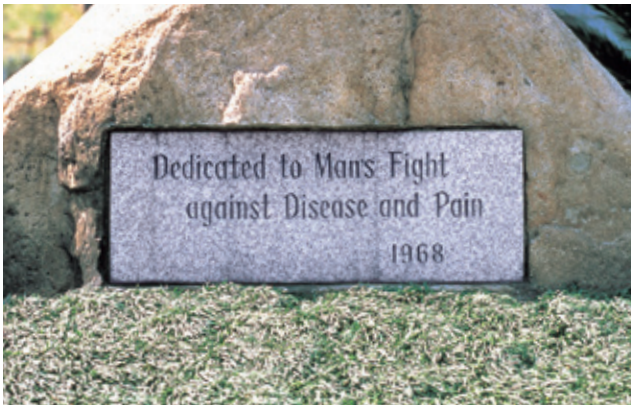
Our Values

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

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, built in 1968. ONO will remain firm to our corporate philosophy and dedicate ourselves to developing pharmaceutical products that benefit health and healthcare.



External ESG Assessment of ONO PHARMACEUTICAL

■ ONO included in premier indices for socially responsible investment (SRI)

FTSE4Good Index Series
Created by FTSE Russell to measure the performance of companies demonstrating strong ESG practices

FTSE Blossom Japan Index
Created by FTSE Russell, designed as an industry neutral benchmark that reflects the performance of Japanese companies demonstrating strong ESG practices

MSCI Japan ESG Select Leaders Index
Designed to target companies that have relatively high ESG performance

■ Recognition of ONO's environmental performance

2018 CDP Climate Change A List
Global accreditation by international environmental NGO CDP to name the world's top-rate businesses leading on environmental performance in climate change

■ Recognition of ONO's environmental and safety & health performance

2019 Certified Health & Productivity Management Outstanding Organization Recognition Program "White 500"
ONO recognized as a company engaging in strategic health and productivity management program efforts for maintaining its employees' health from a management perspective

Contents

■ 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 Report
● Scope 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, 2018 through March 31, 2019
✻ The report is based on activities in FY2018, the period for the financial reports, however, considering the importance of providing the most up-to-date information, some activities conducted in and after April 2019 are also covered.

■ Reference Guidelines
Sustainability Reporting Guidelines Standard by Global Reporting Initiative (GRI)
ISO 26000: 2010 (Guidance on social responsibility)
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 2019

■ 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.

To Achieve Sustained Growth And Continue Being Needed by Society, ONO PHARMACEUTICALS Works Toward Solving Issues Facing Society Respecting its Corporate Philosophy

Since our establishment in 1717, we have upheld the corporate philosophy “Dedicated to Man’s Fight against Disease and Pain,” and remain fully committed to the pharmaceutical business we engage in. We have united our efforts in meeting our challenge.
Making progress for more than 300 years, we have seen social conditions keep on changing but people’s desire to stay healthy and our mission of delivering innovative drugs to patients around the world have been and will be unchanged.
To achieve sustained growth, I believe we must respond rapidly with agility to any changes that challenge our operations. We must also fulfill our responsibility to all stakeholders including not only patients and healthcare professionals but also shareholders and investors, suppliers, local communities, and employees.

The environment surrounding healthcare, both inside and outside Japan, is changing significantly at astonishing speed.
In many developed countries, populations are aging with birth rates declining, and in emerging countries and developing countries, populations are increasing with longer average life expectancies. With these circumstances, increased social security costs are becoming a matter of public concern. Especially, Japan is facing significant increases in medical and nursing care costs, making it harder to secure funding. The country therefore is proceeding with healthcare cost reduction measures including the fundamental review of the NHI drug pricing system.
In addition, changes in disease structure and past innovations have shifted targets with unmet medical needs for drug discovery and development to more complicated diseases. As a result, the success rates of drug discovery have dropped and development periods have been prolonged with increased R&D costs, challenges that pharmaceutical companies have to address.

Meanwhile, life science and medical technology are developing rapidly in scientific and technological advances. In addition, information and engineering technologies are growing more sophisticated and open innovation is progressing, creating merges not limited to within pharmaceutical/healthcare fields. I believe therefore we can be committed to solving many of the challenges as a pharmaceutical company.

Our destination beyond growth is to be a Global Specialty Pharma company, priding ourselves in the original and innovative new drugs we offer and in competing in the global arena. Embracing a wide range of values and hiring a diverse workforce, we are determined to take advantage of our strengths to the fullest extent to work toward that goal.

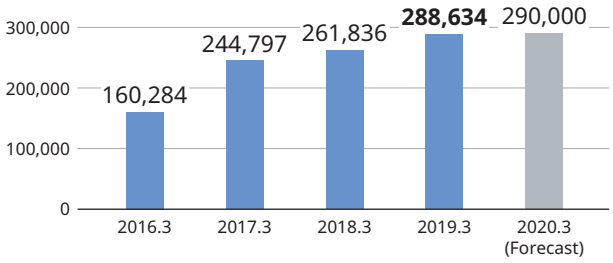
Holding up dignity and pride as a company that engages in the business of pharmaceuticals that impact human lives, we remain acutely aware of our social responsibility and will constantly face up to the challenge of disease and pain.
We highly appreciate your continued and most generous support and cooperation in these endeavors.

Gyo Sagara
President, Representative Director, and CEO

Highlights 2018/4-2019/3
Financial/Non-Financial Highlights

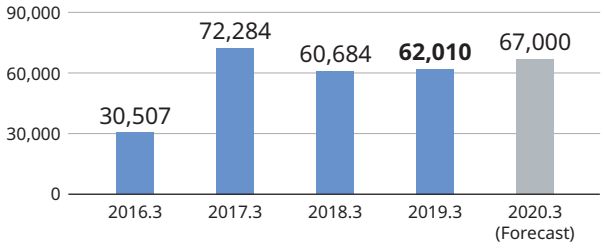
Financial Information

Revenue (Millions of Yen)



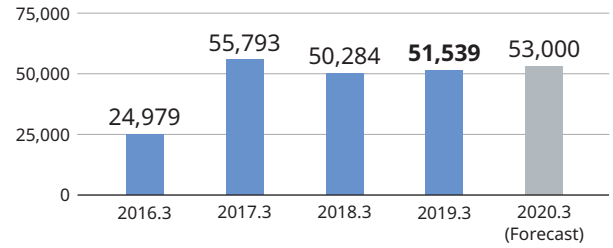
Increased by 10.2% year-on-year due to increased royalty revenue and expanded sales of new key products offsetting the negative impact of the OPDIVO price revision in Japan.

Operating profit (Millions of Yen)



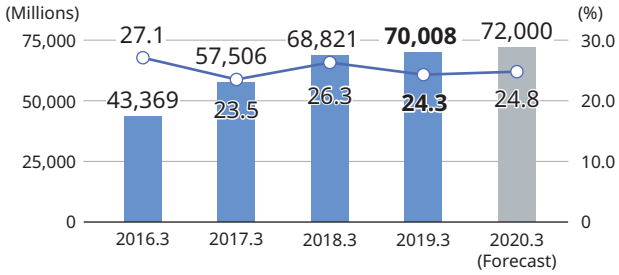
Increased only by 2.2% year-on-year due to increased R&D costs and SG&A expenses, as well as increased sales costs associated with temporary payment for stable supply of OPDIVO APIs.

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



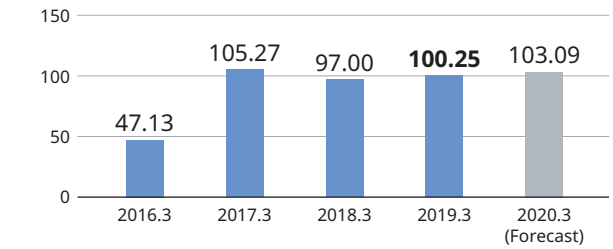
Net financial income decreased from the previous year but the profit before tax increased by 2.5% compared to the previous year due to increased operating profit.

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



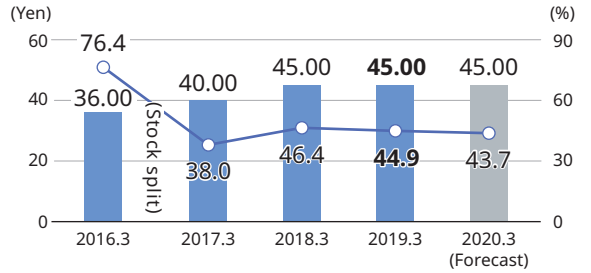
Increased by 1.7% compared to the previous year due to increased OPDIVO-related clinical trials and increased license fees for drug discovery alliance, in active pursuit of R&D activities.

Basic earnings per share (Yen)



The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. The figures are calculated assuming that the stock split was conducted at the beginning of the fiscal year ended March 31, 2016.

Dividend per share / Consolidated payout ratio (Yen / %)

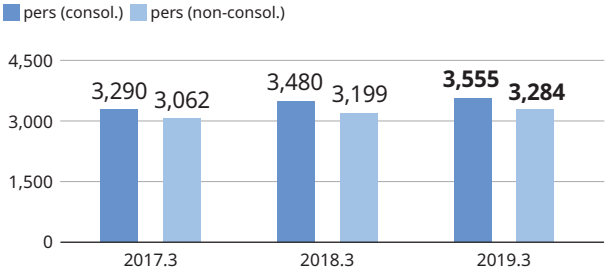


ONO considers the redistribution of profits to shareholders as a vital management policy. ONO will prioritize stable dividend distribution, making appropriate distribution of its profits in line with its business performance.

The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. The figures are calculated assuming that the stock split was conducted at the beginning of the fiscal year ended March 31, 2016.

Non-Financial Information

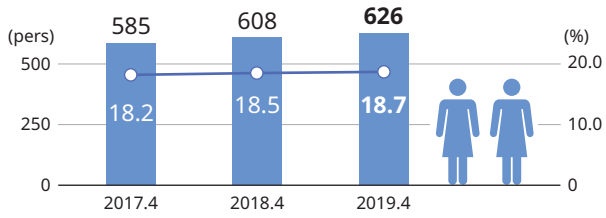
Number of employees



We recruit not only new graduates but also midcareer workers and others with a variety of different backgrounds to strengthen our corporate infrastructure.

▶ Human Resources and Human Rights, p. 045

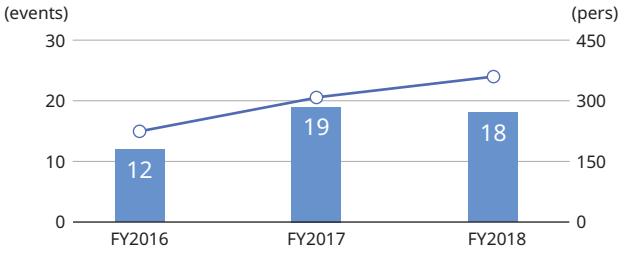
Number of female employees / Ratio of female to male workforce



As part of diversity promotion initiatives, we have made efforts to promote women's participation and advancement in the workplace, and female employees have increased in number across all divisions since 2011.

▶ Human Resources and Human Rights, p. 045

Participation record for “Relay For Life” as part of CSR activities

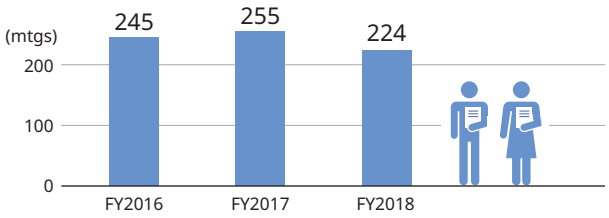


Since FY2014, we have continuously participated in “Relay For Life,” a charity event aimed at supporting cancer patients and their families and making cancer controllable and surmountable through community action against cancer.

▶ Society, p. 049

Meetings with institutional investors

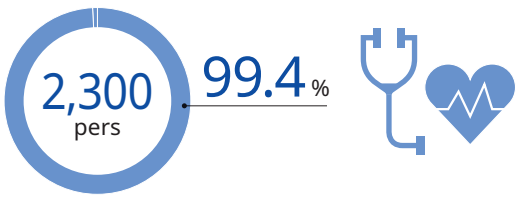
(personal interviews/phone conferences)



We disseminate information based on the policy of pursuing accuracy, fairness, impartiality, and promptness. We actively hold personal interviews and phone conferences with investors inside and outside Japan.

▶ Information Disclosure, p. 038

Comprehensive medical examination rate (FY2018)

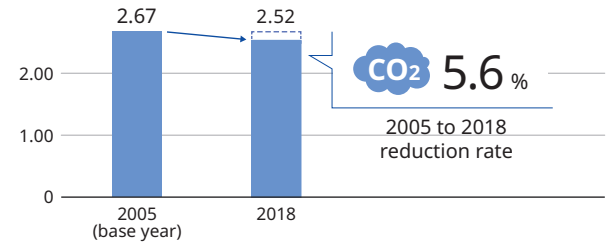


We take a top-down approach to actively maintaining and enhancing the health of employees and their families. We have a support system in place for disease prevention, early detection, and treatment.

▶ Promotion of Health and Productivity Management, p. 047

Eligibility: Insured employees age 35 and over, and their dependent spouses

Energy-derived CO_2 emissions (10,000 tons-CO_2)



In accordance with our environmental policy, we set and work to achieve numerical targets.

▶ Global Environment, p. 051

Sites where data were collected: Fujiyama Plant, Joto Plant, Minase Research Institute, Fukui Research Institute, Tsukuba Research Institute.

Highlights 2018/4-2019/3
Calendar of Events FY2018

R&D Topics

Development
New drugs launch, additional indication approval acquisition, and other achievements

Anticancer Drug OPDIVO Approved for Additional Cancer Indications around the World

- **Japan**: May Melanoma (first-line therapy/combination with YERVOY Injection); August Malignant pleural mesothelioma; August Melanoma (adjuvant therapy); August Renal cell carcinoma (first-line therapy/combination with YERVOY Injection)
- **South Korea**: October Renal cell carcinoma (first-line therapy/combination with YERVOY Injection)
- **Taiwan**: November Renal cell carcinoma (first-line therapy/combination with YERVOY Injection)
- **US**: April Renal cell carcinoma (first-line therapy/combination with YERVOY Injection)
  July MSI-H/dMMR metastatic colorectal cancer (first-line therapy/combination with YERVOY Injection); August Small cell lung cancer

Alliance
Various Types of Strategic Partnerships Promoted Including Drug Discovery Collaborations and Co-development

May New industry-academia cooperation "Immune-mediated Inflammatory Diseases Consortium for Drug Discovery" established by three academic institutions and three pharmaceutical companies in Japan

August Clinical development collaboration agreed with Takeda Pharmaceutical on combination therapy of OPDIVO and multi-kinase inhibitor "cabozantinib"

August Clinical development collaboration agreed with Bristol-Myers Squibb and Clovis (US) on combination therapy of OPDIVO and PARP inhibitor "rucaparib"

2018/4 | 2018/5 | 2018/6 | 2018/7 | 2018/8 | 2018/9

ESG Topics

March to May

Society

After action program of Great East Japan Earthquake reconstruction assistance activity "Operation Slimmer and Healthier in Fukushima" conducted

Activities aimed at conveying the joy of sports and exercises to children of the disaster affected areas

June

Society

Activity contributing to the local community conducted during "Dental and Oral Health Week"

Donating teeth-brushing packs and toothbrushes, produced by an ONO subsidiary company, to the elementary schools, kindergartens and nursery centers near the Minase Research Institute, and the elementary schools near Joto Plant

June

Governance

Number of outside directors increased to three

One new outside director with extensive experience and deep insight as a business executive, invited to join the board to strengthen ONO's corporate governance

August

Society

"ONO SWITCH Project" launched

A project that passes overtime payments reduced through the reform of working style to society and employees

October

Society

Outreach class program "Secrets of Pharmaceuticals!" conducted

Continued conduct of outreach classes for students of the elementary schools near the Minase Research Institute

■ **Europe**: August Melanoma (adjuvant therapy); January Renal cell carcinoma (first-line therapy/combination with YERVOY Injection)
June Oral prostaglandin E_1 analogue "limaprost" approved in Thailand (marketed by Thai Meiji Pharmaceutical Co., Ltd.) for treatment of lumbar spinal stenosis
February Anticancer drugs BRAFTOVI Capsule and MEKTOVI Tablet launched for treatment of malignant melanoma
February Tyrosine hydroxylase inhibitor DEMSER Capsule launched for improvement of status of catecholamine excess secretion in pheochromocytoma
March Short-acting selective β_1 blocker ONOACT for Intravenous Infusion approved for additional indication of ventricular arrhythmia
March Selective SGLT2 inhibitor FORXIGA Tablets approved for additional indication of type 1 diabetes

September Collaboration agreed with Fate (US) for discovery and development of off-the-shelf, iPSC-derived CAR T-cell drugs
January Strategic partnership agreed with Repare (Canada) for Pol-theta inhibitor development and commercialization
March Research collaboration agreed with twoXAR (US) for discovery and development of neurological disease drugs using AI technology
March Drug discovery collaboration agreed with Vect-Horus (France) for discovery and development of neurodegenerative disease drug candidates
March Strategic drug discovery alliance agreed with Cancer Research UK and LifeArc (UK) for cancer immunotherapy

2018/10 | 2018/11 | 2018/12 | 2019/1 | 2019/2 | 2019/3

November

Society

Raising for Osaka Marathon charity

Employees participated as charity runners and donated all contributions collected to the certified NPO Cancer Support Community Japan

January

Environment

ONO selected as a 2018 CDP Climate Change A List Company

ONO earned a top rating as a global leader acting on climate change

CDP A LIST 2018 CLIMATE CHANGE

March

Society

Great East Japan Earthquake reconstruction assistance activity "Operation Slimmer and Healthier in Miyagi" conducted

Activities aimed at conveying the joy of sports and exercises to children of the disaster affected areas

February

Society

ONO recognized under the 2019 Certified Health & Productivity Management Outstanding Organization Recognition Program "White 500"

ONO recognized as a company engaging in strategic health and productivity management program efforts for maintaining its employees' health from a management perspective

February

Environment

ONO received Osaka Stop Global Warming Award excellence prize

ONO awarded as a business in Osaka Prefecture engaging in excellent efforts to reduce greenhouse gas emissions and to level electricity demand

History of Tackling Challenges

We are always committed to meeting our challenges to discover innovative drugs.

Transforming from an apothecary to a pharmaceutical manufacturer

Tackling **"Impossible Challenge"**: Prostaglandins

1962
Professor Bergström determined the chemical structure of PGE_1, $PGF_{1\alpha}$, etc.

1965
PGs came to ONO's knowledge and ONO launched PG research.

1968
ONO became the world's first company to succeed in the total chemical synthesis of PGs.

1974
ONO successfully developed and launched the world's first PG drugs on the market.

The History of our Prostaglandin Research

Established as an apothecary in 1717, ONO transformed into a full-fledged company with both manufacturing and sales functions in the 1947.
In 1965, motivated by the lecture of Dr. Bergström (later Nobel Prize winner) on invitation to the Association for Gerontological Research conference, ONO launched research on the bioactive lipid prostaglandins (PGs) to gamble its future. At that time, PGs were said to be dream substances that had all possibilities to have major impact on pharmaceutical development. However, there was doubt that PGs could be commercialized as pharmaceuticals because they are produced in trace amounts *in vivo* and unstable substances that are lost in a short time. A team of a mere 20 researchers tackled PG biosynthesis, despite the lack of funding and research facilities, successfully producing PGs for research use. The team planned and tried to mass-produce PGs by chemical synthesis but didn't achieve this end.
In 1967, ONO sent its researchers to Professor Corey (later Nobel Prize winner), who pioneered the total chemical synthesis of PGs, to have them learn its process. In 1968, ONO succeeded in the total chemical synthesis of PGs on a commercial basis for the first time in the world.

Contribution to Healthcare

It took 9 years since the start of PG research before ONO launched the world's first PG drug on the market in 1974 and has since delivered 11 PG related products to patients.

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ONO has channeled its abundant resources including research staff into drug discovery research in PGs, while driving forward R&D collaborations with academia as well as pharmaceutical companies both inside and outside Japan.
The world's first PG products ONO developed and marketed were those in obstetrics and gynecology, and ONO subsequently developed and launched drugs to meet healthcare frontline needs in a wide range of domains including cardiovascular medicine, gastroenterology, and respiratory medicine. ONO has so far brought 12 items of PG products into the world.

Tackling **"New Conceptual Challenge"**: Anti-PD-1 Antibody

1992

Kyoto University isolated and identified PD-1 gene.

2002

PD-1 was found to be involved in immune evasion in cancer.

2006–

Clinical trials using anti-PD-1 antibody started in the US in 2006 and in Japan in 2008.

2014

The antibody was launched in Japan for the first time in the world as a therapeutic drug against melanoma.

The History of our Anti-PD-1 Antibody Research

PD-1 was discovered at Kyoto University and ONO started a research collaboration with the university in 1992. The functions of PD-1 had long been unknown. The researchers discovered in 1998 that PD-1 knockout mice develop autoimmune diseases, and found in 2002, 10 years after the identification of PD-1, that it plays a role in cancer immune evasion mechanism.
At that time, ONO was internally not positive to the research project as the company had no experience in anticancer drug development and no antibody generation technology. There was also a strong perception among healthcare professionals that was suspicious of the concept of treating cancer by boosting the immune system. This was a big hurdle that stood in the way of finding a joint development partner and seeking understanding from medical institutions to perform clinical trials. However, the R&D team was persistently committed to the project, without any preconceived ideas, believing in the potential of anti-PD-1 antibody. Their efforts changed the mindset within the company, which led to understanding and cooperation from healthcare professionals.
In 2014, when 22 years passed since the discovery of PD-1, the company obtained marketing approval for and launched cancer immunotherapy OPDIVO.

Contribution to Healthcare

Conventionally, the three pillars of cancer treatment have been surgery, chemotherapy (pharmacotherapy), and radiation therapy. They are added to by a novel approach to treatment brought about by OPDIVO, of which the action mechanism releases the brakes that cancer cells put on the body's immune system. This is accordingly considered as an innovative approach and cancer immunotherapy is currently expected as the "4th cancer therapy." It offers a new treatment option to healthcare professionals as well as patients for which traditional treatments have little therapeutic effect.

Further Innovation

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OPDIVO has an action mechanism that does not directly attack cancer cells but utilizes the immune system to fight cancer, raising expectations for its potential to be effective across a wide range of tumors. Since marketing approval for melanoma in 2014, the drug has been approved up to June 2019 for 11 tumor types around the world, including non-small cell lung cancer, renal cell carcinoma, and gastric cancer. Clinical trials are still ongoing to obtain approval for additional tumor types.

Key Product Profiles

ONCOLOGY

Sales in FY2018 | Percentage increase/decrease from FY2017

OPDIVO

Intravenous Infusion for the Treatment of Malignant Tumors

90.6 billion yen
+0.5%

OPDIVO is an anticancer drug approved in Japan for cancer immunotherapy targeting PD-1, a world first. It is an immune checkpoint inhibitor that reactivates antitumor immune response using the body's own immune system.
In Japan, since its launch to the market in September 2014, OPDIVO has been approved for 7 types of cancer (as of June 2019). Despite the influence of NHI drug price reduction, OPDIVO expanded sales in FY2018 to 90.6 billion yen thanks to an increase in volume terms mainly resulting from addition of cancer indications.

In the world except Japan, South Korea and Taiwan, ONO's partner Bristol-Myers Squibb (US) has obtained regulatory approval in more than 60 countries for the treatment of several types of cancer and has been proceeding with adding indications for other cancers. Accordingly, royalty income based on OPDIVO sales overseas increased to 58.5 billion yen for FY2018.

Competition is heating up in development and marketing of cancer immunotherapy inside and outside Japan, especially in the lung cancer area. While promoting OPDIVO's proper use and collecting information on its safety, ONO is working hard on adding indications for other cancers, extending the therapy line as well as developing combination therapies. ONO will continue working to maximize OPDIVO's value.
In the drive to add more indications to OPDIVO, ONO is currently working to obtain approval for more than 20 additional cancer indications. In Japan, ONO applied for approval of partial changes in approved items for treatment of advanced or recurrent MSI-H or dMMR colorectal cancer in March 2019 and unresectable advanced or recurrent esophageal cancer in May 2019.

KYPROLIS

for Intravenous Injection for the Treatment of Malignant Tumors

4.9 billion yen
-11.1%

KYPROLIS is a highly selective anti-multiple myeloma drug that inhibits the action of proteasome, an enzyme complex within human cells, thereby causing functional cell death of myeloma cells. The sales of KYPROLIS reached 4.9 billion yen in FY2018.
Multiple myeloma is a hematological malignancy caused by abnormality of plasma cells in the bone marrow. Although several regimens for multiple myeloma are currently available, the disease progresses in remitting-relapsing nature and eventually no longer responds to therapy, also known as refractory disease. Additionally, adverse drug reactions and co-morbid conditions have been reported following long-term treatment, making continued treatment difficult.
Amid increased competition from the fast-paced launch of new anti-multiple myeloma drugs, ONO reviewed the framework for information dissemination activities in October 2018 to conduct the activities with higher levels of expertise.
In March 2019, ONO submitted supplemental application of KYPROLIS. With the current dosage and administration, KYPROLIS should be given twice a week. This application is intended for approval for once-weekly administration.

ONCOLOGY

EMEND Capsules / PROEMEND

for Intravenous Injection for the Treatment of Chemotherapy-induced Nausea and Vomiting

10.6 billion yen
+6.6%

EMEND / PROEMEND is the first selective neurokinin (NK) 1 receptor antagonist in the world. It is effective for chemotherapy-induced nausea and vomiting.
More patients with cancer are treated with immunotherapy drugs and a smaller number of patients are using an anticancer drug with high emetogenic risk. Meanwhile, following major overseas guidelines, including NCCN Guidelines and ASCO Guidelines, antiemetic guidelines issued by Japan Society of Clinical Oncology released in October 2018 have recommended the use of EMEND for patients using an anticancer drug with moderate emetogenic risk, and the use of EMEND is expanding. The FY2018 sales of EMEND / PROEMEND increased by 6.6% to 10.6 billion yen from the previous year.

DEMSER Capsule

for the Improvement of Status of Catecholamine Excess Secretion in Pheochromocytoma

Launched in February 2019

DEMSER is a promising drug with an efficacy in the improvement of the symptoms in patients with pheochromocytoma (PC), a neuroendocrine tumor, who are not able to sufficiently control the symptoms caused by catecholamine excessively secreted from PC—including hypertension, tachycardia, headache, palpitation—with sympatholytic drugs which have been usually used.
Launched to the market in February 2019, DEMSER is a product for which development companies were recruited in Japan at the “Review Committee on Unapproved or Off-label Drugs with High Medical Needs,” established by the Ministry of Health, Labour and Welfare (MHLW), and ONO has been developing this product. In May 2015, the product was designated for the orphan drug by the MHLW.

BRAFTOVI Capsule and MEKTOVI Tablet

for the Treatment of Malignant Tumors

Launched in February 2019

BRAF inhibitor BRAFTOVI and MEK inhibitor MEKTOVI suppress the proliferation of tumors by targeting and selectively inhibiting the key enzymes of BRAF and MEK1/MEK2, respectively, which are different kinases associated with cancers. The combination therapy is expected to provide more potent anti-tumor effects.
BRAFTOVI and MEKTOVI were launched in February 2019 for use in combination therapy for the indication of unresectable melanoma with a BRAF mutation. Currently, the drugs are undergoing clinical trials for BRAF-mutated metastatic colorectal cancer.

Key Product Profiles

NEW PRODUCTS | Sales in FY2018 | Percentage increase/ decrease from FY2017

GLACTIV Tablets

for the Treatment of Type 2 Diabetes

26.9 billion yen

–1.8%

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 metabolizes 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. Impacted by competitors such as combination drugs and once-weekly administered formulations in addition to the NHI drug pricing reform, the sales of GLACTIV for FY2018 decreased 1.8% to 26.9 billion yen from the previous year. Appealing the strength of GLACTIV with data of clinical trials in Japanese elderly patients and a large amount of efficacy and safety information accumulated through its long-term use by patients in Japan, ONO will carry on its effort at earning its reputation for GLACTIV Tablets being the first-choice drug in treatment of type 2 diabetes.

ORENCIA

for Subcutaneous Injection for the Treatment of Rheumatoid Arthritis

17.4 billion yen

+23.3%

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 suppression of joint inflammation. The RA drug market is becoming more competitive due to the entrance of generic versions of widely used TNF inhibitors and competing auto-injectors. With the entire RA drug market growing, however, ORENCIA for subcutaneous injection is seeing increased use, well evaluated by healthcare professionals in terms of both efficacy and safety. ONO will continue directing efforts toward raising patients' quality of life. The sales of ORENCIA for FY2018 increased 23.3% to 17.4 billion yen from the previous year.

FORXIGA Tablets

for the Treatment of Diabetes

14.5 billion yen

+31.0%

FORXIGA is an oral drug for the treatment of diabetes. This drug 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. With evidence accumulated for suppressing cardiovascular events, SGLT2 inhibitor is earning growing reputation. Its sales for FY2018 increased 31.0% to 14.5 billion yen from the previous year. In March 2019, FORXIGA was approved for additional indication of type 1 diabetes.

RIVASTACH Patch

for the Treatment of Alzheimer's Disease

8.9 billion yen

+0.2%

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 (inability to recognize time and place) by inhibiting acetylcholinesterase and thereby increasing the amount of acetylcholine in the brain and enhancing neurotransmission. While antidementia drug needs are increasing, acetylcholinesterase inhibitor sales are affected by generic drug use expansion. The sales of RIVASTACH for FY2018 increased 0.2% to 8.9 billion yen from the previous year. In March 2019, ONO obtained approval for the formulation containing a new base of RIVASTACH Patch with a synthetic rubber.

NEW PRODUCTS

PARSABIV Intravenous Infusion

for Dialysis for the Treatment of Secondary Hyperparathyroidism in Patients on Hemodialysis

5.7 billion yen
+66.8%

PARSABIV is a drug to treat secondary hyperparathyroidism, a complication of chronic renal failure. The drug reduces the excessive secretion of the parathyroid hormone by activating the calcium-sensing receptor in the parathyroid glands and lowers the phosphorus and serum calcium levels in the blood. With the market becoming more competitive due to the entrance of competing products, PARSABIV has been adopted by more than 80% of all the dialysis facilities in the country and its use is gradually expanding. The sales of PARSABIV for FY2018 increased 68.8% to 5.7 billion yen from the previous year.

ONOACT

for Intravenous Infusion for the Treatment of Tachyarrhythmia

4.6 billion yen
–18.5%

ONOACT is a short-acting β_1 blocker that selectively blocks β_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). In March 2019, ONOACT was approved for additional indication of ventricular arrhythmia. It is expected that ONOACT can contribute to the therapy of fatal arrhythmia requiring emergency treatment.

STAYBLA Tablets

for the Treatment of Overactive Bladder (OAB)

3.7 billion yen
–10.6%

STAYBLA is a selective anticholinergic antagonist binding to muscarinic acetylcholine M3 and M1 receptors. It comes in two types, regular and orodispersible (OD) tablets. It improves urge to urinate, frequent urination, and urge incontinence, the symptoms of overactive bladder, by suppressing excessive contraction of smooth muscle in the bladder.

OTHER KEY PRODUCTS (LONG-TERM LISTED PRODUCTS)

OPALMON Tablets

for the Treatment of Peripheral Circulatory Disorder

10.4 billion yen
–27.9%

OPALMON is an orally administered prostaglandin-E_1 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.

RECALBON Tablets

for the Treatment of Osteoporosis

7.3 billion yen
–32.8%

RECALBON, the first oral bisphosphonate (BP) discovered in Japan for the treatment of osteoporosis, is a powerful bone resorption inhibitor. It has been verified against placebo of fracture prevention effectiveness in Japanese osteoporosis patients. With the entire BP market shrinking due to strategies to promote generics use, RECALBON is also affected by the generic products launched in June 2018.

ONON Capsules
ONON Dry Syrup

for the Treatment of Bronchial Asthma and Allergic Rhinitis

4.4 billion yen	–20.0%
2.7 billion yen	–19.1%

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

Status of Development Pipeline (As of July 26, 2019)

Main Status of Development Pipelines (Oncology)

Product (Development Code)	Pharmacological Action, etc.	Proposed Indication	Development Stage	Area	
ONO-7643 / Anamorelin	Ghrelin mimetic	Cancer anorexia / cachexia	Filed	(JP)	In-license (Helsinn Healthcare)
Kyprolis for Intravenous Infusion	Proteasome inhibitor	Multiple myeloma	Filed	(JP)	In-license (Amgen)
Opdivo Intravenous Infusion	Human anti-human PD-1 monoclonal antibody	Colorectal cancer	Filed	(JP)	Co-development with Bristol-Myers Squibb
			Ⅲ	(EU)	
		Esophageal cancer	Filed	(JP)	
			Ⅲ	(KR, TW, US, EU)	
		Gastric or esophago-gastric junction cancer	Ⅲ	(JP, KR, TW, US, EU)	
		Small cell lung cancer	Ⅲ	(JP, KR, TW, EU)	
		Hepatocellular carcinoma	Ⅲ	(JP, KR, EU)	
		Glioblastoma	Ⅲ	(JP, US, EU)	
		Urothelial carcinoma	Ⅲ	(JP)	
		Ovarian cancer	Ⅲ	(JP, US, EU)	
		Bladder cancer	Ⅲ	(JP, KR, TW, US, EU)	
		Multiple myeloma	Ⅲ	(US, EU)	
		Gastric cancer	Ⅲ	(US, EU)	
		Malignant pleural mesothelioma	Ⅲ	(US, EU)	
		Solid tumors (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Ⅱ	(JP)	
		Central nervous system lymphoma, Primary testicular lymphoma	Ⅱ	(JP, US, EU)	
		Pancreatic cancer	Ⅱ	(JP, KR, TW, US, EU)	
		Virus positive / negative solid carcinoma	Ⅱ	(JP, KR, TW, US, EU)	
		Diffuse large B cell lymphoma	Ⅱ	(US, EU)	
		Follicular lymphoma	Ⅱ	(US, EU)	
		Prostate cancer	Ⅱ	(US, EU)	
		Solid tumors (Triple negative breast cancer, Gastric cancer, Pancreatic cancer, Small cell lung cancer, Urothelial carcinoma, Ovarian cancer)	Ⅱ	(US, EU)	
		Biliary tract cancer	Ⅰ	(JP)	
		Hematologic cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	Ⅰ	(US, EU)	
		Chronic myeloid leukemia	Ⅰ	(US, EU)	
Yervoy Injection	Anti-CTLA-4 antibody	Non-small cell lung cancer	Ⅲ	(JP, KR, TW)	Co-development with Bristol-Myers Squibb
		Small cell lung cancer	Ⅲ	(JP, KR, TW)	
		Head and neck cancer	Ⅲ	(JP, KR, TW)	
		Gastric cancer	Ⅲ	(JP, KR, TW)	
		Malignant pleural mesothelioma	Ⅲ	(JP)	
		Esophageal cancer	Ⅲ	(JP, KR, TW)	
		Urothelial carcinoma	Ⅲ	(JP, KR, TW)	
		Virus positive / negative solid carcinoma	Ⅱ	(JP, KR, TW)	
BRAFTOVI Capsule	BRAF inhibitor	Colorectal cancer	Filed	(JP)	In-license (Array BioPharma)
MEKTOVI Tablet	MEK inhibitor	Colorectal cancer	Filed	(JP)	In-license (Array BioPharma)
ONO-7701 (BMS-986205)	IDO1 inhibitor	Bladder cancer	Ⅲ	(JP, KR, TW)	Co-development with Bristol-Myers Squibb

Product (Development Code)	Pharmacological Action, etc.	Proposed Indication	Development Stage I	II	III	Filed	Area	
ONO-7702 / Encorafenib	BRAF inhibitor	Colorectal cancer	→				(KR)	In-license (Array BioPharma)
		Melanoma	→				(KR)	
ONO-7703 / Binimetinib	MEK inhibitor	Colorectal cancer	→				(KR)	In-license (Array BioPharma)
		Melanoma	→				(KR)	
ONO-4687 (BMS-986227) / Cabiralizumab	Anti-CSF-1R antibody	Pancreatic cancer		→			(JP, KR, TW)	Co-development with Bristol-Myers Squibb
ONO-4059 / Tirabrutinib	Bruton's tyrosine kinase (Btk) inhibitor	Primary macroglobulinemia, Lymphoplasmacytic lymphoma		→			(JP)	In-house
		Central nervous system lymphoma		→			(JP)	
		B cell lymphoma		→			(EU)	Out-license (Gilead Sciences)
			→				(US)	
ONO-4686 (BMS-986207)	Anti-TIGIT antibody	Solid tumor		→			(JP)	Co-development with Bristol-Myers Squibb
ONO-4482 (BMS-986016) / Relatlimab	Anti-LAG-3 antibody	Melanoma		→			(JP)	Co-development with Bristol-Myers Squibb
ONO-7807 (BMS-986258)	Anti-TIM-3 antibody	Solid tumor		→			(JP)	Co-development with Bristol-Myers Squibb
ONO-4578	PG receptor (EP4) antagonist	Solid tumor		→			(US, EU)	Co-development with Bristol-Myers Squibb
			→				(JP)	In-house
ONO-4483 (BMS-986015) / Lirilumab	Anti-KIR antibody	Solid tumor	→				(JP)	Co-development with Bristol-Myers Squibb
ONO-7705 / Selinexor	XPO1 inhibitor	Multiple myeloma and non-Hodgkin lymphoma	→				(JP)	In-license (Karyopharm Therapeutics)
ONO-7475	Axl / Mer inhibitor	Solid tumor	→				(JP)	In-houose
		Acute leukemia	→				(US)	
ONO-7911 (BMS-986321)	PEGylated interleukin-2	Solid tumor	→				(JP)	Co-development with Bristol-Myers Squibb

Main Status of Development Pipelines (Other than Oncology)

Product (Development Code)	Pharmacological Action, etc.	Proposed Indication	Development Stage I	II	III	Filed	Area	
ONO-1162 / Ivabradine	HCN channel inhibitor	Chronic heart failure	→				(JP)	In-license (Les Laboratoires Servier)
ONO-2370 / Opicapone	Long acting COMT inhibitor	Parkinson's disease	→				(JP)	In-license (Bial)
Orencia IV Orencia SC	T-cell activation inhibitor	Structural damage of the joints in rheumatoid arthritis	→				(JP)	Co-development with Bristol-Myers Squibb
Orencia SC	T-cell activation inhibitor	Untreated rheumatoid arthritis	→				(JP)	Co-development with Bristol-Myers Squibb
		Primary Sjögren syndrome	→				(JP)	
		Polymyositis / Dermatomyositis	→				(JP)	
ONO-5704 / SI-613	Hyaluronic acid-NSAID	Osteoarthritis	→				(JP)	In-license (Seikagaku)
		Enthesopathy		→			(JP)	
Onoact for Intravenous Infusion 50mg / 150mg (ONO-1101)	β_1 blocker (short acting)	Tachyarrhythmia in low cardiac function for pediatric use		→			(JP)	In-house
		Tachyarrhythmia upon sepsis		→			(JP)	
ONO-4059 / Tirabrutinib	Bruton's tyrosine kinase (Btk) inhibitor	Pemphigus		→			(JP)	In-house
		Sjögren syndrome		→			(US, EU)	Out-license (Gilead Sciences)
ONO-7269	FXIa inhibitor	Celebral infarction	→				(JP)	In-house
ONO-5788	Growth hormone secretion inhibitor	Acromegaly	→				(US)	In-house
ONO-7684	FXIa inhibitor	Thrombosis	→				(EU)	In-house
ONO-4685	PD-1×CD3 Bispecific antibody	Autoimmune disease	→				(JP)	In-house

Discovering Innovative Drugs to Enhance ONO's Identity, ONO always Meets the Challenges that Face us to Create Values for our Stakeholders through Business Activities

Q1 Tell us about ONO's business results and prospects for the future.

A1 We achieved increased sales and revenues for FY2018 and see steady future growth prospects.

In our consolidated financial results for FY2018, revenue increased by 10.2% and operating profit increased by 2.2% compared to FY2017, resulting in sales and profit growth.
The revenue of products and goods were 208.9 billion yen. The anticancer drug OPDIVO, one of our core products, faced increased competition in addition to price cutting. However, its sales ended almost flat thanks to a significant year-on-year increase in volume terms supported mainly by the expansion of indications to gastric cancer, with which many patients are afflicted in Japan, and safety information accumulated through its administration to many patients. The sales of rheumatoid arthritis drug ORENCIA and diabetes drug FORXIGA increased by 23.3% and 31.0%, respectively, over the previous year. In addition, royalty and other income from increased overseas OPDIVO sales substantially went up, contributing greatly to the entire business results.
On cost grounds, R&D costs were 70 billion yen, an increase of 1.2 billion yen from the previous year. Selling, general, and administrative expenses excluding R&D costs were 70 billion yen, an increase of 2 billion yen from the previous year. The R&D costs per sales were 24.3%, considerably higher than the pharmaceutical industry's average*. As a pharmaceutical company dedicated to drug development, we continue to actively invest in R&D while curbing nonessential spending to generate earnings and improve profit margins.
In FY2019, we hope to obtain marketing approval applied in FY2018 for several drugs in development pipeline, which will contribute to sales in the second half.
For information, we transferred the domestic marketing approval for our 11 long-listed products (5 brands) to Maruishi Pharmaceutical, leading us to concentrate management resources on the discovery, development and commercialization of new drugs to achieve further sustained growth.

* Top 10 consolidated sales average for FY2017: 17.3%
Data sources: SPEEDA (Uzabase, Inc.), Annual securities reports
Data extracted from JPMA DATA BOOK 2019

Gyo Sagara
President, Representative Director, and CEO

Q2 Tell us about the R&D performance and outlook.

A2 We launched three drugs on the market in FY2018 and applied for approval for new drugs and supplemental approval for many additional indications. In FY2019, we will also launch three new drugs and file many approval applications.

We are currently working to develop combination therapies in an effort to maximize the product value of the anticancer drug OPDIVO, the biggest growth driver at ONO. In FY2018, we made great progress by obtaining approval (for additional indication) for combination therapy with the immunotherapy drug YERVOY in Japan, South Korea and Taiwan. Although OPDIVO had been approved for monotherapy only in renal cell carcinoma patients with treatment history with other anticancer drugs, the drug can now be used in combination with YERVOY in patients without such treatment history.
In addition to OPDIVO, FY2018 saw great progress in the oncology domain. We launched BRAFTOVI and MEKTOVI for treatment of melanoma. We applied for marketing approval of ANAMORELIN for improvement of body weight loss and anorexia in patients with cancer cachexia.
Other than the oncology domain, we launched DEMSER, a product for which we developed as a development company recruited at the Review Committee on Unapproved or Off-label Drugs with High Medical Needs. We obtained approval of ONOACT and FORXIGA for additional indication of ventricular arrhythmia and type 1 diabetes, respectively. In addition, we applied for approval of IVABRADINE for the treatment of chronic heart failure and of OPICAPONE for improvement of the end-of-dose motor fluctuations of Parkinson's disease.
We believe that expanding our product lineup would contribute to treatment of more patients and significantly to our financial results beyond FY2019. In FY2019, we hope to file many applications for approval as in the previous year.

Q3 What do you think the pharmaceutical industry is required to do?

A3 The industry is increasingly required to keep balance between innovation and cost.

Political and economic instability is increasing across the world, and natural disasters, such as earthquakes and heavy rains, occur more frequently causing higher degree of damage to affected countries. We have to always be ready to respond with agility to risks arising from various changes, while always working with good judgement based on accurate information to take change as an opportunity to further grow.
To be a going concern, we are also highly required to contribute to solving social and environmental challenges through business activities. We try to figure out and put into practice in daily business activities what we can do beyond drug discovery for society as a corporate citizen.
The environment surrounding the pharmaceutical industry has been toughening for a long time and this situation is expected to continue in the years to come. Drug discovery is becoming increasingly more difficult and development costs are surging. Meanwhile, healthcare cost reduction measures are inevitably further promoted with populations aging and birthrates dropping in major countries in the world.
Under such severe circumstances, however, we have to develop and distribute innovative drugs, even in next 100 years that bring true benefit to all patients. We need to use management resources effectively to create innovations in years to come, and to discover better drugs faster and at less cost for patients around the world who need new drugs. We also have to work across the pharmaceutical industry to ensure that innovations created undergo proper evaluation, so that pharmaceutical companies can continue to make positive contributions to society.

Q4 What do you think about ONO's relationship with society?

A4 We do not only develop high quality pharmaceuticals that contribute to healthcare. But we also contribute through business activities to solving issues facing society and creating sustainable society.

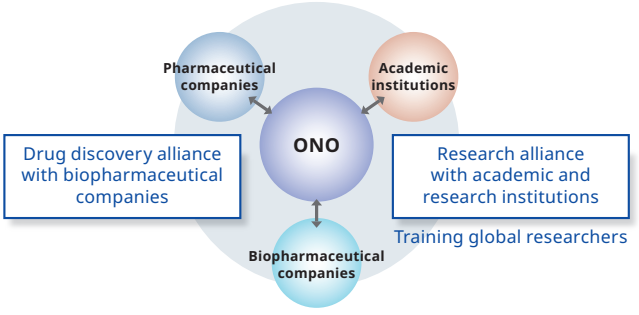
Our social mission is not limited to developing and supplying drugs that conduce to healthcare. Under the ONO PHARMACEUTICAL Codes of Conduct stating that we must work in harmony with society and local environment, we conduct business activities with mutual prosperity in mind. Such ideas and actions are in common with the 17 Sustainable Development Goals (SDGs), adopted by the United Nations in 2015, which are to be achieved by 2030, including actions to end poverty, improve health and well-being, and combat climate change. As the SDGs are common goals for the international community including developing and developed countries, the SDGs can be used to identify business opportunities and risks.
Given that corporate social responsibility (CSR) efforts are increasingly expected to be made and that our corporate scale is expanding, we have redefined our important CSR issues (materiality). We have also chosen SDGs that we should particularly contribute to achieving in relation to our specified materiality.
We strive to develop high-quality drugs that meet healthcare needs, thereby contributing to achieving SDG 3, "Ensure healthy lives and promote well-being for all at all ages," while pursuing business activities that help solve social issues and realize sustainable society.

Q5 Tell us about ONO's business model.

A5 We specialize in and focus management resources into drug development.

To achieve sustained growth in a tough and complex business environment, we believe it important to focus our finite management resources on drug discovery and development as an R&D-based pharmaceutical company specializing in prescription medicines to contribute to realizing social sustainability.
ONO's business model we pursue is not only to take up the challenge of discovering our own innovative drugs but to develop new drugs with promising new drug candidate compounds in-licensed from around the world.

ONO's Unique Drug Discovery Approach and Disease Expertise Enhancement
We work on discovering original and innovative drugs by identifying unique compounds with use of disease expertise. Our drug discovery process is based on our unique drug discovery approach: the "Compound-Orient" approach. Since successful total chemical synthesis of bioactive lipid prostaglandins (PGs) in the 1960s, we have collected a library of compounds that may act on various therapeutic targets such as lipids and enzymes. We utilize this library in the approach to find diseases against which the properties of compounds are most potentially effective. This approach, although highly risky, may lead to discovering compounds with unique pharmacological action.
In addition, we have been driving open innovation for more than 60 years through the adoption of world-leading technologies and knowledge. We globally pursue various forms of collaborations that may lead to discovery of new drug candidate compounds, including research collaborations with world top-class scientists as well as drug discovery alliances with biopharmaceutical companies with leading-edge technologies.



In drug discovery research, we focus on four priority areas: oncology, immunology, neurology, and specialty products. Based on the compound-orient approach, we accumulate knowledge and expertise of diseases in each of the priority areas at the Research Centers of Oncology, Immunology, Neurology, and Specialty Products established in each domain to identify and develop innovative and breakthrough pharmaceutical products for disease treatment that is high in healthcare needs where patient satisfaction with current treatment is low.

Licensing Activities
In addition to in-house drug discovery, licensing strategy is another important point for stable, forward-looking expansion of our development pipeline for the future. We vigorously work on in-licensing of new drug candidate compounds that have high value in terms of corporate strategy and efficiency.
For in-licensing of new drug candidate compounds, we are facing more intense competition with other companies. Taking advantage of our compact corporate scale, we move with speed to seek collaboration partner candidates. Considering the properties of in-house developed compounds and the competitive environment we face, we examine and determine strategy per compound or product to out-license at early development stage or at a stage where the compound is indicated to be effective and safe in clinical practice; or to take the compound forward to in-house development or own marketing outside Japan. Even when determining out-licensing, we take into account per compound or product the possibility of future own marketing operations in candidate destinations.

Q6 Could you tell us what your growth strategy is for the future?

A6 We implement a new growth strategy to push toward becoming a global player.

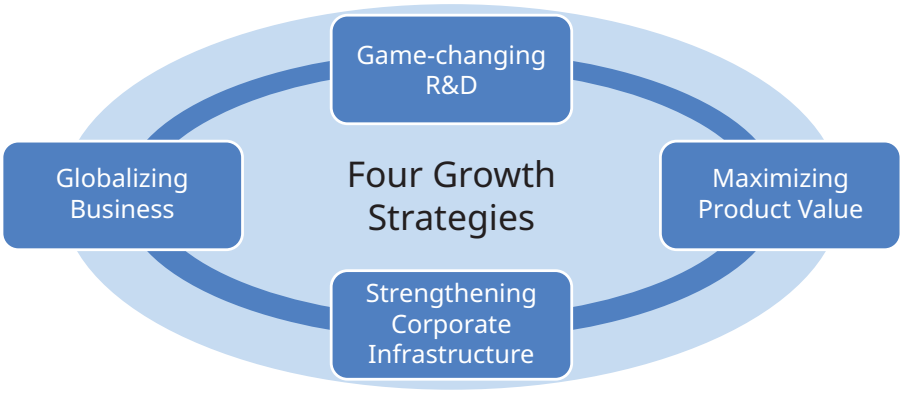
To become a global player, we currently conduct business activities under four growth strategies: “Maximizing Product Value,” “Game-changing R&D,” “Globalizing Business,” and “Strengthening Corporate Infrastructure.”

(a) Maximizing Product Value
Through active R&D efforts, companywide collaboration and enhanced HR development capacity, we will achieve expedited market launch and additional indication approval and peak sales in the shortest period from launch. In addition, we will develop a strategy formation that constantly ensures competitive advantage by adjusting with agility to environmental changes in each stage of the product life cycle. We will thereby maximize the potential of every product we offer.

(b) Game-changing R&D
In the world, there are still many people suffering from disease without therapy at all. We are striving to achieve its vision of becoming a Global Specialty Pharma company that can satisfy as-yet unmet medical needs. Based on our unique drug discovery “Compound-Orient” approach, we have identified the oncology, immunology, neurology, and specialty domains with high medical needs as our priority areas of research, so as to accumulate knowledge and expertise of diseases in each of the priorty areas for developing new drugs that will provide new treatment options with innovation to the frontline of healthcare. For this, we will strengthen and enhance research and drug discovery alliance with world-leading universities, research institutes, and biopharmaceutical companies in specific research areas so that we can expand our development pipeline aiming first-in-class drugs with high originality. We will also drive forward activities in areas with great medical needs, by in-licensing innovative compounds and acquiring novel technologies.

(c) Globalizing Business
To supply the world with new drugs that we have created, we are reinforcing overseas business expansion in anticipation of our own overseas marketing of specialty products such as anticancer drugs and other specialty medicines. In South Korea and Taiwan, we have already set up wholly owned subsidiaries and have started selling our products. We are also working to improve and strengthen our development and other systems, with a view to future marketing through our own sales organizations in US and Europe.

(d) Strengthening Corporate Infrastructure
We continue to reinforce our operational infrastructure, with global standards in mind, in order to expand our overseas business and to continuously beat off the intense competition with other companies. We need to adapt to diverse changes in our business environment and overcome competition. For this purpose, we must develop human resources and encourage diversity so that we can have a stronger framework for development. In addition, we strive to fulfill our social responsibility toward all stakeholders, through advancing activities in line with key challenges that we have identified to address to achieve long-term sustained growth.



Q7 Tell us about your strategic investments to build poles of growth.

A7 We focus on investing in creating new innovations and human resources development.

Creating Innovations

We continue actively driving R&D investment so that we can discover new drugs truly desired by patients and deliver them as quickly as possible to the frontline of healthcare. To create next innovations, we need to ensure the quality of R&D. We also have to work toward expanding our corporate scale to boost funds for R&D spending from around 70 billion yen now to as much as 100 billion yen.

Our past experience tells us that it is difficult to keep on discovering innovative drugs in-house alone. We believe it important to learn outstanding knowledge and technologies from outside around the world. To do this, we actively conduct research collaborations and drug discovery alliances.

Currently, we are conducting more than 300 joint research projects with universities, research institutes and biopharmaceutical companies inside and outside Japan.

We have teams in place at our research division and local subsidiaries in the US and Europe which are in charge of finding exploratory research alliance partners and building productive alliance framework. Our staff assuming this role visit academic institutions, etc. on their own to propose and plan more constructive joint research projects through dialogues with world top-class researchers.

We pursue development of advanced drug discovery technologies on a global basis. During the past several years, we have adopted new discovery modalities and technologies through partnership, including discovery of drug candidate compound exploiting bispecific antibody technology and drug discovery in neurology disease area exploiting artificial intelligence technology.

We post our researches to joint research and drug discovery alliance partners to engage in original research projects and bring knowledge and results gained therefrom back to us at ONO to boost the level of research capabilities that we have as an organization.

We devote prominent resources and efforts toward acceleration of open innovation much more than other companies of the same scale do, striving toward creating new drug seeds that may contribute to the frontline of healthcare in the future.

Human Resource Development

To turn ONO into what can be called a Global Specialty Pharma, we have to keep strengthening our corporate infrastructure in line with global standards. It is essential, among other things, to develop human resources and create employee-friendly working environments. So, we are keenly making investments into, including, organizational improvements and promotion of efforts to build a sense of ownership at work.

To adapt quickly and flexibly to ever-changing business conditions, we have to hire a diverse workforce. We work hard to promote and include diversity in our workplaces. We believe that diversity enhancement means building working environments where everyone can be motivated regardless of race, nationality, gender, career, and other attributes including behavioral characteristics and set of values. We try to improve by learning from others, which could result to create a climate of generation for global innovation.

To develop and energize human resources, we will continue enhancing training programs to provide employees with opportunities for growth and awareness, considering changes inside and outside the company.

We have been strengthening mid-career professional recruitment to promptly reinforce capabilities we need as a company that handles life-supporting products. Notably, we hired more than 400 midcareer professionals in FY2018, compared to only two in FY2012.

Currently, we hold workshops for employees to achieve and deepen understanding of our mission statement, so that all employees with diverse backgrounds can work together toward realizing our vision.

It needs to make our workplaces more worker-friendly to ensure that diverse workers can demonstrate their full potential in their organization. We are implementing programs and improving systems, giving consideration to ensuring that all employees maintain a good work-life balance. We are also reforming the mindset of employees, who can benefit from them. We promote working group activities and information sharing for improving operational efficiency, so that individual employees can maximize their value per hour through reformation of their mindset of the way they work using such programs and systems.

In addition, we conduct health and productivity management. We have increased staffing and strengthening activities of the Health Up Committee—which was set up in April 2018 with members from the company, the labor union, the occupational health staff, and the health insurance society—for promoting health maintenance/improvement of employees and their families.

Q8 Tell us about your governance system.

A8 We work to raise the effectiveness of our corporate governance.

We need to secure the trust of all stakeholders and fulfil our social responsibility to realize sustained growth and increase our medium- to long-term corporate value. We therefore continue working to enhance our corporate governance and to pursue management that fulfill responsibility to all stakeholders.
In terms of corporate governance, we believe that our critical issues are not only the compliance of laws but also the enforcement of our management transparency and soundness to respond to the trust of all stakeholders and increase our corporate value. With this in mind, we are committed to developing a more effective governance system considering the business environment surrounding us and our business results.
Currently, our Board of Directors consists of eight members including three outside directors. Outside directors participate in decision-making process of business strategies and other important management matters. They oversee the execution of directors' duties by checking mainly business reports and the status of internal control system development and operation. As members of the Executive Appointment Meeting and the Executive Compensation Meeting, they also exercise effective supervision over the management. As for operational management, we are striving to improve management efficiency and speed up decision-making through, for example, implementation of a corporate officer system with delegation of authority. We also ensure that operations are managed under the check and balance supervision system. Management challenges are reviewed and decided for execution, depending on their importance and content, at meetings chaired by the responsible director or corporate officer.
Our Board of Auditors consists of two thoroughly independent outside auditors and two full-time auditors who are thoroughly familiar with ONO's business and have the authority to gather high-level information. The outside auditors, the posts assumed by a lawyer and a certified public accountant with broad advanced knowledge of corporate legal or accounting affairs, cooperate with the full-time auditors to raise audit effectiveness. The auditors conduct audits in cooperation with our Internal Audit Capability (Business Audit Department) and accounting auditors.
In December 2017, we participated in the United Nations Global Compact (UNGC), which consists of ten principles in four areas of human rights, labor, the environment and anti-corruption. We signed to join the UNGC to penetrate the ten principles to all employees through daily activities.

Q9 Tell us about your efforts to earn credibility with the public.

A9 We work to ensure product reliability and safety assurance and stable product supply, and to raise compliance awareness.

The effectiveness of ensuring compliance will translate into earning our credibility with the public and improving our corporate value. We work to raise compliance awareness broadly. Internally, we do not only develop and raise compliance awareness by having regulations and programs in place to ensure compliance. But we also strengthen mutually assured compliance under a cross-functional compliance promotion system. Externally, we strongly request our affiliates and suppliers to take same measures for compliance.
Prescription drugs are related to human life and health. Pharmaceutical companies should manage various possible risks that might exist internally and externally and should address them quickly and properly if occurring. To perform proper risk management of our corporate group including subsidiaries, with appropriate internal rules in place, we have prepared handling procedures and regularly review them in response to the business environment. We also overhauled our business continuity plan (BCP) in 2016, improving our emergency response capabilities.
We have also been working to strengthen the emergency response systems at our business operation sites so that each site can continue business activities and secure stable supply in

case of a large-scale emergency. In March 2018, our new Tokyo Building was completed, equipped with facilities in preparation for disasters. It is designed to serve as another emergency command center besides our headquarters in Osaka. In addition, a new plant has been completed in Yamaguchi Prefecture, due to go into operation in spring 2020, joining the current main Fujiyama Plant in Shizuoka Prefecture to strengthen our production systems.
To assure the reliability and safety of drugs on the market, it is essential to implement evidence-based production activities and for medical representatives (MRs) to provide accurate drug information and collect and feedback drug safety information. We have a framework in place that can lead to further quality improvement. In this framework, we can analyze and evaluate, based on latest scientific evidence, information provided by healthcare professionals and patients as well as collected from scientific literature and surveys, and provide latest evidence-based, accurate information to the frontline of healthcare.

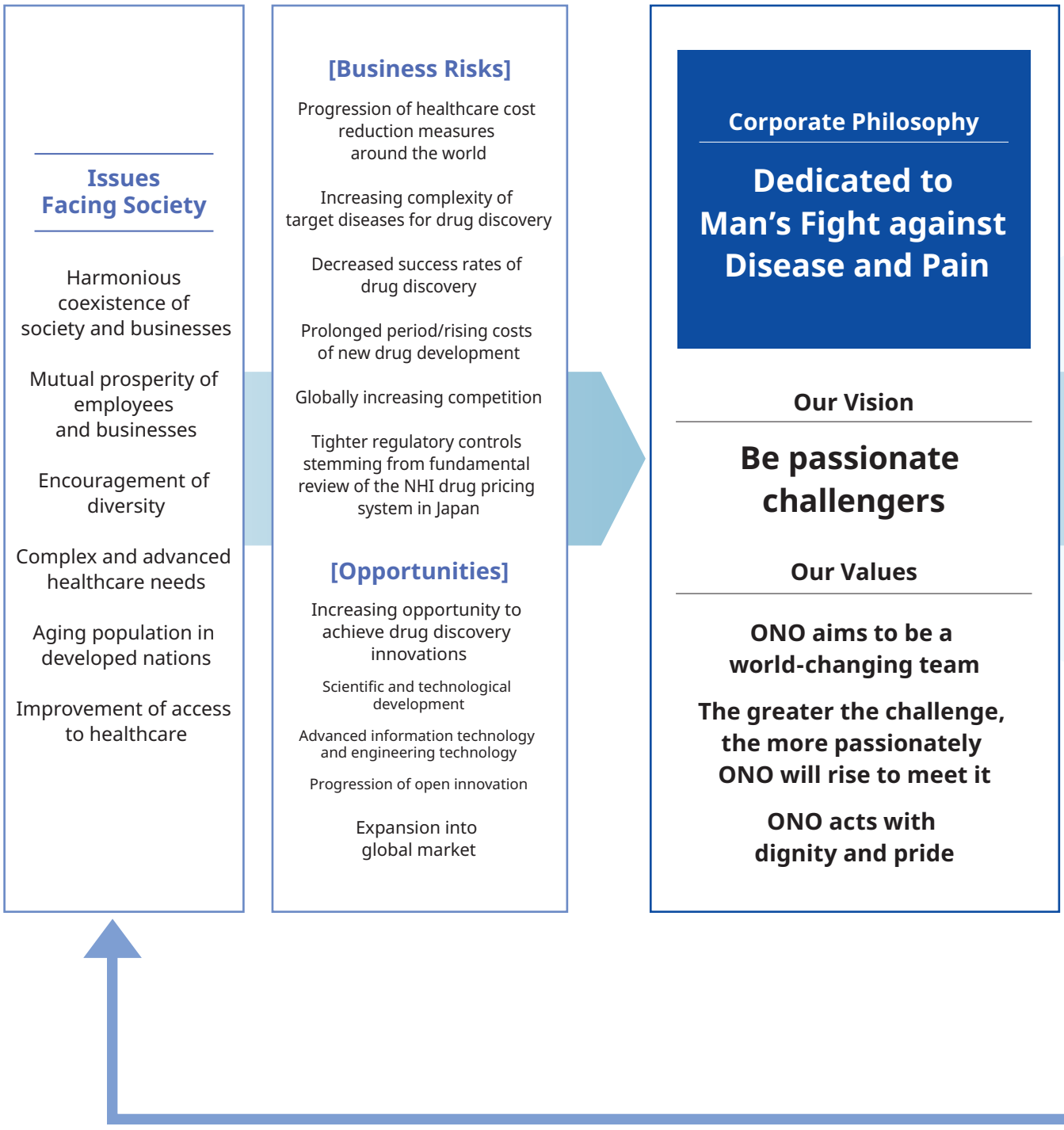
Q10 What do you think about relationships with stakeholders including shareholders?

A10 We strengthen relationships with all stakeholders while communicating with them in pursuing business activities.

Companies work with various stakeholders in pursuing business activities. We have to ensure legal compliance, corporate governance, and transparency. However, we believe we also have to build and continue strengthening relationships with all stakeholders through business activities respecting their interests and dialogues with them, to attain sustained growth toward becoming a Global Specialty Pharma.
We adhere to the policy of disclosing necessary information accurately, fairly, impartially, and promptly to all stakeholders—including patients, healthcare professionals, shareholders, investors, suppliers, local communities, employees, relevant governmental agencies, and industrial associations—to promote communication/constructive dialogues with them.
We consider the redistribution of profits to shareholders as a vital management policy.
In terms of dividend pay-out, we will prioritize stable dividend distribution in the medium to long term while taking account of our business results and general social conditions, making appropriate distribution of our profits in line with our business performance. We regard the purchase of treasury shares as part of raising capital efficiency and comprehensive shareholder returns. As usual, we will flexibly consider and carry out the purchase, keeping future demand for funds in mind, for the purpose of redistributing more profit to shareholders, raising capital efficiency or tightening the supply-demand balance in the stock market. If we purchase our own shares, we intend to hold up to 10 percent of them as treasury stock and cancel the rest.
We periodically review the proper benchmarks of management indices including ROE and work hard to achieve higher performance so that these indices will go up.
As an R&D-based pharmaceutical company, we would like to fulfill the expectations of stakeholders. We will continue to meet various challenges that face us to become a company undergoing growth in middle and long term. We highly appreciate your continued support.

Stakeholder	Opportunity to Build/Strengthen Relationship
Patients and healthcare professionals	Discovery of pharmaceutical products that bring true benefit to patients
	Stable supply of high-quality pharmaceutical products
	Information collecting and provision for proper drug usage
Shareholders and investors	Stable return on investment through sustained growth
	Information disclosure and dialogues to promote understanding
Suppliers	Offering fair and transparent competitive opportunities
	Promoting CSR procurement
Local communities	Contributing to economic development
	Activities for environmental conservation and for local communities
Employees	Provision of opportunities for personal growth
	Creating an environment where employees work with peace of mind

ONO's Value Creation Process



Values ONO offers

To the frontline of healthcare

Discovery of pharmaceutical products that bring true benefit to patients

Stable supply of high-quality pharmaceutical products

Information collecting/provision for proper drug usage

To society

Contribution to economic development

Contribution to the creation of a sustainable society

To shareholders and investors

Stable return on investment through sustained growth

Fair information disclosure

To employees

Provision of opportunities for personal growth

Creating an environment where employees work with peace of mind

About ONO's Materiality

ONO has striven for CSR by defining important areas of focus based on the ISO 26000. In FY2018, in addition to responding to external requirements, we redefined our materiality (important CSR issues) to clarify CSR themes which we should emphasize. ONO actively engages in CSR according to the new materiality that we have established.

Overall Flow for Determining Materiality

Step 1: Identify the Issues

We broadly grasped and organized CSR issues per value chain in our business activities based on the ISO 26000, the GRI Standards, the Ten Principles of the United Nations Global Compact and the evaluation items for socially responsible investment.

Step 2: Analyze Materiality

We analyzed the CSR issues by importance from the point of view of ONO and importance based on expectations of our stakeholders, and then mapped each of those CSR issues on a horizontal and a vertical axis. The importance from the point of view of ONO was assessed by our Directors, Corporate Officers and CSR Committee Members based on our corporate policy, and priority and importance were evaluated for each issue.
The importance based on expectations of our stakeholders incorporated the feedback received from our shareholders and investors in addition to the evaluation items of institutions that practice responsible investment as the representatives of stakeholders outside of ONO. When we review the items and importance of materiality in the future, we will further incorporate the opinions of an even greater number of stakeholders.The results of this materiality analysis were deliberated and determined by the CSR Committee before gaining approval at the Management Meeting chaired by the CEO.

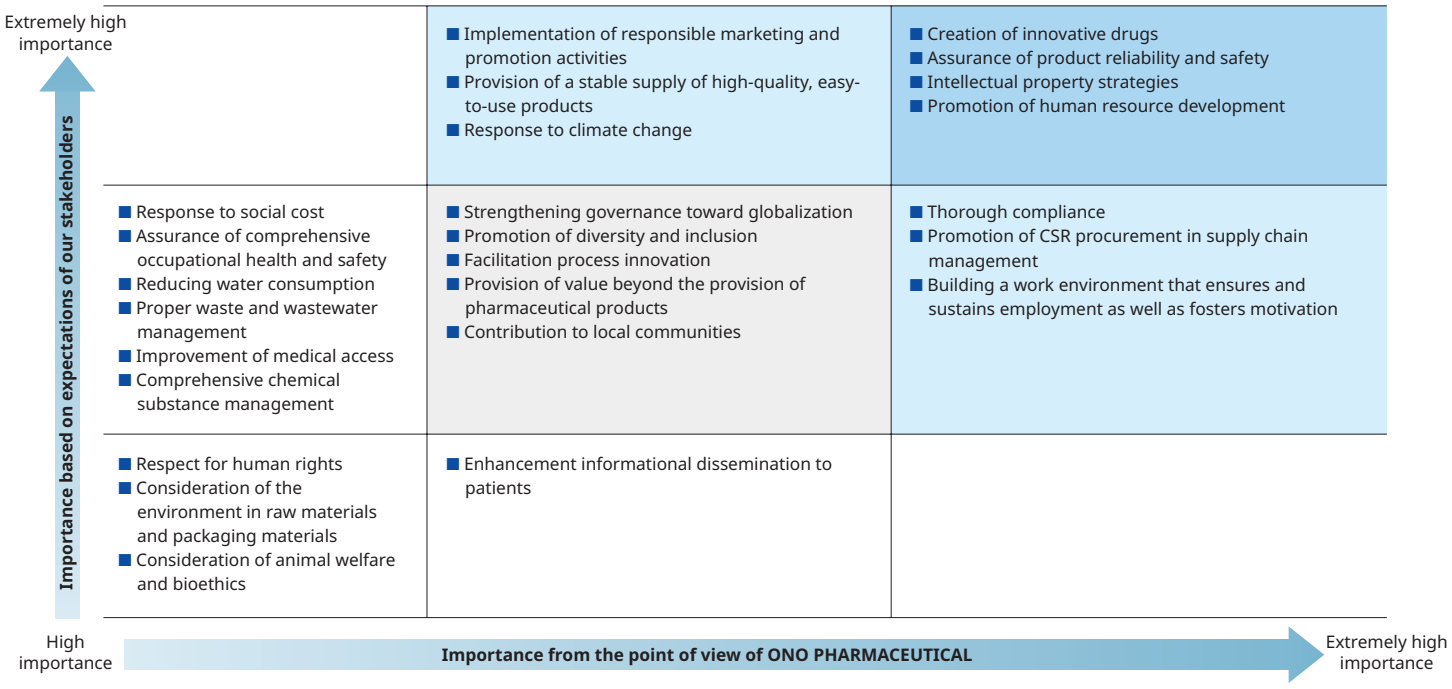
Step 3: Verify Validity

We engaged in a dialogue with external experts about the process of our materiality analysis, the identified themes that are set and future initiatives to verify the validity of each important issue.

■ The dialogue with external experts is described in detail on ONO's CSR site.
→https://ono-csr.disclosure.site/en/themes/123

Step 4: Review

We annually review our materiality in response to environmental changes inside and outside the company.



Materiality Targets and Relevant Sustainable Development Goals (SDGs)

Sustainable Development Goals (SDGs) are composed of 17 goals adopted by the United Nations in 2015 to address the challenges faced by the international community. Each materiality item and the relevant SDGs are as shown in the table to the right:
We report and manage the progress of each materiality target each year at the Management Meeting.

■ The plan and KPIs for FY2019 are provided in detail on ONO's CSR site.
→https://ono-csr.disclosure.site/en/themes/123

Materiality	Relevant SDGs
Creation of innovative drugs	3, 9, 17
Intellectual property strategies	3, 17
Promotion of human resource development	4, 5, 9
Assurance of product reliability and safety	16
Implementation of responsible marketing and promotion activities	12, 16, 17
Provision of a stable supply of high-quality, easy-to-use products	12, 17
Building a work environment that ensures and sustains employment as well as fosters motivation	4, 5, 8
Response to climate change	3, 7, 9, 13, 17
Promotion of CSR procurement in supply chain management	8, 12, 16, 17
Thorough Compliance	16

Our Contribution to the SDGs

Priority: High

Themes by focusing on initiatives as SDGs

We contribute to achieving SDGs 3, 9, and 17 through creation of innovative drugs.

We strive to realize Goal 3, "Ensure healthy lives and promote well-being at all ages," through business operations as a research and development company specializing in prescription drugs based on our corporate philosophy to be dedicated to man's fight against disease and pain. To decrease the mortality rate of non-communicable diseases raised as a target of the SDGs, we concentrate our research efforts into diseases such as cancers, immunological diseases and central nervous system disorders to contribute to the creation of original and innovative therapeutic medications for diseases for which medical needs are still unmet. Furthermore, in addition to aid for diphtheria, whooping cough, diphtheria toxoid and tetanus toxoid vaccines as well as the hepatitis B vaccine to address infectious diseases, ONO contributes to therapeutic medications with low marketability, such as malaria, tuberculosis, neglected tropical diseases, as well as new development, such as vaccines and diagnostic pharmaceuticals, through participation in the Global Health Innovative Technology Fund.

For Goal 9, "Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation," ONO contributes to encouraging innovation and building research and development (R&D) infrastructure. To vitalize R&D in order to create new drugs, we will not only invest in internal R&D but also provide grants, such as those for investigator-initiated clinical trials. Furthermore, the ONO Medical Research Foundation and ONO Pharma Foundation promote research to help build a bedrock for innovation through research grants to researchers inside and outside Japan.

For Goal 17, "Strengthen the means of implementation and revitalize the global partnership for sustainable development," we do not only discover and develop innovative drugs independently using world- leading technology and knowledge in various areas. We also vigorously pursue in-licensing and out-licensing of new drug candidates. In addition to alliances with venture companies and other pharmaceutical companies, we form partnerships with a wide range of stakeholders from universities and research institutes to government agencies, local communities and NPOs in an effort to resolve problems via open innovation.

Game-changing R&D

Our Mission in Research and Development

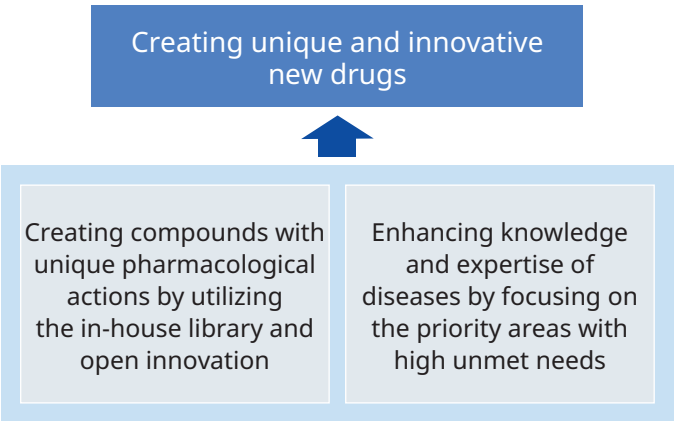
Deliver our contribution to society by developing drugs that truly benefit patients

Keeping in mind our R&D mission "Deliver our contribution to society by developing drugs that truly benefit patients," we are tackling diseases that remain unconquered as yet, and addressing areas that are high in healthcare needs where patient satisfaction with current treatment is low. Our discovery research aims to identify and develop innovative and breakthrough pharmaceutical products.

Drug Discovery Strategy

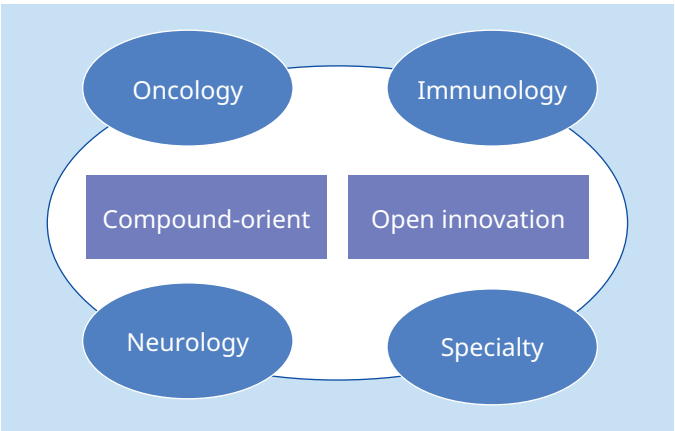
Drug Discovery Research

Based on the "compound-orient" drug discovery approach focusing on characteristic bioactive lipids and unique drug targets to generate innovative new drug candidate compounds, we have established a research organization in each of the newly specified four priority areas of drug discovery. Each organization accumulates knowledge and expertise of diseases in each of the priority areas to properly understand healthcare needs, working toward developing breakthrough pharmaceutical products with medical impacts.
In addition to small molecule drug discovery on which we have focused, we also tackle the challenge of providing new treatment options with innovation to the healthcare frontline by using biologicals including antibodies, cells and viruses.



Drug Discovery Research Domains

We enhance knowledge and expertise of diseases in each of the priority areas by focusing our resources on the oncology, immunology, neurology, and specialty research domains as priority areas with high medical needs. To reinforce our competitiveness in drug discovery in each domain, we performed structural reform in April 2019 by adding the Research Centers of Immunology, Neurology, and Specialty Products to the already-existing Oncology Research Center.



Open Innovation

ONO has discovered new drug discovery seeds and developed breakthrough new drugs initiated therefrom through collaboration with research institutes including universities since before the words “open innovation” started to become widely used. We continue to vigorously pursue research collaborations with world top-class researchers mainly in the priority areas of research. To speed up, and raise success rates of, development of new drug candidate compounds from the seeds, we will strengthen and enhance drug discovery alliances with biopharmaceutical companies using advanced technologies of the partners to further expand our R&D pipeline.

In FY2018, following the forming in FY2017 of alliances for human bispecific antibody development and for advanced computational method-based drug discovery, we joined the establishment of the academic-industrial “Immune-mediated Inflammatory Diseases Consortium for Drug Discovery,” which consists of academic institutions and pharmaceutical companies in Japan. We also continued vigorously forming drug discovery alliances with biopharmaceutical companies with proprietary or superior technology. Such partnering activities successfully initiated include a collaboration agreed with Fate Therapeutics (US) for discovery and development of off-the-shelf, iPSC-derived CAR T*-cell drugs for cancers; a research collaboration agreed with twoXAR (US) for discovery and development of neurological disease drugs using AI technology; a drug discovery collaboration agreed with Vect-Horus (France) for discovery and development of neurodegenerative disease drug candidates; and a strategic drug discovery alliance agreed with Cancer Research UK and LifeArc (UK) for cancer immunotherapy.

We will continue directing our drug discovery efforts into the future toward discovery and development of innovative new drugs in priority areas of diseases with as-yet unmet medical needs, focusing on oncology, immunology, neurology, and specialty products, by maximizing our open innovation strategy. For this, it is important to collect cutting-edge scientific information and proceed with drug discovery based thereon ahead of the competition as fast as possible. We post middle-ranked employees with extensive experience in discovery research to our overseas subsidiaries in the US and UK, and they visit world top-class researchers and biopharmaceutical companies in the US and Europe to launch alliances. Pursuing collaborations with speed, we work to create new drugs that can bring about innovation in the healthcare frontline.

* CAR-T (chimeric antigen receptor T cell) therapy:
CAR-T cell therapy is a type of cancer immunotherapy. The CAR includes parts recognizing cancer antigen and T-cell activating domain. Once the CAR-T cell recognizes cancer via CAR, the CAR-T cell is going to be highly activated and kill the cancer cells.

A Research Capability Combining Knowledge with Technology

The development of innovative new drugs is driven by the spirit of challenge and the motivation of individual scientists and their ability to think creatively responding to change. We set high and achievable targets with clear outcomes, in order to enhance motivation and creative thinking among our researchers. ONO’s 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. Each project team actively promotes open innovation with the aim of discovering innovative drugs with top-class researchers all over the world.

We conduct drug discovery research through coordination of the efforts of three laboratories, the Minase Research Institute, the Fukui Research Institute and the Tsukuba Research Institute, and work to strengthen our research capability to further accelerate, and raise success rates of, drug discovery. In April 2019, a Translational Research Laboratories was newly established in the Research Project Management to bridge between basic and clinical research for the promotion of research. The Minase Research Institute’s research building No. 3, our center for invention and medicinal chemistry, has seen more than three years of operation, which started in March 2016. Now integration of our compound synthesis and analysis functions has further matured, and thereby driving R&D forward by building capability with consistency in chemistry research, from exploration of breakthrough drug seeds through to clinical researches. This has led to strengthening combination of knowledge and technology among researchers and among teams.

The Minase Research Institute

The Institute has a wide variety of research functions, including medicinal chemistry, research into the characteristics and efficacies of compounds, discovery research in oncology, immunology, neurology, and specialty product domains, exploratory research for analysis of disease-causing substances and new compounds that can control these substances, research aimed at the development of formulations whose quality and function as pharmaceutical products can be assured, as well as mass production and cost reduction for the supply of active pharmaceutical ingredients.

The Fukui Research Institute

The Institute focuses on compound safety assessment.

The Tsukuba Research Institute

The Institute undertakes research into immunology based on advanced antibody technology, and the pharmacokinetics of discovered compounds.

Game-changing R&D

Accelerated Clinical Development

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 benefit of people suffering diseases throughout the world.
To create development plans and trial designs with the aim of obtaining marketing approval in the shortest time, we work to properly understand unmet needs of the healthcare frontline by analyzing target diseases multilaterally. We also proceed with activities with the Discovery and Research Division to shorten the period from commencement of drug discovery to establishment of efficacy and safety in humans (POC). In addition, we are speeding up collecting the data required for filing applications for marketing approval in Japan, South Korea, and Taiwan by conducting multinational clinical trials and advancing mutual use of results from overseas studies with our partners.
In April 2019, we strengthened our system for promoting quality enhancement and speedy clinical development by newly establishing within the Clinical Development Division a CRO Management Department specifically designed to increase in quality of trials and in efficiency of relevant management tasks, including clinical trial quality control and regulatory inspection handling.
Currently, we have almost as many as 100 clinical trials ongoing mainly in the immuno-oncology domain, one of our key strategic areas.
In clinical development in the oncology domain, we are progressing investigation of biomarkers and combination therapies as a pioneer in cancer immunotherapy to provide patients with better treatment options.
Starting in January 2018, we have an Oncology Clinical Development Department in place, which consists of the Oncology Early Clinical Development Planning for early clinical development stage and the Oncology Clinical Development Planning for late clinical development stage.
A similar organizational structure was set up for clinical development in the primary care domain. In October 2018, we reorganized the Primary Care Clinical Development into the Early Clinical Development Planning for early clinical development stage and the Clinical Development Planning for late clinical development stage.
We have strengthened our system that can accelerate implementation of POC establishment and validation study, so as to meet the needs of frontline healthcare as soon as possible.

Vigorous Activities for Licensing Initiatives

We continue to forge ahead with licensing activities to take in 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 the oncology domain, we take advantage of our strength with OPDIVO in acquiring product candidate compounds in a wide range of areas such as molecular target drugs including antitumor drugs and cell therapies.
Our licensing activities have brought about results. For example, we launched the MEK inhibitor binimetinib and the BRAF inhibitor encorafenib in Japan for melanoma treatment in February 2019, the inhibitors of which we obtained a license from Array BioPharma (US) in FY2017 for development and commercialization in Japan and South Korea. Clinical trials are also ongoing for colorectal cancer treatment with the products. In FY2018, we started collaboration with Takeda Pharmaceutical to conduct clinical development for the treatment of renal cell carcinoma in Japan in the combination therapy of OPDIVO and the multi-kinase inhibitor “cabozantinib.”
We agreed on clinical collaboration with Bristol-Myers Squibb (“BMS,” US) and Clovis Oncology (US) to evaluate the combination therapy of OPDIVO and the PARP inhibitor “rucaparib” in multiple tumor types including ovarian cancer, breast cancer and prostate cancer in Japan, South Korea and Taiwan. In addition, we entered into a strategic research partnership with Repare Therapeutics (Canada) for development and commercialization of Repare’s small molecule Pol-theta inhibitor.
Meanwhile, we are working in anticipation of our own overseas marketing in the US and Europe. We also have departments in charge of licensing activities keenly out-licensing discovered compounds to our partners upon examining optimum measures to deliver our new in-house developed drugs to patients worldwide as quickly as possible, in light of proposed indication and market size.
We have deepened collaboration activities with our long-time alliance partner BMS, continuously increasing compounds jointly developed by both companies, including BMS assets—IDO1 inhibitor, anti-TIM-3 antibody, and PEG-modified IL-2—in addition to OPDIVO and ONO-4578 created by ONO, a selective antagonist of EP_4 which is a prostaglandin E_2 (PGE_2) receptor.
We continuously and vigorously promote licensing activities as a potential means of expanding our development pipeline and globally marketing new drugs we develop.

■ For information on our main partners inside and outside Japan, see our corporate site’s page below:
→https://www.ono.co.jp/eng/alliances/partners.html

Maximizing Product Value

We conduct R&D activities to maximize the product value of the anticancer drug OPDIVO, the biggest growth driver at ONO. It also works on exploiting the full potential of each of its products through evidence-based information dissemination activities, community-based activities, marketing activities to shorten the time between product market launch to peak sales, and activities to ensure product quality and reliability.

Maximizing OPDIVO's product value

To maximize OPDIVO's product value, we work with its partner Bristol-Myers Squibb (US) with focus on four perspectives.

Activities to maximize OPDIVO's product value

- **Adding indicated tumors**
  We work with corporate partners to progress clinical trials targeting various tumors. In Japan, we have already obtained approval for OPDIVO to treat seven cancers: melanoma, non-small cell lung cancer, renal cell carcinoma, Hodgkin lymphoma, head and neck cancer, gastric cancer, and malignant pleural mesothelioma. We are working on development to obtain additional approval for more than 20 indications for cancers.
  Although the status of development varies from region to region, development is in the final stages for several cancers including esophageal cancer, hepatocellular carcinoma, and ovarian cancer.
- **Adding treatment lines**
  We move ahead with clinical trials to enable OPDIVO's use at earlier stages from third- to second- to first-line anticancer treatment.
  OPDIVO can be used as a first-line anticancer drug in melanoma and renal cell carcinoma. To enable OPDIVO to be used in many other cancers including head and neck cancer and gastric cancer, the Clinical Development Division plays a leading role in efforts toward therapy line expansion.
- **Developing combination therapies**
  OPDIVO may, in combination with anticancer drugs having different action mechanism including another immune checkpoint inhibitor therapy and chemotherapy, or radiotherapy, have more therapeutic effects rather than alone. We already proceed with clinical trials in various combinations in different dosages and dose regimens with IDO1 inhibitors or anti-LAG-3 antibody, mainly with the anti-CTLA-4 antibody Yervoy, which has been already approved for combination with OPDIVO for the treatment of some type of cancer.
- **Searching for biomarkers**
  Biomarkers, substances in a living organism, are indicative of any change in disease or reaction to therapy. Their measurements can be used as an indicator of presence or progress of disease or therapeutic effects. Discovering biomarkers useful in selection of anticancer therapy is beneficial to patients in that they may receive optimum therapy as early as possible.
  We advance the search for optimal biomarkers that will predict patients who are more likely to be expected to exhibit the therapeutic effects of OPDIVO.

Manufacturing Enhancing Product Value Through Stable Supply of High-Quality Drugs

At ONO, all the divisions involved in manufacturing cooperate closely with each other and consistently maintain a strong sense of responsibility and ethics as they faithfully practice scientific evidence-based manufacturing operations according to the operating procedures and continuously make maximum efforts for the stable supply of high-quality drugs. Moreover, we are committed to strengthening our capabilities in both hardware and software related to manufacturing activities for the stable supply of drugs.

Initiatives to Ensure Stable Supply of High-Quality Drugs

It is essential for health and life science business to improve productivity for stable product supply. ONO continually reviews production systems and invests appropriately in 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

Maximizing Product Value

destined for market launch. We also consistently perform cost management from active pharmaceutical ingredient production to commercialization, as well as manages costs of raw and labeling/packaging materials from the supplier selection stage. We ensure that all drugs are produced, whether in-house or through outsourcing, under appropriate quality assurance system. ONO's plants have a quality assurance system in place that is compliant with global regulations such as the US GMP and PIC/S GMP. In outsourcing production, ONO checks, through regular quality auditing, that appropriate manufacturing control and quality control are conducted.
We take various measures to stably supply high-quality drugs, including education and training of all workers involved in production and quality assurance, strengthening the quality system in accordance with ICH Q10 Pharmaceutical Quality System, and upgrading of risk management systems at our manufacturing centers.

Strengthening Production Systems

Our manufacturing centers in Shizuoka and Osaka are compliant with GMP (a set of standards relating to the manufacturing control and quality control of pharmaceuticals). The main Fujiyama Plant proceeds with continual improvement and expansion of its facilities. In addition to strengthening our production capabilities aimed at future business expansion, a new plant has been constructed in Yamaguchi to mitigate the risk of major disaster from the business continuity perspective. This new plant is now in the final stages of verification before beginning operation. Equipped with a production line for highly active antibody drugs, the plant is planned to produce injections including anticancer drug OPDIVO and multiple myeloma drug KYPROLIS. The plant is scheduled to start operation in spring 2020 upon completion of regulatory procedures, including obtaining drug manufacturing license, to serve as a manufacturing center that will support ONO's production capabilities together with the Fujiyama Plant.

Scientific Information Dissemination Enhancing Product Value Through Provision and Collection of Proper Information and Through Activities that Meet Medical Needs and Community Characteristics

Drugs are of no value unless they can be used properly in those who are suffering from disease while undergoing medical treatment. We conduct scientific information dissemination activities based on market research and analysis, not only to properly provide and collect evidence-based information but also to offer therapy options appropriate to patient needs and community characteristics.

Marketing Activities to Enhance Product Value

The Sales & Marketing Division has the Oncology Business Unit, the Primary Care Business Unit, and their respective medical representatives (MRs) develop a strategy formation based on market research that constantly ensures competitive advantage by adjusting with agility to environmental changes in each stage of the product life cycle to maximize the potential of every product we offer.
In addition, we make every effort to collect patient opinions through meetings with healthcare professionals to understand potential healthcare needs toward development of narrative-based medicine (NBM), which is based on actual clinical experiences for patients. We will make use of what has been obtained through these efforts in future information dissemination activities to enhance product value.

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. Our information-sharing framework enables our MRs to share across the company the valuable information they gather from the frontline of healthcare. We also have a system in place that allows all the MRs to access the 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 AI-based FAQ system.
Our framework promotes information sharing and enables rapid responses to healthcare providers' needs. In addition to the FAQ system, we use AI to continually bring efficiency to MR activities.

Relaying Up-To-Date Drug Information to Frontline of Healthcare

Pharmaceuticals and medical technology undergo daily advances. It is one of the roles of drug manufacturers to relay as quickly as possible up-to-date information about such drugs and technology to the frontline of healthcare 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. In addition, we put effort into disseminating up-to-date drug information through operating several websites for medical professionals. In FY2018, we held more than 130 live webinars. We also provide small-scale area live webinars in line with community needs to relay up-to-date drug information to the frontline of healthcare.

Prompt and Appropriate Provision of Medical and Scientific Information

Our Medical Affairs Department works to attain a high level of expertise and academic knowledge in oncology and primary care domains to assess and collect medical and scientific needs of healthcare professionals through meeting with experts or attending at advisory board meetings. In response to request from healthcare professionals, we provide such evidence-based medical and scientific information with transparency to contribute to the healthcare frontline.

Strengthening Community-Based Activities

With medical care zone initiatives for community areas proceeding toward the establishment of community-based integrated care (CBIC) systems, we propose possible improvements in the medical care (MC) systems through consultation with medical providers upon understanding of the characteristics of the healthcare provision system of each community area, so that our drugs will truly benefit each individual patient, to become a player who can carry out information dissemination activities to be appreciated by medical professionals.
In October 2018, we set up an Area Support Promotion Department by expanding its functions that respond to reconstructed MC systems and CBIC systems in local communities. With this department, we work to assess, and promote solutions to, challenges and needs of government bodies and healthcare providers on community-by-community basis. As an activity that distinguishes ONO MRs from the rest, our MRs hold table discussion meetings (TDMs) in each area. TDMs are projects where lectures are organized based on themes proposed in line with the context of local healthcare issues, providing opportunities to solve questions in daily medical care through discussion between lecturers and participants. TDMs are thoughtfully planned and orchestrated so as to contribute to local healthcare through responding to different needs of each area.

Safety and Quality Assurance Enhancing Product Value Through Drug Reliability Assurance Activities

From a patient standpoint, ONO conducts drug reliability assurance activities with global perspective through drug life cycle to constantly check for drug quality assurance and reflect opinions from healthcare professionals and patients on further quality improvement. In addition, we analyze and assess, based on latest scientific evidence, drug quality and efficacy and safety (adverse reaction) information collected from, e.g., reports from patients and healthcare professionals, literature, and surveys, to constantly provide updates to the frontline of healthcare.

Quality Assurance Policy

We not only meet the legal requirements as a marketing authorization holder, but also set out our own quality manual to establish a drug quality system and work to continuously improve systems so as to provide high-quality drugs from the viewpoints of patients, caretakers and healthcare professionals. In addition, we contribute to society through stable supply of pharmaceuticals that are assured to a high-quality standard.

Initiatives for Proper Use of Pharmaceuticals

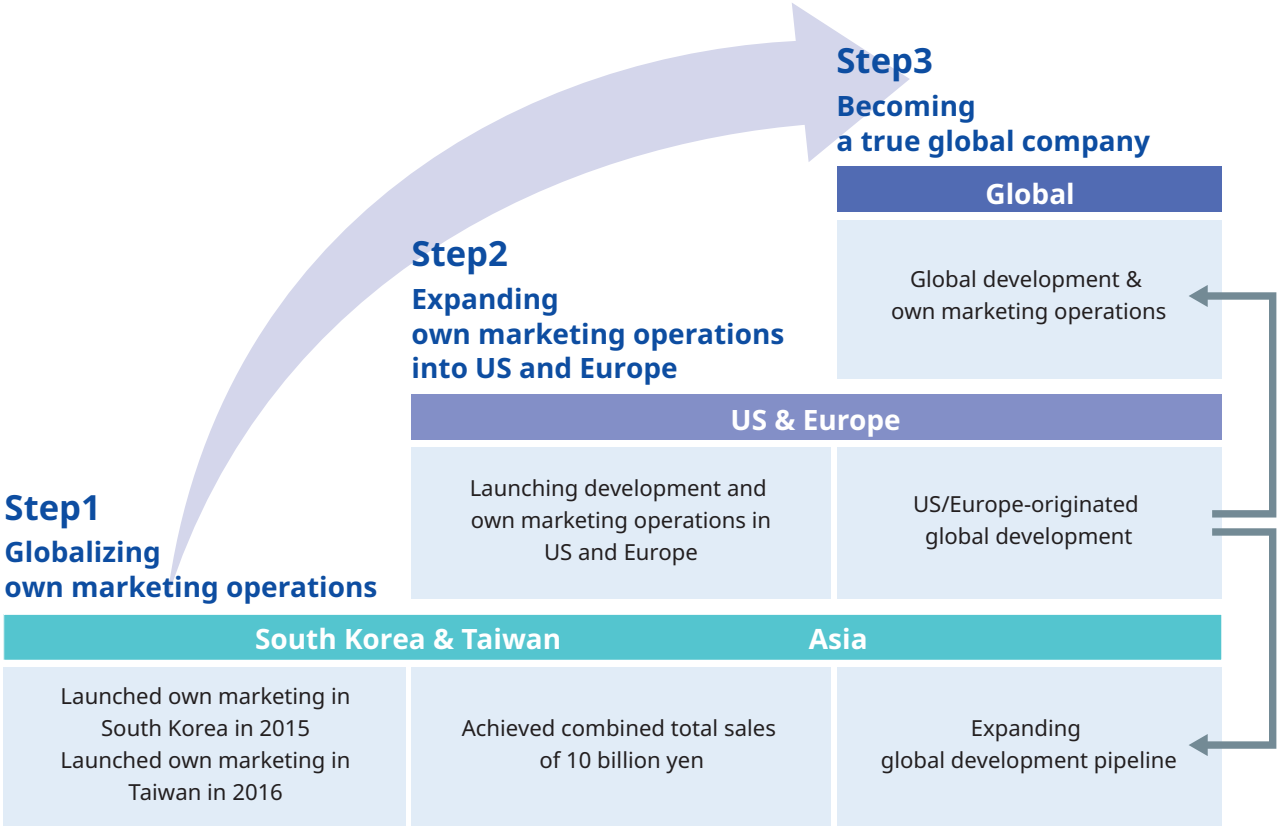
We develop a risk management plan and collect and manage safety (adverse reaction) information for each pharmaceutical. We assess collected data and information and if necessary, revise the cautions on package inserts and make announcements about proper use. As safety information has been drastically increasing inside and outside Japan after market launch of anticancer drugs, we assess such information based on opinions from external medical experts to promote the proper use of the drugs, e.g., by disseminating it through promotional materials, conference presentations, and medical journals. In addition, the Corporate Regulatory Compliance Safety and Quality Assurance Division, containing a section responsible for data, also uses and utilizes medical databases to analyze pharmaceutical product profiles and safety information for proper use.

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 also have relevant departments jointly conduct periodical drills in preparation for product recall to check that they can be executed quickly even in unexpected circumstances.

Globalizing Business

Globally, developed countries are aging and emerging countries are undergoing population growth, generating further unmet medical needs. This means that the global pharmaceutical market is set to continue its growth path. ONO is striding forward in a drive to achieve its vision of becoming a Global Specialty Pharma company in competing in the global arena.



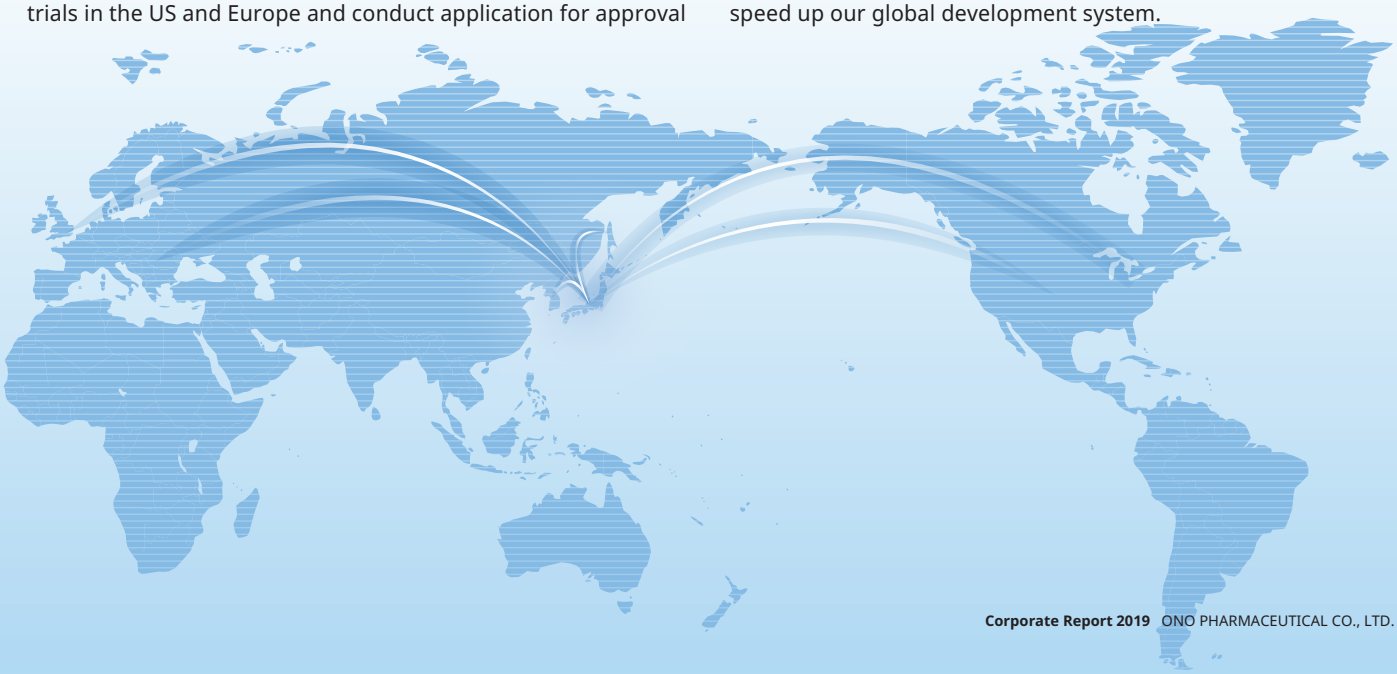
Step1 **Globalizing own marketing operations**	• Launching own marketing in South Korea and Taiwan • Building business base in Asia • Strengthening new drug development framework in US and Europe
Step2 **Expanding own marketing operations into US and Europe**	• Expanding sales in Asia • Launching own marketing in US and European markets
Step3 **Becoming a true global company**	• Expanding global development pipeline • Delivering US/Europe-originated pharmaceutical products to patients around the world

Promotion of Business in Asia

As a beachhead to expand revenue sources into overseas markets, we have been reinforcing overseas business expansion starting in Asia. We established wholly owned subsidiaries, ONO PHARMA KOREA CO., LTD. (OPKR) in South Korea in 2013 and ONO PHARMA TAIWAN CO., LTD. (OPTW) in Taiwan in 2014. The subsidiaries have since launched their own marketing and have demonstrated steady progress.
We have obtained approval for anticancer drug OPDIVO for additional indications not only in Japan but also in the rest of the world. The drug has been approved for 7 and 9 types of cancer in South Korea and in Taiwan respectively (as of June 2019). To significantly contribute to advancement in cancer therapy in South Korea and Taiwan, we also put efforts into safety measures by, e.g., rolling out scientific activities countrywide with Japanese and Western doctors appointed as lecturers to promote proper drug use. In addition, we conduct information dissemination activities not only on a countrywide level but also on a small-scale, locally-focused level to bring a fresh sensitivity to both markets as part of efforts to become the market leader in oncology in Asia.
We have also established a division within our Head Office that is in charge of planning operations in South Korea and Taiwan and expansion into other Asian markets. In close cooperation with the locally incorporated subsidiaries, the division investigates issues and develop overseas business strategies.

Business Expansion into the US and Europe

We have pursued in-licensing of new drug candidates developed in-house to deliver them to healthcare settings outside Japan, except in South Korea and Taiwan, where we have our own sales organization in place. Currently, however, we are establishing a system to sell our drugs on our own, also in the US and Europe, the world's largest markets.
To market globally on our own, we have to set up local centers for clinical development and build a structure that ensures that we can perform clinical development and apply for approval by ourselves. In April 2019, we transferred the functions of the Global Clinical Development Division from Japan to our US subsidiary ONO PHARMA USA, INC. (OPUS). We will pursue organizational improvements that enable us to conduct clinical trials in the US and Europe and conduct application for approval through consultation with the regulators.
For business launch in the US and Europe, we intend to market in-house developed products in disease domains that do not require a large-scale sales force. We will sell such new drugs with efficacy and safety expected superior to those of the competition. Among our current pipelines, we consider, as global development pipelines, compounds under development to treat acute leukemia or intractable diseases with physical changes or metabolic abnormalities due to growth hormone hypersecretion, so that we can deliver new drugs to patients worldwide.
We continue upgrading our drug development infrastructure in Japan, the rest of Asia, the US, and Europe to strengthen and speed up our global development system.



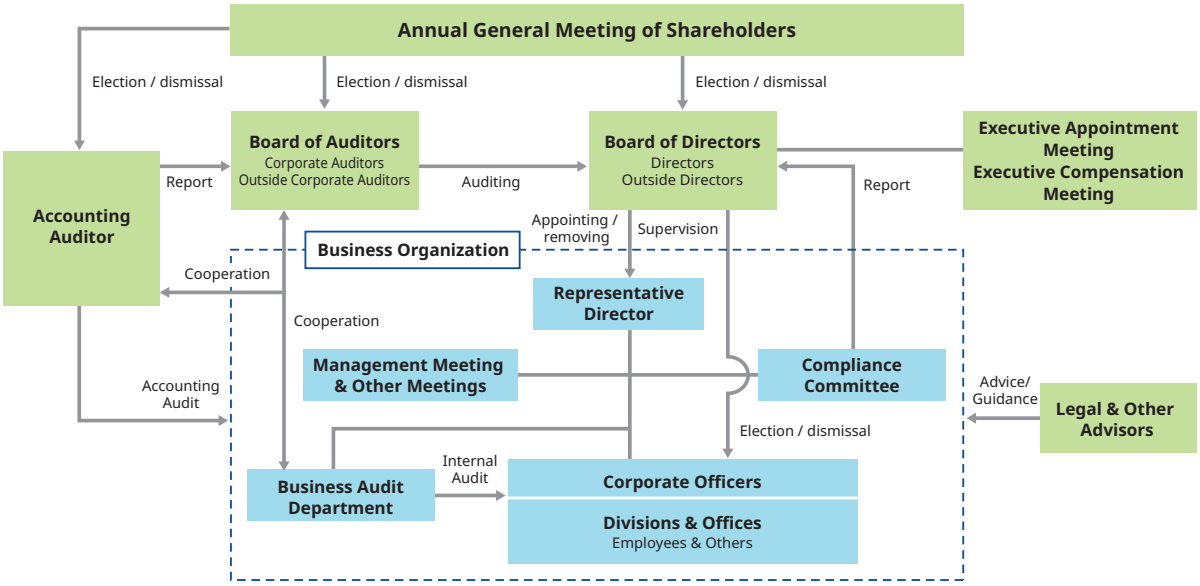
Strengthening Corporate Infrastructure

ONO strengthens corporate infrastructure to conduct company management based on the global standards. It is essential for our sustainable growth to handle corporate governance, the development of human resources, compliance with laws and regulations, and climate change. ONO therefore continues to engage in activities from a long-term perspective.

Corporate Governance

Corporate Governance Structure

ONO has adopted the organizational framework with Corporate Auditors (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

When selecting candidates for directorships we consider the balance of knowledge, experience and skills compatible with the whole Board of Directors' ability to make expert and comprehensive management decisions. We are also more clearly defining the responsibilities of management to our shareholders and have set the term of office for directors at one year, so as to enable rapid responses to changes in the management environment.

We have set the number of directors on the board to a number that is appropriate to enabling rapid and sound decision-making and that enhances managerial transparency and oversight. The Board of Directors currently consists of eight members including three outside directors and generally meets once a month. It is at these meetings when important management matters are decided and oversight of directors' duties takes place. In addition, the Board of Directors also values the opinions of Corporate Auditors and engages in discussions including the perspectives of specialists in law, finance, and accounting as well as gender perspectives.

Board of Auditors

We have strengthened our auditing capability by appointing four auditors to the Board of Auditors, including two thoroughly independent outside auditors and two full-time auditors who are thoroughly familiar with ONO's business and have the authority to gather high-level information. The full-time auditors and the outside auditors work together to strengthen audit effectiveness.

The meeting of the Board of Auditors is held on a regular basis. The auditors are working with our Internal Audit Capability (Business Audit Department) to enforce auditing efficiency, and endeavors to improve its functions of the management oversight by enhancing the effectiveness of audits in cooperation with the accounting auditor.

Executive Appointment Meeting

The Executive Appointment Meeting consists of the President and Representative Director who is the chair, one Internal Director, and three Outside Directors, and it ensures transparency and objectivity in the designation of candidates to be Directors and Corporate Auditors and the appointment of

executive management members and it discusses policies for succession planning of the chief executive officer (President, CEO) and other top management members and corporate governance of ONO. In addition, executive officer appointments are proposed to and approved by the Board of Directors after deliberation by this Meeting.

Executive Compensation Meeting

The Executive Compensation Meeting consists of the President and Representative Director who is the chair, and three Outside Directors, and it ensures transparency and objectivity in the compensation amount of individual Directors and the calculation method and discusses the appropriateness and future of the executive compensation system. In addition, executive compensation, etc. is proposed to and approved by the Board of Directors after deliberation in this Meeting.

Internal Control System

ONO provides for an internal system in accordance with the basic policies of the internal control system decided upon by the Board of Directors. In addition, ONO strives to ensure compliance and to detect internal control issues early through our Internal Audit capability (Business Audit Department) and thereby maintains and increases the appropriateness of organizational operation. Furthermore, we have established compliance windows in and outside the company to increase the self-maintenance function of the organization and we are striving to reduce reputation risks from whistle-blowing outside the company. Development and operation conditions of the Internal Control System are reported periodically to the Board of Directors to improve organizational operation continuously.

Operational Management Structure

ONO is striving to ensure and increase the efficiency and correctness of decision-making and operational management by, for example, the President and Representative Director, the Directors and Corporate Officers who take responsibility for each division, as well as the managers of relevant departments to deliberate important operational management matters and above all, matters to put before the Board of Directors from various angles in Management Meeting & Other Meetings. We are also seeking to strengthen operational management capabilities and to accelerate decision-making by implementing our Corporate Officer system, transferring authorities, and taking other measures. In addition, ONO also includes attendance at Management Meetings and inspection of the minutes within the scope of auditors' work.

Corporate Governance Code

Based on the aim of the Corporate Governance Code stipulated by the Tokyo Stock Exchange, we develop structures appropriate for our businesses through assessment of the effectiveness of the meeting of the Board of Directors that is held annually and other measures and thereby strive to increase management efficiency, soundness, and transparency, etc.

■ For more details on our company's corporate governance, please refer to the following Corporate Governance Report (only available in Japanese).
→https://www.ono.co.jp/jpnw/csr/pdf/c_governanc/c_governanc20190627.pdf

Information Disclosure

As specified in our Codes of Conduct, we strive to establish 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 a policy of pursuing accuracy, fairness, impartiality, and promptness.
We disclose financial results and other timely disclosure information on our website and at the same time through TDnet, the timely disclosure network of the Tokyo Stock Exchange. Information that is not subject to the timely disclosure rules is also disclosed swiftly through our website and by other means.
For securities analysts and institutional investors, we provide financial results briefings or conference calls at the time of each quarterly statement and these details are disclosed on our company's website in both Japanese and English. In addition, through the following activities, we strive to communicate our business activities and management strategies broadly in an easy-to-understand way and gain more understanding.

- Individual meetings and phone conferences / Results in FY2018: Approximately 220 times
- Briefings for individual investors (held by security companies) / Results in FY2018: 9 times
- Provision of information by posting on IR Library of our website / progress of development products, financial highlights from the past five years, etc.
- Business report "ONO'S VIEW" (shareholder newsletter) / Semi-annually
- Corporate Report (Annual Report, leaflet to introduce ONO) / Annually

We continue to address the disclosure of information in more accurate and prompt ways.

Risk Management

Based on recognition of the possibility of major risks, ONO engages in the prevention of their occurrence and develops systems to handle cases where risks actually occur appropriately. In April 2019, a new organization to perform entire risk management (ERM) was established to reinforce the system.

Rules and other systems on the management of the risk of losses

(1) We manage risks related to compliance, product quality and safety, safety and health, the environment, disasters, information security, and other issues on the basis of internal rules and through the preparation and distribution of procedures in the relevant sections, as well as through training and other measures.

Strengthening Corporate Infrastructure

Corporate Governance

(2) Cross-organizational risks and risks deemed to have a significant impact on management are monitored and addressed at a meeting attended by the President and Representative Director, the Directors and Corporate Officers in charge, and the managers of relevant divisions. In case of unexpected risks, the President gathers the relevant persons to solve any problems promptly as necessary.
(3) Risks specific to a division are addressed by that division through the preparation of handling procedures, which are reviewed constantly in accordance with changes in the business environment.

Structure to ensure proper business operations of the corporate group composed of ONO and its subsidiaries

We provide consultation and guidelines for our group companies with regard to their legal compliance and risk management. While respecting their autonomy, we request that each company provides us with regular business reports and consult with us on important business issues in advance.

Business Continuity Plan (BCP)

We have organized the Crisis Management Headquarters and established a structure designed to minimize the impact of an emergency on mission-critical operations according to the instructions of the Emergency Response Committee chaired by the President, so that we can continue business activities or recover promptly and resume them if they are suspended in cases of an emergency such as a natural disaster or serious accident. The BCM Committee, which is chaired by the General Administration Headquarters and in charge of business continuity management (BCM), and the Secretariat have been formed to maintain and strengthen our abilities to respond to crisis and continue our business operations, and promote relevant management activities during normal times.
Equipment for disasters, including emergency power equipment, two-line power receiving systems, and other measures, have been adopted at the Head office, Tokyo Building, each manufacturing plant, and each research institute, and seismic isolation devices against earthquakes have been introduced at the Head office, Tokyo Building, and Minase Research Institute. Furthermore, we have established a system to handle emergencies at two bases, in Osaka and Tokyo.

■ Messages from Outside Directors (Independent Executives)

Outside Director Yutaka Kato

I assumed the office of Director of ONO PHARMACEUTICAL as an independent executive in June 2013. Outside directors attend at meetings of the Board of Directors and get involved in management decision-making from a third-party perspective. Through such involvement, the outside 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, and can give advice accordingly. I believe that reflecting social perspectives in management decisions on various issues enables the support that can ensure true competitive advantage. For this reason, I proactively provide helpful information from my study results, the details of my serial articles in business magazines, and the papers of my seminar students.
In general, outside directors cannot even 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.

Fortunately, business results have been good. However, ONO is expected to begin a new era after celebrating its 300th anniversary. It is important at this milestone juncture to comprehensively revise internal systems and adopt a clear strategy to take us into the future. In particular, I consider the following activities to be important: further strengthening research and development abilities; maximizing product value and strengthening corporate infrastructure in order to ensure sustainable competitive superiority; and sales expansion of ONO's products in overseas markets. Outside directors are expected to cooperate with internal management members concerning the issues involved in these management strategies.
We need to remind ourselves constantly of our Corporate Philosophy: Dedicated to Man's Fight against Disease and Pain. It is imperative that we are aware of our duty to engage in corporate activities for people around the world.

Outside Director Jun Kurihara

Artificial Intelligence (AI), which has been discussed in various ways, is drastically changing the corporate environment and competitive conditions throughout the world. These new technologies offer companies the possibility of prosperity and at the same time they have the risk of causing a crisis of decline and disappearance. Pharmaceutical companies that strive to promote more effective use of management resources and to reduce risks in association with drug discovery by using AI will strengthen their company structure and will be able to overcome various issues despite increasing uncertainty. I strongly expect that ONO will continue to develop new technologies and to enjoy its excellent results as a leading company in the biomedical field.

The situation where the birthrate is declining and the number of elderly people is growing has become more serious in Japan; nevertheless, we must restore financial soundness. It is essential for Japan-based Japanese companies to make internal structures more efficient and to expand to overseas markets. Although my abilities are limited, I have directly experienced habits and values that are different from Japan through my more than 10 years of overseas life. At the same time, I understood overseas habits and values and then learned how Japanese companies and individuals grow. Concerning AI technologies, I also learned differences in technology levels and use methods inside and outside Japan and their respective advantages and disadvantages. In addition, I have also learned by trial and error what qualifications are required for persons who can work to bridge the gap between Japan and overseas and how these qualifications can be acquired.

I would like to participate in decision-making for management along with other Outside Directors while identifying the differences between perspectives both inside and outside Japan. In other words, I will keep my eyes sharp with an "externally cool gaze" on ONO, prick up my ears, and distinguish dangerous sounds, and thereby contribute to decision-making for management.

Outside Director Masao Nomura

One year has elapsed since I assumed the office of Outside Director of ONO as an independent director. I participated in all major meetings, including meetings of the Board of Directors for one year.

Since I have engaged in company management in an industry that has no direct relationship with the pharmaceutical industry, I participated in management from a different perspective. Through discussions at the meetings of the Board of Directors, the attitude of top management members to face corporate governance honestly and comply with it touched my heart.

Under the lofty corporate philosophy "Dedicated to Man's Fight against Disease and Pain," ONO engages in reinforcing corporate governance and the entire company engages in achieving the company philosophy. Needless to say, the purpose of company management is appropriate profit seeking and sustainable growth. In order to achieve this purpose, it is a basic premise to maintain company soundness and to gain reliability from society and stakeholders under a defined corporate philosophy.

Japan is facing a declining birthrate and an aging population more than other developed countries and it is one of the first in the world to reach the 100-year life.

When we face this new era, our major theme is to overcome every disease and pain and to live a healthy and fulfilling life at every age. ONO is a company that carries out a big social mission to make this theme a reality. In the pharmaceutical industry where the business environment is drastically changing, ONO must observe compliance and reinforce the corporate governance structure to increase its social presence and value and to continue trying to enter the global market in the new era as well. Although my ability is limited, I would like to use my experience in company management, participate in management from an independent and objective perspective as an Outside Director with an "external perspective," and thereby contribute to the development of ONO.

Strengthening Corporate Infrastructure

Corporate Governance

(Front row, left to right) Hishiyama, Sakka, Sagara, Kato, Kurihara, Nomura
(Back row, left to right) Fujiyoshi, Nishimura, Awata, Sano, Kawabata, Ono

Expected Roles of Outside Directors and Outside Auditors

	Name	Expected Roles	Attendance at meetings (Results in the fiscal year that ended in March 2019)
Outside Director	Yutaka Kato	With advanced academic knowledge and abundant experience as a professor of management accounting and cost accounting, Mr. Kato has fulfilled important roles as an outside director by providing appropriate supervision of our company management from an independent standpoint as well as useful advice and suggestions. We expect that he will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of our company as an outside director.	Meeting of Board of Directors: 13 times / 13 times Executive Appointment Meeting: 2 times / 2 times Executive Compensation Meeting: 2 times / 2 times
	Jun Kurihara	With broad knowledge and abundant experience gained from research inside and outside Japan and as one of the leading researchers in fields related to politics, the economy, and society, Mr. Kurihara has fulfilled important roles as an outside director by providing appropriate supervision to our company management from an independent standpoint as well as useful advice and suggestions. We expect that he will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of our company as an outside director.	Meeting of Board of Directors: 13 times / 13 times Executive Appointment Meeting: 2 times / 2 times Executive Compensation Meeting: 2 times / 2 times
	Masao Nomura	Mr. Nomura has abundant experience and advanced knowledge as he has served as a management executive over the years and he has fulfilled important roles as an outside director by providing appropriate supervision of our company management from an independent standpoint as well as useful advice and suggestions. We expect that Mr. Nomura will continue to be involved in our company management as an outside director and thereby contribute to increasing our company value.	(Appointed in June 2018) Meeting of Board of Directors: 9 times / 9 times Executive Appointment Meeting: 1 time / 1 time Executive Compensation Meeting: 1 time / 1 time
Outside Auditor	Hiromi Sakka	With abundant experience and considerable knowledge of accounting as a certified public accountant, Ms. Sakka has fulfilled important roles as an outside auditor by providing supervision of the operations of our company directors from an expert and independent standpoint as well as findings and suggestions if needed. We expect that she will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of our company as an outside auditor.	Meeting of Board of Directors: 13 times / 13 times Meeting of Board of Auditors: 14 times / 14 times
	Yasuo Hishiyama	With abundant experience and advanced knowledge of corporate legal affairs as an attorney-at-law, Mr. Hishiyama has fulfilled important roles as an outside auditor by providing appropriate supervision of the operations of our company directors from an expert and independent standpoint as well as findings and suggestions if needed. We expect that he will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of our company as an outside auditor.	Meeting of Board of Directors: 13 times / 13 times Meeting of Board of Auditors: 14 times / 14 times

Management (as of June 20, 2019)

Members of the Board of Directors

President, Representative Director, and Chief Executive Officer	Gyo Sagara	
Member of the Board of Directors, Vice President Executive Officer/ Tokyo Branch Head	Hiroshi Awata	
Member of the Board of Directors, Senior Executive Officer/ Executive Director, General Administration Headquarters	Kei Sano	
Member of the Board of Directors, Executive Officer/ Executive Director, Corporate Regulatory Compliance, Safety and Quality Assurance	Kazuhito Kawabata, 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	Professor, Doshisha Business School
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
Member of the Board of Directors, Outside Director	Masao Nomura	Senior Adviser to the Board, Iwatani Corporation Outside Director, Keihanshin Building Co.,Ltd.

Audit & Supervisory Board Members

Audit & Supervisory Board Member	Katsuyoshi Nishimura	
Audit & Supervisory Board Member	Shinji Fujiyoshi	
Outside Audit & Supervisory Board Member	Hiromi Sakka	CPA Partner of Kyoritsu Audit Corporation
Outside Audit & Supervisory Board Member	Yasuo Hishiyama	Attorney-at-law Partner Attorney at Law, TANABE & PARTNERS

Corporate Officers

Corporate Executive Officer/ Executive Director, Sales and Marketing	Hiroshi Ichikawa
Corporate Executive Officer/ Director, Corporate Communications	Yukio Tani
Corporate Executive Officer / Executive Director, Corporate Strategy & Planning	Toshihiro Tsujinaka
Corporate Executive Officer / Executive Director, Discovery & Research	Toichi Takino, Ph.D
Corporate Officer/ Director, Nivolumab Strategic Planning & Chairman, Scientific Review Committee of R&D Programs	Shozo Matsuoka, Ph.D
Corporate Officer/ Business Unit Director, Sales Department, Western Japan Region	Katsuji Teranishi
Corporate Officer/ Executive Director, CMC-Production	Takuya Seko, Ph.D
Corporate Officer/ Deputy Executive Director, Discovery and Research	Hiromu Habashita, Ph.D
Corporate Officer/ Business Unit Director, Sales Department, Metropolitan Region	Katsunori Morio
Corporate Officer / Executive Director, Clinical Development	Kiyoaki Idemitsu
Corporate Officer/ Head of Medical Affairs	Shinji Takai, M.D

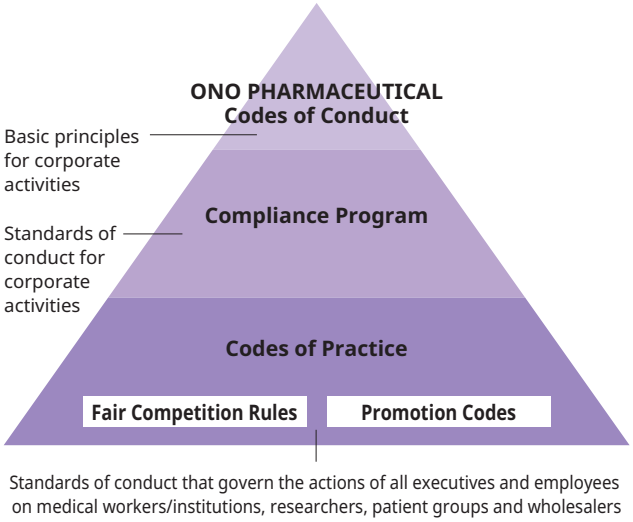
Strengthening Corporate Infrastructure

Fair Operating Practices

ONO PHARMACEUTICAL Compliance Structure

ONO has the ONO PHARMACEUTICAL Codes of Conduct to be aware of the responsibilities it holds as a pharmaceutical company in the development and provision of medicines on which human lives depend and to ensure that it acts in compliance with laws and regulations and that it meets high ethical standards.
Our compliance structure consists of the ONO PHARMACEUTICAL Codes of Conduct, which serve as a foundation for guiding our corporate activities; the Compliance Program, which provides standards of conduct for the activities; and the Codes of Practice, which are based on the pharmaceutical industry standards on promotion and other activities.
When putting compliance with laws and regulations into practice, we repeatedly remind our employees of their duties to ensure transparency in transactions and prevent fraud and corruption, and to act taking consideration of the social context at home and abroad.
As a pharmaceutical company keenly aware of corporate ethics both in principle and in practice, we will continue to strengthen our level of compliance in line with our ethical principles.

ONO PHARMACEUTICAL Compliance Structure



Compliance Promotion Initiatives

Compliance Promotion System

To promote compliance, we have appointed a Corporate Compliance Officer and set up a Compliance Committee. The Compliance Committee examines and deliberates compliance-related issues, plans and promotes training and cooperates with the internal auditing department to check the extent to which compliance has been disseminated and practiced.

We have internal and external contacts for reporting and consulting on compliance issues for all group companies, including the 24-hour external contact for counseling service. This system ensures harassment and other compliance violations are prevented as well as stopped from reoccurring. Likewise, an appropriate working environment can be ensured, and necessary actions and measures can be taken to minimize any damage or decline in credibility in the event of a compliance violation.
From the perspective of protection of informants, matters related to the privacy of informants, such as their name, etc., and matters related to the details of reporting will be kept strictly confidential and only provided to relevant persons necessary for investigation. In addition to the measure to prohibit prejudicial treatment of any kind when making the report and the measure to corrective actions in cases where a disadvantage is found, we prohibited the reported person from divulging the details of the reporting and the names of informants and other matters in the course of fact finding. Furthermore, this system also accepts anonymous reports.

■ For more detailed reporting and consultation systems, please see our website on CSR.
→https://ono-csr.disclosure.site/en/themes/101

Engagement in Fair Promotion Activities

In terms of pharmaceutical marketing, so that the Compliance Promotion Department, Sales and Marketing Division, and other relevant departments cooperated with each other in order to provide optimal medical treatment from the patient standpoint, we established the Pharmaceutical Promotion Code in our Codes of Practice as an action guideline and we practice this Promotion in accordance with the guidelines.
ONO defines the term “Promotion” as “providing and conveying pharmaceutical information to medical workers so as to disseminate the appropriate use of pharmaceuticals based on such information.” We proactively carry out promotion activities, while always examining whether they are acting in accordance with the spirit of the Pharmaceutical Promotion Code in our Codes of Practice regardless of whether there are any specific provision or description in the Code. We also comply with the Code and adhere to the Guidelines for Provision of Marketing Information of Prescription Drugs that are proposed by the Ministry of Health, Labour and Welfare, the JPMA (Japan Pharmaceutical Manufacturers Association) Code of Practice, and the Rules of the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry, as well as respecting the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Practice, which is a code established by an association in which the JPMA participates. Furthermore, in response to the commencement of operation of the Guidelines for Provision of Marketing Information of Prescription Drugs, we established the division supervising provision of marketing information and the examination and supervising committee and also the contact window for marketing information provision, and disseminated the contact window to healthcare personnel, and we will thereby conduct further fair promotion activities.

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 give special companywide training to prevent occurrence or recurrence of violation of compliance, depending on the nature of the case.

In particular, with regard to harassment, not only do we provide training courses for management staff, but we also have external lecturers hold sessions on harassment, thereby enhancing awareness of compliance.

Concerning the thorough implementation of fair promotion activities, compliance promotion staff members visit each sales branch twice a year to provide MRs with compliance training focusing on dissemination and raising awareness of the Pharmaceutical Promotion Code in our Codes of Practice. The Compliance Promotion Department and Sales and Marketing Division hold monthly joint meetings with Trade Practice Committee members of the Fair Trade Council to share information and provide training. Furthermore, at meetings held by leaders in the Sales & Marketing Division, systems to improve familiarity with the aforementioned standards within the Division are developed.

Ethical Considerations

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

We have established internal ethical rules for research using human-derived samples (blood, tissue, cells, genes, etc.) based on the basic guidelines issued by the Japanese government. We have also established the Ethics Committee for Medical and Health Research Involving Human Subjects, as the advisory body comprising members from inside and outside the company. Such research is conducted only after the Committee conducts strict assessment of its ethical and scientific validity.

For research using laboratory animals, we have an Institutional Animal Care and Use Committee in place. The committee reviews such research in advance to determine whether the protocols are prepared with due consideration of the 3Rs - replacement (to use alternative methods), reduction (to use a smaller number of 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, for example, and obtain third-party certification of these activities from the Center for Accreditation of Laboratory Animal Care and Use in the Japan Health Sciences Foundation.

Clinical trials, which are essential for verifying the safety and efficacy of investigational drugs, must be performed with respect for the rights of trial subjects. Clinical trials are closely monitored for patients' safety and are stringently conducted under high ethical standards. We are committed to evaluating the real merit of investigational drugs by steadily applying essential and complete testing procedures that comply with Japan's Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (PMD Act) and other related legislation, as well as the global standards based on the spirit of the Declaration of Helsinki.

■ For more details on ethical considerations, please see our website.
→https://www.ono.co.jp/eng/rd/animal_ethics.html

Fair and Transparent Business Activities

In promoting fair and transparent business activities, we ensure thorough awareness of the prevention of unfair and corrupt practices by repeatedly training our employees.

In order to contribute to healthcare and people's health around the world through continuous new drug R&D, along with a stable supply of our products, 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 public interest rises globally on compliance to laws governing unfair and corrupt practices, we are mindful of the need to be aware of both domestic and international social contexts, and we therefore adopted in 2017 the ONO Anticorruption Global Policy and Regulations on the Prevention of Corruption. These are intended to clearly define and state our company's stance and system in preventing bribery and corruption. We are endeavoring to put these more strictly into practice.

As for publicly funded research, we instituted our Guideline on Publicly Funded Research as well as our Regulations on Publicly Funded Research in compliance with Japanese government guidelines and we are committed to ensuring proper operation and management.

■ For more details on the corruption prevention system, please see the ONO Anticorruption Global Policy.
→https://www.ono.co.jp/eng/csr/pdf/anti-bribery-global-policy201704.pdf

Promotion of CSR Procurement

ONO established the Basic Policy for Procurement Activities and CSR Procurement Guidelines and ONO promotes CSR procurement so that the entire supply chain can achieve the development of a sustainable society. The Basic Policy for Procurement Activities is a basic policy for all employees involved in procurement activities. The CSR Procurement Guidelines compile matters for which the cooperation of suppliers is required. In addition, in March 2019, we started to use CSR management evaluation system, EcoVadis, and prepared a system where the CSR management level of important suppliers in the supply chain can be identified objectively and continuously.

ONO established a sound network with suppliers through CSR procurement, developed a greater cooperation system, and thereby aims to increase mutual corporate value.

■ For more details on the CSR procurement, please see our website on CSR.
→https://ono-csr.disclosure.site/en/themes/106

Strengthening Corporate Infrastructure

Human Resources and Human Rights

Promotion of Human Resources Development

Based on the belief that "Business is people," we actively support the development of individual abilities and positive action taken where they are never afraid to fail so that individual abilities can fully demonstrate.

Basic Concept for the Development of Human Resources

We aim to invest in individuals who can work as members of a pharmaceutical company dealing in pharmaceuticals related to human lives and in members who can have competitive capability to help us make the leap to becoming a R&D-based pharmaceutical company that can grow and develop in a global field. While investing in the development of human resources, ONO sets the concept of recruitment and career development as follow:
Self-disciplined persons who keep trying to achieve goals, such as persons who:

- are innovation-minded and never give up trying until the end;
- can demonstrate their abilities as one of team the members 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.

Provision of Growth Opportunities

We provide opportunities for growth and awareness for our employees through various training programs. We organize a wide range of collective training for employees in each phase of career development, including companywide joint training for new employees from all divisions and departmental introductory training. To develop global human resources with capability for success irrespective of environment and location, we offer training programs and secondment to our overseas subsidiaries. We also aim to provide good training for managerial staff with a focus on the management skills required for organizational growth and the capability demanded of each role and job position. Contents of these training programs are being enhanced continuously.
Furthermore, we encourage the self-development efforts made by employees by enhancing the voluntary training system and support system for self-learning in order to foster "self-disciplined" human resources. Concerning the voluntary training, we provide the learning content beyond the framework of positions and departments and the opportunities to increase awareness for cooperation between departments. Under the supporting system for self-learning, we are always preparing an environment where attendees can learn a broad range of subjects, including leadership, management, accounting, and more. The number of available subjects for correspondence learning increased from approximately 140 as of March 2018 to 500 or more in FY2019.
In order to accelerate organizational globalization, we are engaging in various activities to enhance employee language abilities, including English training camps, study abroad, schooling, dispatching lecturers, and granting subsidies for online English conversation class, and approximately 440 employees in total received English-related training in FY2018.
Moreover, we provide training at medical institutions so that MRs can understand the needs of patients and their families and can deliver our products that bring true benefit to patients. We conduct training at facilities related to diabetes and at medical institutions specialized in dialysis thanks to agreements for this type of our training and cooperation with medical institutions. In addition to MRs, employees engaging in research and development also participate in training at medical institutions. We consider that these activities will result in drug discovery that meets the medical needs of patients more than ever.

Respect for Human Rights

In all of our business activities, ONO respects the human rights of every person and will act accordingly.
In upholding this principle, we have adopted the policy of "no discrimination due to race, nationality, ethnicity, gender, age, religion, belief or philosophy, academic background, disability or illness, or other attributes," in creating and managing our HR system. We have prohibited any form of harassment and conduct compliance training.
ONO supports international codes of conduct including the Universal Declaration of Human Rights, International Labor Standards, and the Voluntary Principles on Security and Human Rights.

Enhancing the Creation of Workplace Environments with Job Satisfaction

ONO is moving ahead to create workplace environments where employees can work with job satisfaction and a sense of security. We are continuously committed to the development of support systems and working conditions that help employees work in various styles, as well as the improvement of their work-life balance, so that each and every person in our diverse workforce can bring energy to their work and demonstrate their full potential.

Promotion of the Reviewing the Way Employees Work

For the purpose of creating employee-friendly workplace environments where employees can experience job satisfaction, we consider that the shortening of work hours is an essential and fundamental challenge to be addressed for the development of a pleasant work environment. To this end, we focus on the review of working styles.
Since FY2014, we appoint a promotion committee member in each department to involve the whole company in the activities, and the members work to raise awareness and encourage employees to make operations more efficient and to take paid holidays. In FY2018, we have also improved flexibility, including system correction and expansion of use, by updating the web conference system, promoting the use of IT, flexible working time systems, and telecommuting systems. In April 2019, we newly introduced a system that enables employees to take paid leave by the hour.
Through these initiatives, we achieved positive results such as a year-on-year decrease in overtime working hours by 5.7% and a year-on-year increase in the rate of taking paid holidays by 17.2% in comparison of FY2014 and FY2018.

Childcare Support Initiatives

We believe that society as a whole should give more support to families raising children and that businesses should tackle the issue of creating environments that facilitate child bearing and parenting.
At this time, we established the 6th Action Plan (from April 2019 through March 2021) and included the promotion of childcare leave for male employees and the creation of a system to support career development for employees reinstated from childcare leave or employees who are raising children. Since April 2017, we have been promoting initiatives to build an environment in which men can actively take part in child-raising, such as the introduction of a new childcare support system, holidays to encourage employees to take part in child-raising, as well as the strengthening of activities to ensure that the male employees who wish to participate in child-raising by taking childcare leave can obtain the consent of the people around them.
ONO has been certified as a general business operator meeting the criteria based on the Act on Advancement of Measures to Support the Development of the Next Generation in 2008, 2012, 2014, and 2017.

Programs to Enhance Worker-friendliness

ONO offers various employment and support systems.
We have systems that allow employees to continue working during various major life events and to achieve a good work-life balance, as well as support systems that help employees who develop cancer, together with leave and subsidy systems. ONO designs systems so that employees can have more options in the way they work, for example, in cases of legally required systems, ONO's systems exceeds the statutory standards.
We continuously improve these systems by listening to the workers' wishes so that they meet the actual needs of employees. Furthermore, ONO strives to disseminate the details of the systems thoroughly by preparing and delivering handbooks that describe the benefit programs, application procedures for each system, FAQs and other information and by providing announcements via Intranet so that enhanced systems are correctly understood and utilized.

Commitment to Safety and Health

For safety and health, ONO regularly hold safety and health committee meetings to continuously improve the working environment and employees' health. In our production and research sites, 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 disaster prevention measures, fire extinguishing and disaster prevention equipment, safe handling of machinery, safety procedure implementation levels, transportation operations, as well as cleanliness and tidiness. At the ONO Head Office and other company sites which have a health committee, health patrols are conducted every two months to check desks and cabinets, thereby providing thorough control of cleanliness and tidiness. Each committee discusses health issues based on the results of workplace environmental measurements. We established the Central Safety and Health Committee as a place to share information and exchange opinions between all of the safety and health committees and have implemented safety and health activities across the entire company. Labor and management proactively engage together in measures for the prevention of industrial accidents and early reinstatement after an industrial accident.

■ For more details on training systems, support systems, and changes in the number of occurrences of industrial accidents, see our website on CSR.
→https://ono-csr.disclosure.site/en/themes/104
→https://ono-csr.disclosure.site/en/themes/105

Strengthening Corporate Infrastructure

Human Resources and Human Rights

Promotion of Health and Productivity Management

For ONO to contribute to society by creating and developing innovative pharmaceuticals under its corporate philosophy, it is essential that employees and their families are mentally and physically healthy, that our worksite is a place where individual abilities can be fulfilled to their utmost, and that lives of employees and their families are satisfying. For further implementation of activities in a systematic way, our company, labor union, industrial health staff members, and health insurance association organized the "Health Up Committee" in April 2018 based on the Representative Director's health declaration.
As a result of "Health and Productivity Management" implemented by all relevant persons, ONO was certified in 2019 as an Outstanding Health and Productivity Management Organization in the large enterprise category (White 500) by METI and Nippon Kenko Kaigi (large-sized corporation department).

Prevention of Diseases / Early Detection / Early Treatment Support

- ONO requires its employees to receive an annual health checkup and employees over 35 years old and their dependent spouses optionally undergo a complete medical checkup instead of a statutory health checkup. The complete medical checkup rate has continued to be approximately 99% excluding unavoidable reasons, such as employees taking leave, etc.
- Contract facilities for complete medical checkup exist in prefectures throughout Japan. The number of contract facilities as of April 2019 is 184 so that employees and their dependent spouses can easily receive the complete medical checkup.
- ONO supports the cost of screening tests for each cancer and many employees receive optional screening tests related to cancer when they undergo a complete medical checkup. We provide mail-in-type cervical cancer screening to female employees under 35 years old.

Cancer screening test rate (FY2018)
(Target: cervical cancer, employees over 20 years old; other cancers, employees over 40 years old)

	Cancer screening rate
Gastric cancer screening test	97.3%
Lung cancer screening test	99.7%
Colorectal cancer screening test	93.6%
Breast cancer screening test	88.3%
Cervical cancer screening test	42.3%

- After employees receive their health checkup, industrial health staff members recommend pursuing a consultation at a medical institution or give health instructions as necessary, or they recommend that employees with a high risk of lifestyle-related disease and their families receive specific health instructions.

Mental Health Measures

- ONO has provided internal training on mental health and conducted individual consultations by industrial health staff members in order to contribute to prevention, early detection, and early treatment of mental disorders, and we engage in these activities in cooperation with industrial physicians.
- We conduct stress checks once a year for all employees and the implementation rate is approximately 98%. After the checks, we continuously improve our worksites based on the results of organization analysis.
- ONO established a free consulting service counter operated by an external company and developed a system where employees can consult with experts via phone or e-mail in addition to face-to-face consultation.

Measures Against Passive Smoking and Promotion of Health

- ONO started a total ban on smoking on ONO premises from April 2019. We had been increasing awareness organizationally by establishing "No Smoking Day," by implementing an internal questionnaire, by preparing and displaying original posters using employee illustrations, and by other means. Thereby, we transferred to the phase of a total ban of smoking and took other measures, including removing smoking areas on the premises and other measures.
- In order to support employees who are trying to quit smoking, we have conducted an internal Quit Smoking Competition with the aim to stop smoking within six weeks in a fun and smart way. ONO supports employee activities to promote their health by providing allowances for treatment as an outpatient of the quit-smoking department, by providing an online quit smoking program, and by other measures.
- ONO conducts a walking campaign every year. Employee teams and their family members can participate in the campaign in addition to individual employees so that everyone can voluntarily join in the campaign. In addition, people who achieve a specific goal will receive local products from a disaster area as an achievement award. The number of participants is increasing year by year and the campaign is expected to encourage employees to make a habit of walking.
- Physical checkup meetings are conducted every year at major offices, and they include measurement of body composition, age of the blood vessels, bone density, and other items. Participants can check the conditions of muscles and bones that are not made clear by health checkups alone and they can also receive individual advice on diet and exercise from medical staff members. Therefore, the number of participants is increasing every year.

Health Management Support

- ONO operates a portal site where employees can check the results of their complete medical checkups and periodic health checkups at any time with their terminal device regardless of where they received the checkups. The portal site provides information to help employees with accurately understanding checkup results and to correct lifestyle habits.
- We also established a "Health Management Site" which compiled the stress check system, health consultation window, and other systems. ONO is making efforts so that employees can correctly understand and use systems contributing to health maintenance.

Promotion of Diversity and Inclusion

At ONO, we make continuous efforts to promote diversity in our workplaces. For the purpose of responding promptly and flexibly to environmental changes and increasing corporate value, we believe that it is important to enhance the diversity of our corporate members' attributes, set of values and behavior, while recognizing their individualities.

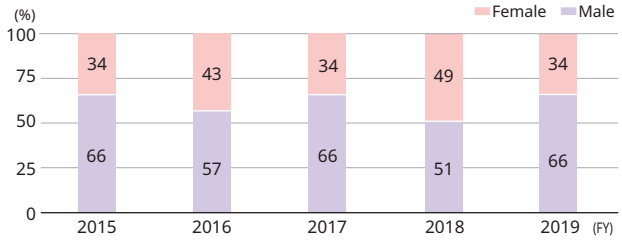
Establishment of Diversity Inclusion Promotion Structure

In order to understand the meaning of diversity and to make them use for management of diversified human resources, we provide Diversity Management Training to all managers. In addition, we are promoting an increase in internal understanding by including content in the training for employees by year of employment or by position and other training with the aim of increasing "Diversity & Inclusion." In addition to internal activities, we are striving to share information on know-how and activities for increasing diversity by participating in cross-industry study meetings and seminars.

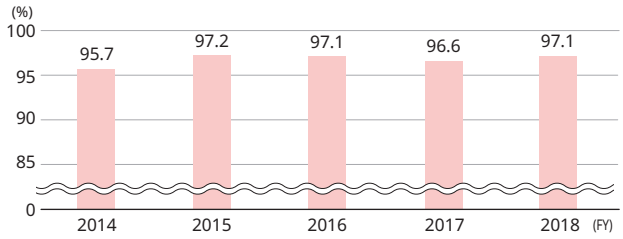
Women's Participation Promotion Activities

We direct our strong endeavors in this area especially for the creation of systems that enable women to flourish. We have made strong drives to recruit women and to promote measures to prevent women from leaving the company due to major life events. Thanks to these efforts, the number of female employees has steadily increased and the employment rate of female employees as of March 2019 increased by 4.0% from March 2013 and the retention rate of female employees in FY2018 is 97.1%. We are continuing to move ahead with the creation of systems to increase the number of female employees and to support them in building up a career. We will do this by steadily implementing our Five-Year Action Plan (for the period from April 1, 2016 to March 31, 2021), which is based on the Act of Promotion of Women's Participation and Advancement in the Workplace (Women's Participation Promotion Act), set out in 2015.

The Male-to-Female Ratio of New Graduate Employees



Retention Rate of Female Employees

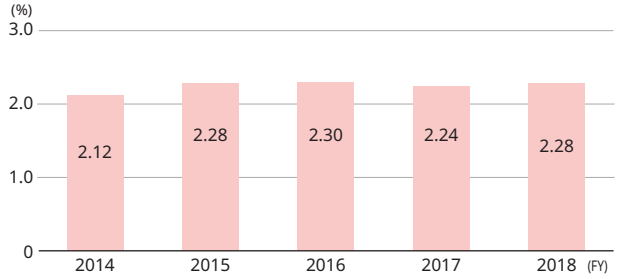


✻ Retention rate: 100- turnover rate in each fiscal year

Activities to Promote Opportunities for Persons with Disabilities to Thrive

As part of our diversity enhancement effort, we have been actively recruiting persons with disabilities.
An employment rate as of March 31, 2019 is 2.28%, which exceeds the legally stipulated rate (2.2%). Some 50 employees with disabilities currently show their abilities and enjoy working in their respective departments.

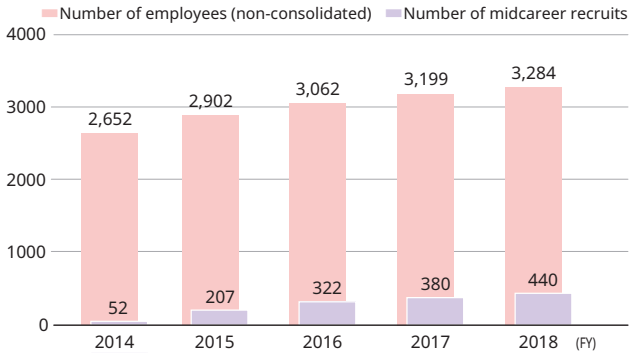
Employment Rate of Persons with Disabilities



Activities to Promote of Midcareer Employment

Since FY2014 when we started to adopt active steps toward midcareer recruitment in view of our business environment, we have been directing efforts toward employing people midcareer as an industry-ready workforce equipped with the skills, knowledge, and experience that ONO requires. The number of midcareer employees that have joined ONO has increased substantially among a wide range of employees and departments, including MRs, development staff members as well as pharmacovigilance department members and administrational department members. In FY2018, approximately 70 midcareer recruits joined ONO. They are playing their respective roles by applying their experience and expertise.

Number of Midcareer Recruits



Strengthening Corporate Infrastructure

Society

Efforts Towards Improvement of Medical Access

ONO engages in improvement of access to medicine through the efforts of our companies and activities via partnerships.
We are striving to contribute to researches in diseases for unmet medical needs and for rare diseases and intractable diseases and countries and regions where medical infrastructure has not yet matured.

Improvement of Access to Medicine through Research and Development

We are developing pharmaceuticals and providing pharmaceuticals through drug discovery and licensing activities for rare diseases for which the number of patients is small and therefore it is difficult to develop therapeutic agents. In addition, we consider pharmaceuticals that are appropriately assessed for children should be used for child patients and we engage in obtaining additional approval for indications for child patients. For drug discovery and research for intractable diseases, we are engaging in activities to provide new options for treatment in industry-academia cooperation.

Improvement of Medical Infrastructure by Support Activities and Donations

In August 2018, we started the ONO SWITCH Project, which is an activity to donate a specified amount to medical-related NPOs and NGOs based on overtime payments that have been reduced by work-style reforms. Furthermore, ONO joined the Global Health Innovative Technology Fund (GHIT Fund) in 2018. We empathize with their activities and ideas and we are making a financial contribution to improve access to medicine in low- and middle-income countries.

Example of Projects Donated to by ONO: Scene of the basic life support drill in Cambodia

■ For more details on efforts towards improvement of medical access, support activities, and donations, see our website on CSR.
→https://ono-csr.disclosure.site/en/themes/124

Various Corporate Social Responsibility (CSR) Activities

We are providing research grants for the medical advancement and disseminating information on diseases and their treatments and thereby working to support patients and their family members.
Our business facilities in various locations are actively involved in activities that contribute to local communities.

Initiatives for Medical Advancement

We are making efforts to contribute to the medical advancement of unmet medical needs.
We cooperate with the operations of endowed chairs and we have opened endowed chairs throughout Japan, focusing on disease domains where rapid increases in patient numbers are foreseen in line with the aging population, for example, cancer, diabetes and neuropathy and musculoskeletal diseases. The ONO Medical Research Foundation was established in 1988 based on donations from ONO. It aims to provide grants for research activities related to the field of dyslipidemia, to encourage treatment and research in this field through various projects, and thereby to contribute to people's health and welfare. Since its establishment, the ONO Medical Research Foundation has been providing research grants and grants to encourage research every year.
Furthermore, we have pledged 10-year support starting in FY2017 to the Japanese Biochemical Society for the Osamu Hayaishi Memorial Scholarship for Study Abroad to fund the overseas study of highly motivated life science researchers in biochemistry.

Scene of the Osamu Hayaishi Memorial Award Presentation

Web-Based Information Dissemination

Our Japanese edition corporate website contains a section, for patients and their families that explains specific symptoms of the clinical conditions, therapeutic methods, and things that the patients and their

families should do in their daily lives to support themselves concerning common diseases and other diseases for which patients are increasing as the population ages in an easy-to-understand manner.
We also have other web sources to disseminate useful information widely and at all times. We operate a website specializing in dementia, "Medicine for Dementia Connected with Smile and Heart," which provides comments and messages from a wide range of healthcare professionals involved in the treatment and care of people with dementia and allows people to consider dementia together, as well as a website focused on oncology, "ONO ONCOLOGY (information for the general public and patients)," created in cooperation with supervising physicians so that people can learn about diseases and treatments in oncology, including the concept of immuno-oncology, in an easy-to-understand way. In addition, we offer a free smartphone application that widely transmits the latest information that is helpful for medicine by making said information continuously available to support to patients suffering from diabetes or other lifestyle diseases.

Activities to Support the Health of People

We conduct the following activities to provide a wide range of support for people such as patients and their families.

- Cooperation in holding disease-related seminars for citizens (To be held to raise awareness and provide correct information about diseases)
- Participation in "Relay for Life" (Since FY2014 / an activity to support cancer patients and their families and make cancer controllable and surmountable through actions of the whole local community against cancer)
- All our MRs: To take the Dementia Supporters Training Program and put into action what they learn.
- Showing of a series of short movies titled "Grandma's World" which are aimed at raising dementia awareness
- Held 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.
- Held the fifth "Operation Slimmer and Healthier" in FY2018 (A Great East Japan Earthquake reconstruction assistance activity that contributes to address to childhood obesity, a social issue in the earthquake-affected areas in cooperation with top athletes and specialists in lifestyle disease and provide a program)

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

Activities for Students and Children

ONO proactively engages in activities that support the development of children who will carry our future.

- Giving lessons on the theme of dementia by visiting schools (Since FY2014 / An activity with an aim to give junior and senior high school students the idea that dementia is not an uncommon event and to instruct them with the correct knowledge about dementia)
- Giving lessons on the theme of drugs by visiting schools (Since FY2015 / Our researchers visited schools and gave lessons in the town where the Minase Research Institute is located, for elementary school students with the aim of increasing interest in science.)
- Sponsored experience training (Since FY2015 / Provided by local governments around the Fujiyama Plant, for elementary school students with the aim of having students voluntarily consider the global environment and mainly the water environment.)
- Sponsored "Kokoro no Gekijo (Theater of the Heart)" performed by the Shiki Theatre Company and Butaigeijutsu Center (Since FY2017 / A project that invites children to theaters for free and conveys emotions in order to talk to the children's hearts about the importance of life, caring for others, the pleasures of mutual trust, and other information through theater.)
- Sponsored a project, "Kodomo Hon no Mori, Nakanoshima" (Since FY2017 / A project to help children pursue their abundant creativity by building libraries filled with books, art, and culture.)

Relationship with Local Communities

In one of our roles as a corporate citizen, we have each of our business sites take part in various activities such as cleanups, disaster prevention activities, and conservation of the natural environment. In addition, ONO will go on contributing to the local community in various ways, for example by selling bakery products handmade by people with disabilities in their work centers, by continually supporting Japanese Red Cross Society blood donations; and by donating teeth-brushing packs and toothbrushes that are produced by an ONO subsidiary company, to the elementary schools, kindergartens and nursery centers near the Minase Research Institute and elementary schools adjacent to the Joto Plant, during Dental and Oral Health Week.
From the perspective of sustainability where the local community and company live and achieve sustainable development together, ONO will proactively participate in and engage in a variety of activities to contribute to local communities as a member of society.

Giving lesson on the theme of dementia

■ For more details on our corporate social responsibility activities, please see our website on CSR.
→https://ono-csr.disclosure.site/en/themes/115

Strengthening Corporate Infrastructure

Global Environment

Activities to Achieve an Abundant Global Environment

ONO established the ONO PHARMACEUTICAL Environmental Guidelines for our environmental activities and formulated a voluntary environment action plan and **E**nvironment **C**hallenging **O**no Vision (ECO VISION 2050) based on the Guidelines. We defined the specific content of actions as well as numerical goals by means of which we will strive to reduce greenhouse gas emissions from business activities on a company-wide basis. In this and other ways, we will fulfill our corporate social responsibility towards the environment and engage in activities by prioritizing the environment in all business areas and by contributing to the realization of an abundant global 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 an effort to protect and preserve the environment, including natural resources and biodiversity.
- We will make environmental considerations in all our business operations and we will implement environment-focused measures such as saving resources and energy, the conservation of water resources, recycling, reducing waste, and preventing pollution.
- We will endeavor to do “Monozukuri” to produce eco-friendly products and will cooperate with society.
- We will strive to further understand environmental issues and to promote environment related activities with the participation of every employee.

Promotion of Environmental Management

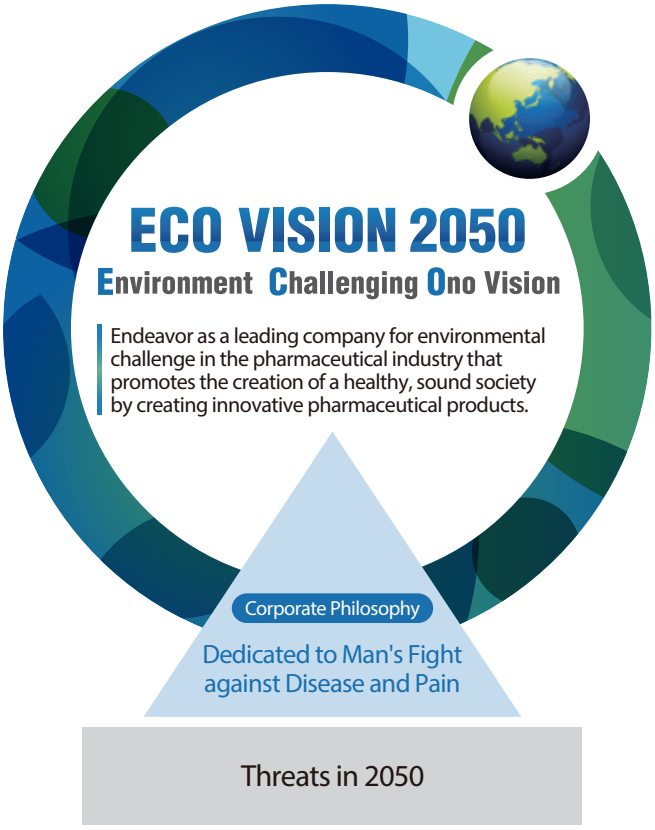
Our environmental management promotion structure is developed so that Members of the Board of Directors, Senior Executive Officers/ Executive Directors, General Administration Headquarters supervise company-wide environment management, the CSR Promotion Section operates the structure, and the Environment Committee consists of committee members from each department who are 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. Progress of activities is required to be reported once or more per year at the Management Meeting chaired by the CEO.

In addition, employees receive necessary training on environmental management concerning the operations that could have impact on the environment, to reduce environmental risks.

Furthermore, we also have a structure to minimize environmental impact arising from emergency disasters, by providing training and onsite education and formulating manuals to prepare for them.

Environmental Vision

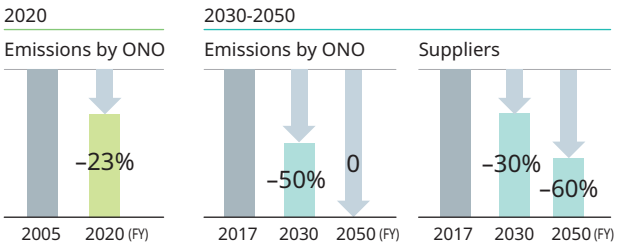
ONO has established a mid- and long-term environmental vision towards 2050, **E**nvironment **C**hallenging **O**no Vision (ECO VISION 2050). ONO will promote activities to reduce its environmental burden under the ECO VISION 2050.



Mid- and Long-Term Goals

In order to achieve "ECO VISION 2050," we determined three priority items, Achievement of Low-Carbon Society, Achievement of Water Circulation Society, and Achievement of Resource Circulation Society and established specific mid- and long-term goals related to greenhouse gases, water consumption, and waste.

- Greenhouse Gas



✻ Emissions by ONO represents the total value of Scope 1 and Scope 2 and Emissions by suppliers represents Scope 3.

- Water Consumption

  Reduce water resource consumption (water intake quantity) by 15% per unit of production in FY2030 (compared with FY2017).

- Waste

  1. Final disposal amount of industrial waste shall be 1% or lower every year*.

  ✻ The ONO's standard of Zero Emissions is defined to achieve a rate of non-recycling (landfilling, simple incineration) that shall be 1% or lower of the total amount.

  2. Reduce industrial waste emission amount by 15% per unit of production in FY2030 (in comparison with FY2017).
  3. Promote reduction of environmental burden in business activities.

Achievement of Low Carbon Society

Achievement of low carbon society is regarded as one of the most important ONO's environmental goals. All our places of business - production sites, research institutes, and offices – engaged in reduction of greenhouse gas appropriate to the nature of their business operations and CO_2 emissions from production sites and research institutes were 25,200 tons in this fiscal year while they were 26,700 tons on a location basis in FY2005 and this resulted in a decrease of 5.6% from FY2005. In addition, concerning the progress of newly established greenhouse gas reduction goals for all our places of business (reduce by 50% on a market basis in FY2030 by setting FY2017 as the standard), it was reduced by 5.5% from FY2017.
The entire company promotes Cool Biz and Warm Biz.
Production sites and research institutes use the latest energy-saving devices when renewing old air conditioning equipment and electric equipment. The Head Office, Minase Research Institute, and Tokyo Building use solar power generation system for which the CO_2 emissions factor is zero.
ONO was selected to the A List company which is the highest evaluation in FY2018 under the climate change investigation conducted by CDP in UK. This was the result when ONO's activities were evaluated globally. At the same time, ONO is a specified business operator under Japan's Act on the Rational Use of Energy (Energy Saving Act) and has been evaluated at the highest rank, S Rank, for four consecutive years as an excellent business operator where energy saving activities are advancing. In addition, ONO received an Osaka Stop Global Warming Award Excellence Prize in FY2018 from Osaka Prefecture as a business operator who engaged in particularly excellent activities in terms of global-warming prevention measures and other measures.

Achievement of Water Circulation Society

In order to achieve a water circulation society, ONO addresses the preservation of water resources from the perspective of both production activities and research activities. The use of quality freshwater is essential for our business activities. Based on the water risk evaluation using the tool of the World Resources Institute (WRI AQUEDUCT), our main sites have not been located in high water stress areas as of 2018.
In FY2018, water consumption was 350,000 m^3 where water consumption per unit of production increased by 8.7% from FY2017. We make efforts to reduce water consumption amounts and to provide strict quality control of water discharge as we promote activities that take biodiversity into consideration.

Achievement of Resource Circulation Society

We promote company-wide initiatives to reduce the amount of industrial waste landfilled in order to achieve resource circulation society. Residues after intermediate treatment were sent to landfill sites where materials can be recycled to reduce the amount of landfilled industrial waste, which decreased by 94.0% to 0.45 tons in FY2018 compared to the previous fiscal year. In addition, industrial waste landfilled per unit of production decreased by 37.2% compared to FY2017.
The production and research sites have achieved "Zero Emissions" and commit to continue the status. Also, we visit intermediate and final waste disposal contractors to confirm that our industrial waste is properly disposed of. We are promoting efforts aimed at recycling industrial waste, using thermal recycling by authorized heat recovery facilities and choosing final waste disposal sites that utilize the material recycling system.

■ For more details on factor for change, please see our website on CSR.
→https://ono-csr.disclosure.site/en/themes/107

Consolidated Financial Summary FY2018

	Millions of Yen	Millions of Yen	Millions of Yen	Thousands of U.S. Dollars[*1]
	2017.3 (IFRS)	2018.3 (IFRS)	**2019.3 (IFRS)**	**2019.3 (IFRS)**
Operating Results				
Revenue	244,797	261,836	**288,634**	**2,600,305**
Research and development costs	57,506	68,821	**70,008**	**630,703**
Operating profit	72,284	60,684	**62,010**	**558,647**
Profit for the year attributable to owners of the parent company	55,793	50,284	**51,539**	**464,316**
Financial Position				
Total assets	617,461	609,226	**655,056**	**5,901,407**
Total equity	524,211	529,619	**562,736**	**5,069,691**
Cash flows from operating activities	74,450	15,727	**66,774**	**601,567**
Cash flows from investing activities	(17,989)	(34,189)	**(49,763)**	**(448,314)**
Cash flows from financing activities	(20,552)	(62,549)	**(22,279)**	**(200,708)**
Amount per share	Yen	Yen	Yen	U.S. Dollars[*1]
Basic earnings	105.27	97.00	**100.25**	**0.90**
Equity attributable to owners of the parent company	979.42	1,019.97	**1,084.08**	**9.77**
Cash dividends	40.00	45.00	**45.00**	**0.41**
Financial indicators				
Equity ratio (%)	84.1	86.1	**85.1**	
ROA (%)[*2]	12.9	10.4	**10.3**	
ROE (%)[*3]	11.3	9.6	**9.5**	
Payout ratio (%)	38.0	46.4	**44.9**	
Number of employees	3,290	3,480	**3,555**	

*1 U.S. Dollar amounts are translated at a rate of US$1 = ¥111, the approximate rate of exchange at March 29, 2019. See Notes to consolidated financial statements.

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

*3 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)

Details of Revenue

(Billions of yen)

	FY2015	FY2016	FY2017	**FY2018**	FY2019 (Forecast)
Sales of Major Products					
OPDIVO Intravenous Infusion	21.2	103.9	90.1	**90.6**	85.0
GLACTIV Tablets	31.4	29.4	27.4	**26.9**	26.5
ORENCIA for Subcutaneous Injection	8.0	11.6	14.1	**17.4**	19.0
FORXIGA Tablets	4.3	7.8	11.1	**14.5**	16.5
EMEND Capsules / PROEMEND for Intravenous Injection	9.5	9.9	9.9	**10.6**	11.5
RIVASTACH Patch	7.8	8.9	8.9	**8.9**	9.5
OPALMON Tablets	22.7	17.0	14.4	**10.4**	9.0
PARSABIV Intravenous Infusion	—	0.2	3.4	**5.7**	7.0
KYPROLIS for Intravenous Injection	—	2.0	5.5	**4.9**	5.5
RECALBON Tablets	11.3	11.3	10.9	**7.3**	5.0
ONOACT for Intravenous Infusion	5.7	5.7	5.6	**4.6**	4.5
ONON Capsules	9.0	6.8	5.5	**4.4**	3.5
STAYBLA Tablets	5.2	4.8	4.1	**3.7**	3.5
ONON Dry Syrup	5.6	4.1	3.3	**2.7**	2.0

✻ Based on ex-manufacturer prices

Breakdown of Revenue					(Billions of yen)
Revenue of goods and products	144.6	214.3	205.9	**208.9**	202.0
Royalty and other revenue	15.7	30.5	55.9	**79.7**	88.0

Sales Revenue by Region				(Billions of yen)
Japan	147.1	214.0	204.0	**207.4**
America	10.9	27.3	52.5	**72.3**
Asia	2.0	3.1	5.1	**7.4**
Europe	0.3	0.4	0.2	**1.6**

Financial Review

The following is a summary of the consolidated business results for the fiscal year ended March 31, 2019.

Area of Business

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

Results for Fiscal Year Ended March 31, 2019

	Millions of Yen	Thousands of U.S. Dollars
Revenue	¥ 288,634	$ 2,600,305
Operating profit	62,010	558,647
Profit for the year (attributable to owners of the parent company)	51,539	464,316

Revenue

Revenue increased by 10.2% or ¥26.8 billion (US$241 million) from the previous consolidated fiscal year to ¥288.6 billion (US$2,600 million).

- Despite the impact of drug price revision in association with the fundamental reform of the drug price system, sales of OPDIVO Intravenous Infusion for malignant tumor increased by ¥0.5 billion (0.5%) from the previous consolidated fiscal year to ¥90.6 billion (US$816 million) thanks to expansion of the use of OPDIVO expanded for the treatment of renal cell cancer and head and neck cancer approved two fiscal years ago and gastric cancer and other symptoms approved last fiscal year.
- Sales of our key new products: GLACTIV Tablets for type-2 diabetes decreased by 1.8% year-on-year to ¥26.9 billion (US$242 million), ORENCIA for rheumatoid arthritis increased by 23.3% year-on-year to ¥17.4 billion (US$157 million), FORXIGA Tablets for type-2 diabetes increased by 31.0% year-on-year to ¥14.5 billion (US$131 million), the combined sales of EMEND Capsules and PROEMEND for Intravenous Injection for chemotherapy induced nausea and vomiting increased by 6.6% year-on-year to ¥10.6 billion (US$96 million), RIVASTACH Patch for Alzheimer's disease increased by 0.2% year-on-year to ¥8.9 billion (US$80 million), PARSABIV Intravenous Injection for Dialysis for secondary hyperparathyroidism in patients on hemodialysis increased by 66.8% year-on-year to ¥5.7 billion (US$52 million), and KYPRORIS for Intravenous Injection for multiple myeloma decreased by 11.1% year-on-year to ¥4.9 billion (US$44 million).
- Sales of the main long-term listed products were affected by the drug price revision and the new generics use promotion measures. OPALMON Tablets for peripheral circulatory disorder decreased by 27.9 % year-on-year to ¥10.4 billion (US$93 million), and RECALBON Tablets for osteoporosis decreased by 32.8% year-on-year to ¥7.3 billion (US$66 million) respectively.
- Royalty and Other Revenue increased by 42.4% year-on-year to ¥79.7 billion (US$718 million) thanks to increase of the royalty for OPDIVO Intravenous Infusion from Bristol-Myers Squibb (BMS) and inclusion of revenue from the transfer of long-term listed products, including 11 items for 5 brands, to Maruishi Pharmaceutical Co., Ltd.

Profit and Loss

Operating profit for the current consolidated fiscal year totaled ¥62 billion (US$559 million), an increase by 2.2% or ¥1.3 billion (US$12 million) from the previous consolidated fiscal year.

- Cost of sales increased by 28.2% or ¥18.4 billion (US$166 million) from the previous consolidated fiscal year to ¥83.8 billion (US$755 million) due to temporary burden charge to receive stable supply of drug substances for OPDIVO, as well as the impact of applying IFRS 15 (increased by ¥9.6 billion from the previous accounting standards) as indicated in the following (Note).
- R&D costs increased by 1.7% or ¥1.2 billion (US$11 million) from the previous consolidated fiscal year to ¥70 billion (US$631 million) due to increases in costs related to OPDIVO Intravenous Infusion or licensing fees related to partnerships in drug discovery.
- Selling, general, and administrative expenses (excluding R&D costs) increased by 2.9% or ¥2 billion (US$18 million) from the previous consolidated fiscal year to ¥70 billion (US$631 million) due to an increase in operating expenses and other costs for OPDIVO Intravenous Infusion, FORXIGA Tablets, and other key new products.
- Other expenses include settlement payments as the result of the settlement with Pfizer Inc. concerning patent-related litigation. In addition, other revenue includes gain on sale of tangible fixed assets ¥2.9 billion in the previous consolidated fiscal year.

Profit of the current fiscal year (attributable to owners of the parent company) increased by 2.5% or ¥1.3 billion (US$11 million) from the previous consolidated fiscal year to ¥51.5 billion (US$464 million) in association with increases in profit before tax.

Note: IFRS 15 Revenue from Contracts with Customers has been applied from the current consolidated fiscal year. In addition, in comparison with the case of applying previous accounting standards to the consolidated profit and loss statement of the current consolidated fiscal year, revenue increased by ¥8,889 million (US$80,080 thousand) and costs of sales increased by ¥9,553 million (US$86,059 thousand) respectively, and operating profit decreased by ¥664 million (US$5,978 thousand) and profit before tax decreased by ¥664 million (US$5,978 thousand) respectively.

Consolidated Cash Flows

The cash and cash equivalents balance at the end of current consolidated fiscal year decreased by 8.1% or ¥5.3 billion (US$48 million) from ¥65.3 billion (US$588 million) at the end of previous consolidated fiscal year to ¥60 billion (US$540 million). The main factors were cash flows from operating activities ended in a positive balance of ¥66.8 billion (US$602 million), cash flows from investing activities ended in a negative cash flow balance of ¥49.8 billion (US$448 million), and cash flows from financing activities ended in a negative cash flow balance of ¥22.3 billion (US$201 million).

■ Cash Flows from Operating Activities
Cash flows from operating activities for the current consolidated fiscal year ended in a positive cash flow balance of ¥66.8 billion (US$602 million) (The cash flows for the previous consolidated fiscal year ended in a positive balance of ¥15.7 billion). The main factor was profit before tax ended in a positive balance of ¥65.1 billion (US$587 million).

■ Cash Flows from Investing Activities
Cash flows from investing activities for the current consolidated fiscal year ended in a negative balance of ¥49.8 billion (US$448 million) (The cash flows for the previous consolidated fiscal year ended in a negative balance of ¥34.2 billion). The main factors were proceeds from sales and redemption of investments of ¥27.1 billion (US$244 million), payments into time deposits of ¥55.8 billion (US$503 million), and purchases of tangible fixed assets of ¥22.3 billion (US$201 million).

■ Cash Flows from Financing Activities
Cash flows from financing activities for the current consolidated fiscal year ended in a negative balance of ¥22.3 billion (US$201 million) (The cash flows for the previous consolidated fiscal year ended in a negative balance of ¥62.5 billion). The main factors were the dividends paid to owners of the parent company of ¥21.8 billion (US$197 million).

Investment in Plant and Equipment

Plant and equipment investment during the current consolidated fiscal year totaled ¥21,351 million (US$192,356 thousand). This included investment in enhancement and maintenance of manufacturing facilities (¥14,412 million, or US$129,840 thousand), research facilities (¥4,064 million, or US$36,615 thousand), and business facilities (¥2,875 million, or US$25,901 thousand).
The main investment in plant and equipment during the current consolidated fiscal year was factory facilities under construction in Yamaguchi Prefecture.

Consolidated Statement of Financial Position

Year Ended March 31, 2019

Assets	Notes	Millions of Yen		Thousands of U.S. Dollars [Note 2 (6)]
		March 31, 2018	March 31, 2019	March 31, 2019
Current assets:				
Cash and cash equivalents	7, 34	¥ 65,273	¥ 59,981	$ 540,373
Trade and other receivables	8, 34	77,577	76,285	687,252
Marketable securities	9, 34	9,670	687	6,192
Other financial assets	10, 34	10,833	10,800	97,297
Inventories	12	31,290	32,821	295,686
Other current assets	11, 20	14,821	14,042	126,506
Total current assets		209,464	194,617	1,753,306
Non-current assets:				
Property, plant, and equipment	13	94,321	108,870	980,814
Intangible assets	14	55,715	63,059	568,095
Investment securities	9, 34	188,803	171,476	1,544,825
Investments in associates		116	113	1,018
Other financial assets	10, 34	46,685	91,672	825,876
Deferred tax assets	2, 16	10,192	21,079	189,900
Other non-current assets	11	3,929	4,171	37,572
Total non-current assets		399,761	460,439	4,148,101
Total assets		¥ 609,226	¥ 655,056	$ 5,901,407

Liabilities and Equity	Notes	Millions of Yen		Thousands of U.S. Dollars [Note 2 (6)]
		March 31, 2018	March 31, 2019	March 31, 2019
Current liabilities:				
Trade and other payables	2, 17, 34	¥ 34,015	¥ 36,833	$ 331,828
Borrowings	18, 21, 34	392	435	3,918
Other financial liabilities	19, 34	3,756	515	4,641
Income taxes payable		8,742	15,980	143,965
Provisions	2, 24	11,696	17,206	155,012
Other current liabilities	2, 22	9,869	12,181	109,736
Total current liabilities		68,469	83,150	749,100
Non-current liabilities:				
Borrowings	18, 21, 34	320	1,765	15,900
Other financial liabilities	19, 34	8	5	47
Retirement benefit liabilities	23	3,856	5,515	49,687
Provisions	24	30	—	—
Deferred tax liabilities	16	1,016	1,053	9,484
Long-term advances received	2	5,095	—	—
Other non-current liabilities	22	814	832	7,499
Total non-current liabilities		11,138	9,171	82,617
Total liabilities		79,607	92,321	831,717
Equity:				
Share capital	25	17,358	17,358	156,381
Capital reserves	25	17,175	17,202	154,971
Treasury shares	25	(38,148)	(38,151)	(343,699)
Other components of equity	25	68,021	61,852	557,225
Retained earnings	2, 25	459,985	499,088	4,496,292
Equity attributable to owners of the parent company		524,390	557,350	5,021,169
Non-controlling interests		5,228	5,386	48,521
Total equity		529,619	562,736	5,069,691
Total liabilities and equity		¥ 609,226	¥ 655,056	$ 5,901,407

Consolidated Statement of Income

Year Ended March 31, 2019

	Notes	Millions of Yen		Thousands of U.S. Dollars [Note 2 (6)]
		For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Revenue	2, 6, 27	¥ 261,836	¥ 288,634	$ 2,600,305
Cost of sales	2	(65,391)	(83,829)	(755,217)
Gross profit		196,445	204,805	1,845,089
Selling, general, and administrative expenses	28	(68,055)	(70,033)	(630,932)
Research and development costs		(68,821)	(70,008)	(630,703)
Other income	30	3,255	646	5,822
Other expenses	30	(2,139)	(3,400)	(30,630)
Operating profit	2	60,684	62,010	558,647
Finance income	31	3,277	3,282	29,572
Finance costs	31	(36)	(150)	(1,351)
Share of loss from investments in associates and others	15	(4)	(1)	(11)
Profit before tax	2	63,922	65,141	586,855
Income tax expense	16	(13,525)	(13,462)	(121,282)
Profit for the year		50,397	51,679	465,573
Profit for the year attributable to:				
Owners of the parent company		50,284	51,539	464,316
Non-controlling interests		113	140	1,257
Profit for the year		¥ 50,397	¥ 51,679	$ 465,573

		Yen		U.S. Dollars [Note 2 (6)]
Earnings per share:				
Basic earnings per share	33	¥ 97.00	¥ 100.25	$ 0.90
Diluted earnings per share	33	96.99	100.24	0.90

Consolidated Statement of Comprehensive Income

Year Ended March 31, 2019

	Notes	Millions of Yen		Thousands of U.S. Dollars [Note 2 (6)]
		For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Profit for the year		¥ 50,397	¥ 51,679	$ 465,573
Other comprehensive income:				
Items that will not be reclassified to profit or loss:				
Net (loss) gain on financial assets measured at fair value through other comprehensive income	32, 34	17,797	(43)	(389)
Remeasurement of defined benefit plans	32	(478)	(890)	(8,020)
Share of net (loss) gain on financial assets measured at fair value through other comprehensive income of investments in associates	15, 32	2	(1)	(12)
Total of items that will not be reclassified to profit or loss		17,321	(935)	(8,421)
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of foreign operations	32	(112)	78	698
Total of items that may be reclassified subsequently to profit or loss		(112)	78	698
Total other comprehensive (loss) income		17,210	(857)	(7,723)
Total comprehensive income for the year		67,607	50,821	457,851
Comprehensive income for the year attributable to:				
Owners of the parent company		67,477	50,658	456,382
Non-controlling interests		130	163	1,469
Total comprehensive income for the year		¥ 67,607	¥ 50,821	$ 457,851

Consolidated Statement of Changes in Equity

Year Ended March 31, 2019

	Notes	Millions of Yen							
		Equity attributable to owners of the parent company							
		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, 2017		¥ 17,358	¥ 17,144	¥ (59,382)	¥ 51,752	¥ 492,237	¥ 519,110	¥ 5,101	¥ 524,211
Profit for the year						50,284	50,284	113	50,397
Other comprehensive income	32				17,193		17,193	17	17,210
Total comprehensive income for the year		–	–	–	17,193	50,284	67,477	130	67,607
Purchase of treasury shares	25			(38,773)			(38,773)		(38,773)
Retirement of treasury shares	25			60,007		(60,007)	–		–
Cash dividends	26					(23,453)	(23,453)	(3)	(23,457)
Share-based payments	35		30				30		30
Transfer from other components of equity to retained earnings	25				(924)	924	–		–
Total transactions with the owners		–	30	21,234	(924)	(82,536)	(62,196)	(3)	(62,199)
Balance at March 31, 2018		17,358	17,175	(38,148)	68,021	459,985	524,390	5,228	529,619
Changes in Accounting Policies	2					4,127	4,127		4,127
Restated Balance		17,358	17,175	(38,148)	68,021	464,112	528,517	5,228	533,746
Profit for the year						51,539	51,539	140	51,679
Other comprehensive income	32				(881)		(881)	24	(857)
Total comprehensive income for the year		–	–	–	(881)	51,539	50,658	163	50,821
Purchase of treasury shares	25			(3)			(3)		(3)
Cash dividends	26					(21,850)	(21,850)	(5)	(21,856)
Share-based payments	35		27				27		27
Transfer from other components of equity to retained earnings	25				(5,288)	5,288	–		–
Total transactions with the owners		–	27	(3)	(5,288)	(16,562)	(21,826)	(5)	(21,831)
Balance at March 31, 2019		¥ 17,358	¥ 17,202	¥ (38,151)	¥ 61,852	¥ 499,088	¥ 557,350	¥ 5,386	¥ 562,736

	Notes	Thousands of U.S. Dollars [Note 2 (6)]							
		Equity attributable to owners of the parent company							
		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, 2018		$ 156,381	$ 154,726	$ (343,673)	$ 612,797	$ 4,144,008	$ 4,724,238	$ 47,102	$ 4,771,340
Changes in Accounting Policies	2					37,179	37,179		37,179
Restated Balance		156,381	154,726	(343,673)	612,797	4,181,187	4,761,417	47,102	4,808,519
Profit for the year						464,316	464,316	1,257	465,573
Other comprehensive income	32				(7,935)		(7,935)	212	(7,723)
Total comprehensive income for the year		–	–	–	(7,935)	464,316	456,382	1,469	457,851
Purchase of treasury shares	25			(26)			(26)		(26)
Cash dividends	26					(196,848)	(196,848)	(49)	(196,898)
Share-based payments	35		245				245		245
Transfer from other components of equity to retained earnings	25				(47,637)	47,637	–		–
Total transactions with the owners		–	245	(26)	(47,637)	(149,211)	(196,629)	(49)	(196,679)
Balance at March 31, 2019		$ 156,381	$ 154,971	$ (343,699)	$ 557,225	$ 4,496,292	$ 5,021,169	$ 48,521	$ 5,069,691

Consolidated Statement of Cash Flows

Year Ended March 31, 2019

	Notes	Millions of Yen		Thousands of U.S. Dollars [Note 2 (6)]
		For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Cash flows from operating activities				
Profit before tax		¥ 63,922	¥ 65,141	$ 586,855
Depreciation and amortization		9,213	10,621	95,685
Impairment losses		306	209	1,885
Interest and dividend income		(2,990)	(3,164)	(28,505)
Interest expense		14	27	241
(Increase) decrease in inventories		(5,971)	(1,567)	(14,117)
(Increase) decrease in trade and other receivables		(4,333)	1,251	11,268
Increase (decrease) in trade and other payables		300	998	8,994
Increase (decrease) in provisions		5,611	6,333	57,056
Increase (decrease) in retirement benefit liabilities		362	378	3,402
Increase (decrease) in long-term advances received		(181)	—	—
Other		(17,138)	1,854	16,699
Subtotal		49,114	82,081	739,464
Interest received		95	77	698
Dividends received		2,902	3,092	27,856
Interest paid		(14)	(27)	(241)
Income taxes paid		(36,370)	(18,449)	(166,210)
Net cash provided by (used in) operating activities		15,727	66,774	601,567
Cash flows from investing activities				
Purchases of property, plant, and equipment		(15,620)	(22,303)	(200,924)
Proceeds from sales of property, plant, and equipment		4,663	11	101
Purchases of intangible assets		(14,218)	(7,299)	(65,754)
Purchases of investments		(60)	(873)	(7,865)
Proceeds from sales and redemption of investments		21,315	27,123	244,353
Payments into time deposits		(30,800)	(55,800)	(502,703)
Proceeds from withdrawal of time deposits	2	800	10,800	97,297
Other	2	(269)	(1,423)	(12,820)
Net cash provided by (used in) investing activities		(34,189)	(49,763)	(448,314)
Cash flows from financing activities				
Dividends paid		(23,414)	(21,828)	(196,646)
Dividends paid to non-controlling interests		(3)	(5)	(49)
Repayments of long-term borrowings		(417)	(361)	(3,249)
Net increase (decrease) in short-term borrowings		58	(84)	(754)
Purchases of treasury shares		(38,773)	(1)	(10)
Net cash provided by (used in) financing activities		(62,549)	(22,279)	(200,708)
Net increase (decrease) in cash and cash equivalents		(81,011)	(5,268)	(47,456)
Cash and cash equivalents at the beginning of the year		146,323	65,273	588,043
Effects of exchange rate changes on cash and cash equivalents		(40)	(24)	(214)
Cash and cash equivalents at the end of the year	7	¥ 65,273	¥ 59,981	$ 540,373

Notes to Consolidated Financial Statements

Year Ended March 31, 2019

Note 1

Reporting Entity

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

The consolidated financial statements of the Company were closed at its year-end of March 31, 2019, and comprise the Company and its subsidiaries (collectively, the "Group") and equity interests in associates of the Group. The Group manufactures and sells medical and general pharmaceutical products. The business descriptions and principal activities of the Group are described in "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 of the Designated International Financial Reporting Standards" 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 "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) Changes in Accounting Policies

The Group has applied the following standards from the fiscal year ended March 31, 2019.

IFRS		Overview of establishment and amendments
IFRS 15	Revenue from Contracts with Customers	Issuance of a single and comprehensive model for accounting treatment for revenue from contracts with customers
IFRS 9 (Revised in July 2014)	Financial Instruments	Impairment of financial assets and revision of hedge accounting
IFRIC 22	Foreign Currency Transactions and Advance Consideration	Clarification of the accounting for transactions that include the receipt or payment of advance consideration in a foreign currency

1) IFRS 15 "Revenue from Contracts with Customers"

The Group has applied IFRS 15, "Revenue from Contracts with Customers" (published in May 2014), and "Clarifications to IFRS 15" (published in April 2016) (hereinafter collectively referred to as "IFRS 15") from the fiscal year ended March 31, 2019.

Along with application of IFRS 15, excluding the interest and dividend income, etc., based on IFRS 9, "Financial Instruments," revenue is recognized by applying the following five steps:

Step 1: Identify the contract with a customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

(i) Sale of merchandise
For the sale of merchandise, revenue is recognized at the point when it is delivered, since material risks and economic value associated with ownership of the merchandise are transferred to customers at the time of its delivery, and customers acquire control over it, and thereby the Group's performance obligations are considered to be satisfied.
The revenue arising from sale of merchandise is calculated by deducting the amount of rebates and discounts based on the number and amount of sales from the consideration in the sales contract, and the consideration to be refunded to customers and the amounts to be collected on behalf of third parties are recognized as a refund liability. The most likely amount method based on contractual conditions and past results is used to estimate rebates, etc. Revenue is recognized only to the extent that it is highly probable that there will not be a significant reversal of revenue previously recognized.
Consideration related to sale of merchandise is mainly received within one year from the delivery of merchandise to customers. This does not include significant financing components.

(ii) Royalty revenue, etc.
Royalty revenue is consideration for license contracts, etc., calculated on the basis of revenue, etc., of the other party in the contract, and it is recognized as revenue taking the time of occurrence into consideration.
License revenue is up-front payment and milestone revenue received under license contracts, etc., related to development or rights to develop or sell products, etc., executed between the Group and third parties. For license contracts, etc., when performance obligations are satisfied at a specific point in time, performance obligations under the contract are considered to be satisfied at the time of granting development or selling rights, etc., for up-front payment and milestone revenue, and at this point, the up-front payment and milestone revenue are recognized as revenue. When performance obligations are satisfied over a certain period of time, the consideration is recognized as contract liabilities, and up-front payment and milestone revenue are recognized as revenue over a certain period of time, such as the estimated development period according to the method of measuring the degree of progress regarding satisfaction of the performance obligations determined for each individual contract.
Milestone revenue is recognized as revenue, considering the probability that there will be a significant reversal of revenue previously recognized, from the time that milestones specified in the contract are achieved.
Royalty revenue, etc., are mainly received within one year from the vesting under the contract. This does not include significant financing components.

Based on the five-step approach above, as a result of reviewing the revenue recognition period for license revenue such as up-front payment received under license contracts in light of satisfying performance obligations, up-front payment received from license contracts, which was recognized over time as deferred income under the previous standard, is recognized as one-time income at the time of granting development or selling rights, etc. Also, as a result of a review in light of the definition of customers, certain items which were formerly deducted from revenue are treated as cost of sales from the fiscal year ended March 31, 2019.
For the application of these standards, the Group adopted a method to recognize the cumulative effect recognized as a transitional measure on the date of initial application. Also, certain accounts payable formerly included and presented within trade and other payables, as well as certain provisions, are included and presented within trade and other payables as refund liabilities from the fiscal year ended March 31, 2019.
Consequently, compared with cases calculated using the previous accounting standards, at the beginning of the fiscal year ended March 31, 2019, mainly trade and other payables increased by ¥618 million ($5,566 thousand), retained earnings increased by ¥4,127 million ($37,179 thousand), deferred tax assets decreased by ¥1,820 million ($16,393 thousand), provisions decreased by ¥823 million ($7,414 thousand), other current liabilities decreased by ¥646 million ($5,824 thousand), and long-term advances received decreased by ¥5,095 million ($45,899 thousand).
For the consolidated statement of income for the fiscal year ended March 31, 2019, compared with cases calculated using the previous accounting standards, revenue increased by ¥8,889 million ($80,080 thousand), cost of sales increased by ¥9,553 million ($86,059 thousand), operating profit decreased by ¥664 million ($5,978 thousand), and profit before tax decreased by ¥664 million ($5,978 thousand).
Also, for the consolidated statement of financial position as at the end of the fiscal year ended March 31, 2019, compared with cases calculated using the previous accounting standards, mainly trade and other payables increased by ¥996 million ($8,971 thousand), retained earnings increased by ¥3,666 million ($33,030 thousand),

deferred tax assets decreased by ¥1,617 million ($14,564 thousand), provisions decreased by ¥1,231 million ($11,092 thousand), other current liabilities decreased by ¥17 million ($155 thousand), and long-term advances received decreased by ¥5,030 million ($45,318 thousand).

2) IFRS 9, "Financial Instruments"
The Group has applied IFRS 9, "Financial Instruments" (revised in July 2014), from the fiscal year ended March 31, 2019. The Group applied the exception, not restating the comparative periods presented, according to the transitional option. The application of this standard does not have a significant effect on the Group's financial results and financial position.

3) IFRIC 22, "Foreign Currency Transactions and Advance Consideration"
The Group has applied IFRIC 22, "Foreign Currency Transactions and Advance Consideration," from the fiscal year ended March 31, 2019. The application of this standard does not have a significant effect on the Group's financial results and financial position.

(5) Changes in Method of Presentation
Consolidated Statement of Cash Flows
"Proceeds from withdrawal of time deposits" included in "Other" in cash flows from investing activities for the fiscal year ended March 31, 2018 are separately presented from the fiscal year ended March 31, 2019 due to the increased quantitative materiality. In order to conform with the current years presentation, the consolidated financial statements are reclassified for the fiscal year ended March 31, 2018. As a result, ¥531 million for "Other," which was shown in cash flows from investing activities in the consolidated statement of cash flows for the fiscal year ended March 31, 2018, is reclassified into ¥800 million in "Proceeds from withdrawal of time deposits" and ¥(269) million in "Other."

(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 ¥111 to $1, the approximate rate of exchange at March 29, 2019. 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 thousand U.S. dollars have been rounded to the nearest one thousand U.S. dollars in the presentation of the accompanying consolidated financial statements. As a result, the totals in 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
Subsidiaries are entities controlled by the Group. The Group controls an entity when the Group has power over the entity, is exposed to, or has rights to variable returns from its involvement with the entity, and has the ability to affect those returns through its power over the entity. 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. Changes in ownership interest in a subsidiary without a loss of control are accounted for as equity transactions, and a difference between the amount by which the non-controlling interests are adjusted and the fair value of the consideration paid or received is recognized directly in equity as equity attributable to owners of the parent company.
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.
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.

The Group measures the consideration for an acquisition as the sum of the consideration transferred in a business combination, the amount of any non-controlling interest and in a business combination achieved in stages, the acquisition-date fair value of the acquirer's previously held equity interest in the acquisition. The consideration transferred is measured at fair value at the acquisition date. The non-controlling interest is measured at fair value or based on the appropriate share of the acquiree's identifiable net assets.

The Group recognizes goodwill as any excess of the consideration for acquisition over the net amount of the identifiable assets acquired and the liabilities assumed at the acquisition date. If the net amount of the identifiable assets and liabilities of the acquiree exceeds the consideration for acquisition, the acquirer recognizes the excess amount as profit or loss on the acquisition date.

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

(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 presentation currency using spot exchange rates as of the closing date, while income and expenses are translated into the presentation 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

Trade receivables, etc., are initially recognized on the date when they are incurred. All other financial assets are initially recognized on the contract date when the Group becomes a party to the contractual provisions of the financial instruments. Financial assets are classified as either financial assets measured at fair value or financial assets measured at amortized cost.

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 timeframe generally established by regulation or convention in the marketplace.

At initial recognition, all financial assets, except for those measured at fair value through profit or loss (FVPL), are measured at fair value plus transaction costs that are directly attributable to the financial assets. Transaction costs of financial assets measured through profit or loss are recognized in profit or loss.

(ii) Classification and Subsequent Measurement

a. 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 financial asset is held within a business model whose objective is to hold financial 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.

After initial recognition, the carrying amounts of the financial assets measured at amortized cost are calculated using the effective interest method. Amortization using the effective interest method and gains or losses arising in the case of derecognition are recognized in profit or loss.

b. Debt instruments measured at fair value through other comprehensive income (FVOCI)
Financial assets are classified as debt instruments measured at FVOCI if both of the following conditions are met:
- The financial asset is held within a business model whose objective is achieved by both collecting contractual cash flows and selling financial assets; 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.

c. Equity instruments measured at FVOCI
After initial recognition, equity instruments designated to be measured at FVOCI are measured at fair value, and any changes in fair value are included in net gain (loss) on financial assets measured at FVOCI in other components of equity.
When such financial assets are derecognized, the accumulated other comprehensive income is immediately transferred to retained earnings. Meanwhile, dividends from such financial assets are recognized as profit when the shareholder's right to receive payment is established.

d. Financial assets measured at FVPL
Financial assets, except for financial assets measured at amortized cost, debt instruments measured at FVOCI, and equity instruments measured at FVOCI stated above, are classified as financial assets measured at FVPL.
After initial recognition, financial assets measured at FVPL are measured at fair value, and any changes in fair value are recognized in profit or loss.

(iii) 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.

(iv) Impairment of Financial Assets
At the end of each fiscal year, the Group evaluates whether the credit risk on financial instruments has increased significantly since initial recognition. With respect to impairment of financial assets measured at amortized cost, the Group recognizes an allowance for expected credit losses on such financial assets. If credit risk on a financial instrument has not increased significantly since initial recognition, the allowance for such financial instrument is measured at an amount equal to the 12-month expected credit losses. If credit risk on a financial instrument has increased significantly since initial recognition, the allowance for such financial instrument is measured at an amount equal to the lifetime expected credit losses. Whether credit risk is significantly increased or not is determined based on the changes in default risk. The assessment of whether or not there is a change in default risk takes into account information that is reasonably available to the Group and supportable as well as past due information. When the credit risk on a financial asset is considered low at the end of the fiscal year, the Group determines that the credit risk on the financial asset has not increased significantly since initial recognition. Expected credit losses are measured based on the discounted present value of the differences between the contractual cash flows and the cash flows expected to be received. However, with regards to trade receivables, etc., the allowance is always measured at an amount equal to the lifetime expected credit losses, regardless of whether or not there has been a significant increase in credit risk since initial recognition. The amount of expected credit losses or reversal is recognized in profit or loss.

§2 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 using 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.

§3 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.

§4 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.

§5 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 a hedging instrument expires, 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.

§6 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 the acquisition date, which are readily convertible to cash and are subject to insignificant risk of changes in value.

(5) The Standard for Measurement and the Value of 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 use.

Property, plant, and equipment 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 an asset or a cash-generating unit to which the asset belongs is estimated.

The recoverable amount is computed at the higher of the fair value less costs to sell or value in use of the asset or cash-generating unit. If the carrying amount of an asset or a cash-generating 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 a 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 — 17 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)

Costs 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" as 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 is a pretax rate that 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 or 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 the shorter of their estimated useful lives or the lease terms. 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 by the straight-line method over the lease terms in the consolidated statement of income. Contingent rents are recognized as an expense in the period when incurred.

Determining whether an arrangement is, or contains, a lease is identified based on the substance of the arrangement in accordance with 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 and presented as "finance income" or "finance costs." 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

Contributions paid for defined contribution plans are expensed in the period in which the employees provide the related service.

(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 the 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

Revenue, excluding interest and dividend income, etc., is recognized by applying the following five steps:

Step 1: Identify the contract with a customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

§1 Sale of Merchandise

For the sale of merchandise, revenue is recognized at the point when it is delivered, since material risks and economic value associated with ownership of the merchandise are transferred to customers at the time of its delivery, and customers acquire control over it, and thereby the Group's performance obligations are considered to be satisfied.

The revenue arising from sale of merchandise is calculated by deducting the amount of rebates and discounts based on the number and amount of sales from the consideration in the sales contract, and the consideration to be refunded to customers and the amounts to be collected on behalf of third parties are recognized as a refund liability. The most likely amount method based on contractual conditions and past results is used to estimate rebates, etc. Revenue is recognized only to the extent that it is highly probable that there will not be a significant reversal of revenue previously recognized.

Consideration related to sale of merchandise is mainly received within one year from the delivery of merchandise to customers. This does not include significant financing components.

§2 Royalty Revenue, etc.

Royalty revenue is consideration for license contracts, etc., calculated on the basis of revenue, etc., of the other party in the contract, and it is recognized as revenue taking the time of occurrence into consideration.

License revenue is up-front payment and milestone revenue received under license contracts, etc., related to development or rights to develop or sell products, etc., executed between the Group and third parties. For license contracts, etc., when performance obligations are satisfied at a specific point in time, performance obligations under the contract are considered to be satisfied at the time of granting development or selling rights, etc., for up-front payment and milestone revenue, and at this point the up-front payment and milestone revenue are recognized as revenue. When performance obligations are satisfied over a certain period of time, the consideration is recognized as contract liabilities, and up-front payment and milestone revenue are recognized as revenue over a certain period of time, such as the estimated development period according to the method of measuring the degree of progress regarding satisfaction of the performance obligations determined for each individual contract.

Milestone revenue is recognized as revenue, considering the probability that there will be a significant reversal of revenue previously recognized, from the time that milestones specified in the contract are achieved.

Royalty revenue, etc., are mainly received within one year from the vesting under the contract. This does not include significant financing components.

(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 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, sale, or retirement of the treasury shares. Any difference between the carrying amount and proceeds on sales is treated as capital reserve.

(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 are calculated adjusting the effects of all dilutive potential ordinary shares.

(16) Share-based Payments

The Company has a share option plan as an incentive plan for the Board of Directors (excluding outside directors). Share options are recognized as expenses over the vesting period and the corresponding amount is recognized as an increase in equity. In addition, the fair value of share options is calculated using the Black-Scholes model at the grant date.

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 effects 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 trends 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 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 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 major new standards, interpretations, and amendments that have been issued but are not yet effective as of the date of the approval for the consolidated financial statements that may affect the Group are as follows. The Group has not elected early application of them.

IFRS		Mandatory application (from the year beginning)	To be applied by the Group	Subject of new standard / amendment
IFRS 16	*Leases*	January 1, 2019	Fiscal year ending March 31, 2020	Revision of accounting treatment for lease contracts

Applying IFRS 16, the Group recognizes right-of-use assets and lease liabilities in the consolidated statement of financial position at the inception of the lease, and the Group recognizes depreciation of right-of-use assets and interest expense arising from lease liabilities over lease terms for leases previously classified as operating leases applying IAS 17.
The Group recognizes the cumulative effect of applying this standard at the date of initial application according to the transitional option, with no restatement of the comparative periods presented. The Group anticipates that the new standard will result in the carrying value of total assets being increased by approximately ¥6.2 billion ($56 million) and total liabilities being increased by ¥6.2 billion ($56 million) at the date of initial application, and that the impact on its consolidated statement of income will be immaterial.

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:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Revenue of goods and products	¥ 205,888	¥ 208,947	$ 1,882,406
Royalty and others	55,948	79,687	717,900
Total	¥ 261,836	¥ 288,634	$ 2,600,305

Note: The Group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "2. Basis of Preparation (4) Changes in Accounting Policies." Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

(3) Revenue by Geographic Area

Details of revenue by geographic area are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Revenue of goods and products			
Japan	¥ 204,023	¥ 207,371	$ 1,868,211
Americas	52,525	72,298	651,333
Asia	5,071	7,354	66,252
Europe	218	1,610	14,509
Total	¥ 261,836	¥ 288,634	$ 2,600,305

Notes: 1. Revenue by geographic area is presented on the basis of the place of customers.
2. The Group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "2. Basis of Preparation (4) Changes in Accounting Policies." Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

(4) Major Customers

Details of revenue from major customers are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Bristol-Myers Squibb Company and the group	¥ 43,662	¥ 63,442	$ 571,553
Suzuken Co., Ltd. and the group	45,662	45,832	412,899
Medipal Holdings Corporation and the group	48,932	45,744	412,111
Alfresa Holdings Corporation and the group	31,987	32,213	290,206
Toho Holdings Co., Ltd. and the group	31,392	31,242	281,456

Note: The Group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "2. Basis of Preparation (4) Changes in Accounting Policies." Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

Note 7

Cash and Cash Equivalents

Details of cash and cash equivalents are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
(Cash and cash equivalents)			
Cash and deposits	¥ 65,273	¥ 59,981	$ 540,373
Cash and cash equivalents in the consolidated statement of financial position	¥ 65,273	¥ 59,981	$ 540,373
Cash and cash equivalents in the consolidated statement of cash flows	¥ 65,273	¥ 59,981	$ 540,373

Note 8

Trade and Other Receivables

Details of trade and other receivables are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Notes receivable	¥ 2,315	¥ 2,885	$ 25,990
Trade accounts receivable	70,398	67,868	611,422
Other accounts receivable	4,871	5,539	49,897
Allowance for doubtful accounts	(6)	(6)	(57)
Net	¥ 77,577	¥ 76,285	$ 687,252

Note: Credit risk management is described in “34. Financial Instruments.”

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, 2018	March 31, 2019	March 31, 2019
Marketable securities	Financial assets measured at amortized cost	Bonds	¥ 9,670	¥ 687	$ 6,192
	Total		¥ 9,670	¥ 687	$ 6,192
Investment securities	Financial assets measured at FVOCI	Stock	¥ 183,967	¥ 166,464	$ 1,499,677
	Financial assets measured at FVPL	Other	547	464	4,185
	Financial assets measured at amortized cost	Bonds	4,289	4,547	40,963
	Total		¥ 188,803	171,476	$ 1,544,825

Note: 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) 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, 2018	
Description	Millions of Yen
SANTEN PHARMACEUTICAL CO., LTD.	¥ 15,961
DAIKIN INDUSTRIES, LTD.	14,258
Nissan Chemical Industries, Ltd.	10,502
DAIICHI SANKYO COMPANY, LIMITED	10,158
T&D Holdings, Inc.	9,633
NISSIN FOODS HOLDINGS CO., LTD.	9,077
YAKULT HONSHA CO., LTD.	6,354
Astellas Pharma Inc.	5,345
MEIJI Holdings Co., Ltd.	4,904
Kurita Water Industries Ltd.	4,894
OBAYASHI CORPORATION	4,526
Nippon Shinyaku Co., Ltd.	4,414
KOKUYO CO., LTD.	3,888
Sumitomo Dainippon Pharma Co., Ltd.	3,837
HISAMITSU PHARMACEUTICAL CO., INC.	3,694
MIURA CO., LTD.	3,512
KIKKOMAN CORPORATION	3,069
SHIMADZU CORPORATION	2,750
Otsuka Holdings Co., Ltd.	2,500
KISSEI PHARMACEUTICAL CO., LTD.	2,433
Shiseido Company, Limited	2,255
Alfresa Holdings Corporation	2,246
CKD Corporation	2,189
MAEDA CORPORATION	1,992
KYORIN Holdings, Inc.	1,929
SUZUKEN CO., LTD.	1,899
OKAMURA CORPORATION	1,850
Carna Biosciences, Inc.	1,849
SUMITOMO CHEMICAL COMPANY, LIMITED	1,780
DAIWA HOUSE INDUSTRY CO., LTD.	1,775

March 31, 2019		
Description	Millions of Yen	Thousands of U.S. Dollars
DAIKIN INDUSTRIES, LTD.	¥ 15,759	$ 141,969
SANTEN PHARMACEUTICAL CO., LTD.	15,346	138,256
DAIICHI SANKYO COMPANY, LIMITED	14,693	132,370
Nissan Chemical Corporation	10,054	90,575
NISSIN FOODS HOLDINGS CO., LTD.	9,348	84,216
T&D Holdings, Inc.	6,641	59,824
YAKULT HONSHA CO., LTD.	6,249	56,300
Sumitomo Dainippon Pharma Co., Ltd.	5,879	52,967
Astellas Pharma Inc.	5,492	49,478
MEIJI Holdings Co., Ltd.	5,443	49,032
Nippon Shinyaku Co., Ltd.	4,997	45,020
Kurita Water Industries Ltd.	4,100	36,934
KIKKOMAN CORPORATION	3,893	35,075
Alfresa Holdings Corporation	2,988	26,920
SHIMADZU CORPORATION	2,941	26,494
SUZUKEN CO., LTD.	2,769	24,950
MIURA CO., LTD.	2,670	24,055
KISSEI PHARMACEUTICAL CO., LTD.	2,453	22,095
KOKUYO CO., LTD.	2,414	21,746
HISAMITSU PHARMACEUTICAL CO., INC.	2,282	20,557
OBAYASHI CORPORATION	2,166	19,510
KYORIN Holdings, Inc.	2,085	18,787
Otsuka Holdings Co., Ltd.	2,040	18,379
FUJIFILM Holdings Corporation	2,007	18,077
MEDIPAL HOLDINGS CORPORATION	1,908	17,187
MAEDA CORPORATION	1,743	15,698
FUJIMOTO CHEMICALS CO., LTD.	1,718	15,481
OKAMURA CORPORATION	1,479	13,323
Osaka Gas Co., Ltd.	1,261	11,365
Mitsubishi Logistics Corporation	1,253	11,288

(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, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Stock held at year-end	¥ 2,829	¥ 2,691	$ 24,239
Stock disposed of during the year	71	382	3,445
Total	¥ 2,901	¥ 3,073	$ 27,684

(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 losses are as follows:

	Millions of Yen				Thousands of U.S. Dollars	
	For the year ended March 31, 2018		For the year ended March 31, 2019		For the year ended March 31, 2019	
	Fair value at the date of sale	Cumulative gains or losses	Fair value at the date of sale	Cumulative gains or losses	Fair value at the date of sale	Cumulative gains or losses
Stock	¥ 3,761	¥ 2,018	¥ 17,444	¥ 8,799	$ 157,151	$ 79,272

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) from other components of equity to retained earnings of ¥1,403 million and ¥6,178 million ($55,657 thousand) for the years ended March 31, 2018 and 2019, respectively.

Note 10

Other Financial Assets

Details of other financial assets are as follows:

	Classification	Millions of Yen		Thousands of U.S. Dollars
		March 31, 2018	March 31, 2019	March 31, 2019
(Current assets)				
Time deposits	Financial assets measured at amortized cost	¥ 10,800	¥ 10,800	$ 97,297
Other	—	33	—	—
	Total	¥ 10,833	¥ 10,800	$ 97,297
(Non-current assets)				
Long-term time deposits	Financial assets measured at amortized cost	¥ 40,000	¥ 85,000	$ 765,766
Insurance reserve fund	Financial assets measured at FVPL	6,685	6,672	60,111
	Total	¥ 46,685	¥ 91,672	$ 825,876

Note 11

Other Assets

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

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
(Other current assets)			
Prepaid expenses	¥ 5,174	¥ 7,871	$ 70,908
Consumption taxes receivable	3,619	0	0
Advance payments	1,848	1,914	17,244
Other	4,179	4,257	38,354
Total	¥ 14,821	¥ 14,042	$ 126,506
(Other non-current assets)			
Lease deposits	¥ 858	¥ 872	$ 7,854
Long-term prepaid expenses	350	1,134	10,217
Other	2,722	2,165	19,502
Total	¥ 3,929	¥ 4,171	$ 37,572

Note 12

Inventories

Details of inventories are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Merchandise and finished goods	¥ 18,982	¥ 19,320	$ 174,050
Work in process	4,012	4,433	39,936
Raw materials and supplies	8,296	9,069	81,700
Total	¥ 31,290	¥ 32,821	$ 295,686

Note: Inventories recognized as an expense for the years ended March 31, 2018 and 2019, amounted to ¥39,348 million and ¥43,579 million ($392,608 thousand), respectively. In addition, the write-downs of inventories recognized as an expense for the years ended March 31, 2018 and 2019, were ¥126 million and ¥131 million ($1,184 thousand), respectively.

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

	Millions of Yen					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Construction in progress	Total
Balance at April 1, 2017	¥ 26,223	¥ 86,209	¥ 22,853	¥ 25,409	¥ 4,184	¥ 164,878
Acquisition	—	1,055	505	3,031	15,383	19,975
Transfer	—	9,545	1,087	880	(11,512)	—
Sale or disposal	(1,220)	(3,307)	(1,204)	(1,059)	—	(6,790)
Exchange differences on translation of foreign operations	—	8	—	5	—	14
Other	—	—	—	—	(1,217)	(1,217)
Balance at March 31, 2018	¥ 25,003	¥ 93,511	¥ 23,241	¥ 28,266	¥ 6,838	¥ 176,859
Acquisition	3,984	1,919	1,039	1,522	13,928	22,393
Transfer	—	12,879	379	268	(13,525)	—
Sale or disposal	—	(1,395)	(1,087)	(1,805)	(24)	(4,311)
Exchange differences on translation of foreign operations	—	(5)	—	(3)	(0)	(7)
Other	—	—	—	—	(1,115)	(1,115)
Balance at March 31, 2019	¥ 28,987	¥ 106,908	¥ 23,572	¥ 28,249	¥ 6,101	¥ 193,818

	Thousands of U.S. Dollars					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Construction in progress	Total
Balance at March 31, 2018	$ 225,256	$ 842,438	$ 209,379	$ 254,651	$ 61,600	$ 1,593,324
Acquisition	35,889	17,289	9,364	13,713	125,480	201,735
Transfer	—	116,023	3,410	2,416	(121,850)	—
Sale or disposal	—	(12,572)	(9,791)	(16,260)	(220)	(38,842)
Exchange differences on translation of foreign operations	—	(41)	—	(23)	(0)	(64)
Other	—	—	—	—	(10,042)	(10,042)
Balance at March 31, 2019	$ 261,144	$ 963,138	$ 212,363	$ 254,498	$ 54,968	$ 1,746,111

Accumulated depreciation and accumulated impairment losses

	Millions of Yen					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Construction in progress	Total
Balance at April 1, 2017	¥ —	¥ (47,545)	¥ (15,689)	¥ (17,984)	¥ —	¥ (81,219)
Depreciation	(1)	(2,792)	(1,046)	(1,791)	—	(5,629)
Impairment losses	—	(300)	(5)	(0)	—	(305)
Sale or disposal	—	2,436	1,139	1,046	—	4,622
Exchange differences on translation of foreign operations	—	(2)	—	(5)	—	(7)
Other	—	—	—	—	—	—
Balance at March 31, 2018	¥ (1)	¥ (48,203)	¥ (15,601)	¥ (18,734)	¥ —	¥ (82,538)
Depreciation	(8)	(3,497)	(1,139)	(1,942)	—	(6,587)
Impairment losses	—	(56)	(12)	(2)	(24)	(94)
Sale or disposal	—	1,393	1,059	1,790	24	4,267
Exchange differences on translation of foreign operations	—	2	—	2	—	4
Other	—	—	—	—	—	—
Balance at March 31, 2019	¥ (9)	¥ (50,361)	¥ (15,693)	¥ (18,885)	¥ —	¥ (84,948)

	Thousands of U.S. Dollars					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Construction in progress	Total
Balance at March 31, 2018	$ (6)	$ (434,260)	$ (140,547)	$ (168,771)	$ —	$ (743,584)
Depreciation	(76)	(31,508)	(10,257)	(17,497)	—	(59,339)
Impairment losses	—	(502)	(112)	(14)	(220)	(848)
Sale or disposal	—	12,553	9,538	16,128	220	38,439
Exchange differences on translation of foreign operations	—	17	—	19	—	36
Other	—	—	—	—	—	—
Balance at March 31, 2019	$ (82)	$ (453,700)	$ (141,378)	$ (170,136)	$ —	$ (765,296)

Carrying amount

	Millions of Yen					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Construction in progress	Total
Balance at April 1, 2017	¥ 26,223	¥ 38,664	¥ 7,164	¥ 7,425	¥ 4,184	¥ 83,659
Balance at March 31, 2018	25,003	45,308	7,640	9,533	6,838	94,321
Balance at March 31, 2019	28,978	56,548	7,879	9,364	6,101	108,870

	Thousands of U.S. Dollars					
	Land	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Construction in progress	Total
Balance at March 31, 2019	$ 261,062	$ 509,438	$ 70,985	$ 84,361	$ 54,968	$ 980,814

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 “38. 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, 2017, and March 31, 2018 and 2019, are as follows:

	Millions of Yen			
	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Total
Balance at April 1, 2017	¥ 179	¥ 629	¥ 99	¥ 907
Balance at March 31, 2018	163	354	78	595
Balance at March 31, 2019	1,202	802	57	2,060

	Thousands of U.S. Dollars			
	Buildings and structures	Machinery and vehicles	Tools, furniture, and fixtures	Total
Balance at March 31, 2019	$ 10,825	$ 7,222	$ 510	$ 18,557

(3) Impairment Losses

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

The Group recognized impairment losses for property, plant, and equipment of ¥305 million and ¥94 million ($848 thousand) for the years ended March 31, 2018 and 2019, respectively, which are included in "Other expenses" in the consolidated statement of income.

Impairment losses recognized for the years ended March 31, 2018 and 2019, 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.

Note 14

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, 2017	¥ 44,190	¥ 8,749	¥ 3,380	¥ 56,319
Acquisition	11,694	955	1,677	14,326
Transfer	—	2,428	(2,428)	—
Disposal	(200)	(188)	(69)	(456)
Exchange differences on translation of foreign operations	—	(0)	—	(0)
Other	—	—	(227)	(227)
Balance at March 31, 2018	¥ 55,683	¥ 11,945	¥ 2,333	¥ 69,962
Acquisition	9,496	1,009	1,227	11,732
Transfer	—	2,138	(2,138)	—
Disposal	—	(1,021)	(3)	(1,024)
Exchange differences on translation of foreign operations	—	(0)	—	(0)
Other	—	—	(288)	(288)
Balance at March 31, 2019	¥ 65,179	¥ 14,070	¥ 1,132	¥ 80,381

	Thousands of U.S. Dollars			
	Patents and licenses	Software	Other	Total
Balance at March 31, 2018	$ 501,652	$ 107,610	$ 21,022	$ 630,284
Acquisition	85,549	9,086	11,055	105,690
Transfer	—	19,258	(19,258)	—
Disposal	—	(9,194)	(27)	(9,221)
Exchange differences on translation of foreign operations	—	(2)	—	(2)
Other	—	—	(2,597)	(2,597)
Balance at March 31, 2019	$ 587,202	$ 126,757	$ 10,195	$ 724,153

Accumulated amortization and accumulated impairment losses

	Millions of Yen			
	Patents and licenses	Software	Other	Total
Balance at April 1, 2017	¥ (5,558)	¥ (5,095)	¥ (429)	¥ (11,082)
Amortization	(2,613)	(960)	(4)	(3,577)
Disposal	200	170	43	413
Impairment losses	—	—	—	—
Exchange differences on translation of foreign operations	—	0	—	0
Other	—	—	—	—
Balance at March 31, 2018	¥ (7,971)	¥ (5,885)	¥ (390)	¥ (14,247)
Amortization	(2,721)	(1,306)	(1)	(4,028)
Disposal	—	1,017	0	1,017
Impairment losses	—	(65)	—	(65)
Exchange differences on translation of foreign operations	—	0	—	0
Other	—	—	—	—
Balance at March 31, 2019	¥ (10,692)	¥ (6,239)	¥ (392)	¥ (17,322)

	Thousands of U.S. Dollars			
	Patents and licenses	Software	Other	Total
Balance at March 31, 2018	$ (71,811)	$ (53,020)	$ (3,518)	$ (128,349)
Amortization	(24,511)	(11,762)	(13)	(36,287)
Disposal	—	9,161	3	9,164
Impairment losses	—	(587)	—	(587)
Exchange differences on translation of foreign operations	—	1	—	1
Other	—	—	—	—
Balance at March 31, 2019	$ (96,322)	$ (56,207)	$ (3,528)	$ (156,058)

Carrying amount

	Millions of Yen			
	Patents and licenses	Software	Other	Total
Balance at April 1, 2017	¥ 38,632	¥ 3,654	¥ 2,951	¥ 45,237
Balance at March 31, 2018	47,712	6,059	1,943	55,715
Balance at March 31, 2019	54,488	7,831	740	63,059

	Thousands of U.S. Dollars			
	Patents and licenses	Software	Other	Total
Balance at March 31, 2019	$ 490,879	$ 70,549	$ 6,667	$ 568,095

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 ¥20,285 million and ¥19,162 million ($172,632 thousand) as of March 31, 2018 and 2019, 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 “38. 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:

Item	Details	Millions of Yen		Thousands of U.S. Dollars
		March 31, 2018	March 31, 2019	March 31, 2019
Patents and licenses	In-process research and development costs acquired separately	¥ 18,758	¥ 18,835	$ 169,683
	Sales licenses	28,955	35,653	321,196

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, 2018	March 31, 2019
In-process research and development costs acquired separately	ONO-7643/Anamorelin ONO-1162/Ivabradine ONO-2370/Opicapone ONO-7702/Encorafenib ONO-7703/Binimetinib ONO-7701(BMS-986205) ONO-5704/SI-613 ONO-7705/Selinexor ONO-7706/KPT-8602	ONO-7643/Anamorelin ONO-1162/Ivabradine ONO-2370/Opicapone ONO-7701(BMS-986205) ONO-5704/SI-613 ONO-7705/Selinexor ONO-7706/KPT-8602
Sales licenses	STAYBLA RIVASTACH FORXIGA KYPROLIS PARSABIV	STAYBLA RIVASTACH FORXIGA KYPROLIS PARSABIV BRAFTOVI, MEKTOVI

§2 Remaining Amortization Period

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

Item	Details	March 31, 2018	March 31, 2019
Patents and licenses	Sales licenses (years)	12.4	11.3

(3) Impairment Losses

Intangible assets are grouped into the smallest cash-generating 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.

The recoverable amount of an asset is calculated based on value in use. The Group's discount rate used in calculating value in use is calculated based on the weighted-average cost of capital, and the pretax discount rate used in the calculation of value in use is from 7.5% to 11.8% for the year ended March 31, 2019.

As a result of impairment testing, the Group does not recognize any impairment losses for patents and licenses for the years ended March 31, 2018 and 2019. The Group recognized impairment losses for software of ¥65 million ($587 thousand) for the year ended March 31, 2019. Impairment losses on software were included in "Other expenses" 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, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Profit from continuing operations attributable to the Group	¥ (4)	¥ (1)	$ (11)
Other comprehensive income attributable to the Group	2	(1)	(12)
Total comprehensive income attributable to the Group	¥ (1)	¥ (3)	$ (24)

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

Note 16

Income Taxes

(1) Deferred Income Taxes

Amounts of deferred tax assets and deferred tax liabilities for each consolidated fiscal year end are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Deferred tax assets	¥ 10,192	¥ 21,079	$ 189,900
Deferred tax liabilities	1,016	1,053	9,484
Net	¥ 9,176	¥ 20,026	$ 180,417

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

For the year ended March 31, 2018

	Millions of Yen			
	Balance at April 1, 2017	Recognized in profit or loss	Recognized in other comprehensive income	Balance at March 31, 2018
Deferred tax assets				
Accrued bonuses	¥ 1,670	¥ (95)	¥ —	¥ 1,575
Accrued enterprise tax	1,296	(570)	—	727
Expenses for research and development commissions and others	22,307	7,269	—	29,576
Property, plant, and equipment	3,438	(1,006)	—	2,433
Intangible assets	309	(87)	—	222
Retirement benefit liabilities	2,838	93	211	3,141
Long-term advances received	1,614	(55)	—	1,559
Other accounts payable	2,541	(414)	—	2,127
Provision for patent royalties	1,870	1,454	—	3,324
Other	3,287	1,071	—	4,358
Total	¥ 41,171	¥ 7,660	¥ 211	¥ 49,042
Deferred tax liabilities				
Property, plant, and equipment	¥ (3,342)	¥ (323)	¥ —	¥ (3,665)
Intangible assets	(2,689)	(1,007)	—	(3,695)
Investment securities	(25,277)	(21)	(7,208)	(32,505)
Other	(6)	6	—	—
Total	¥ (31,314)	¥ (1,344)	¥ (7,208)	¥ (39,866)
Net	¥ 9,858	¥ 6,315	¥ (6,997)	¥ 9,176

For the year ended March 31, 2019

	Millions of Yen					
	Balance at March 31, 2018	Changes in Accounting Policies	Balance at April 1, 2018	Recognized in profit or loss	Recognized in other comprehensive income	Balance at March 31, 2019
Deferred tax assets						
Accrued bonuses	¥ 1,575	¥ —	¥ 1,575	¥ 163	¥ —	¥ 1,738
Accrued enterprise tax	727	—	727	253	—	980
Expenses for research and development commissions and others	29,576	—	29,576	6,690	—	36,266
Investment securities	—	—	—	29	—	29
Property, plant, and equipment	2,433	—	2,433	(105)	—	2,328
Intangible assets	222	—	222	(178)	—	44
Retirement benefit liabilities	3,141	—	3,141	109	393	3,642
Long-term advances received	1,559	(1,559)	—	—	—	—
Other accounts payable	2,127	(63)	2,064	(333)	—	1,731
Provision for patent royalties	3,324	—	3,324	1,941	—	5,265
Other	4,358	(198)	4,160	696	—	4,857
Total	¥ 49,042	¥ (1,820)	¥ 47,222	¥ 9,265	¥ 393	¥ 56,880
Deferred tax liabilities						
Property, plant, and equipment	¥ (3,665)	¥ —	¥ (3,665)	¥ (370)	¥ —	¥ (4,035)
Intangible assets	(3,695)	—	(3,695)	211	—	(3,484)
Investment securities	(32,505)	—	(32,505)	25	3,145	(29,335)
Total	¥ (39,866)	¥ —	¥ (39,866)	¥ (133)	¥ 3,145	¥ (36,854)
Net	¥ 9,176	¥ (1,820)	¥ 7,357	¥ 9,132	¥ 3,537	¥ 20,026

	Thousands of U.S. Dollars					
	Balance at March 31, 2018	Changes in Accounting Policies	Balance at April 1, 2018	Recognized in profit or loss	Recognized in other comprehensive income	Balance at March 31, 2019
Deferred tax assets						
Accrued bonuses	$ 14,190	$ —	$ 14,190	$ 1,466	$ —	$ 15,655
Accrued enterprise tax	6,547	—	6,547	2,281	—	8,828
Expenses for research and development commissions and others	266,452	—	266,452	60,270	—	326,722
Investment securities	—	—	—	264	—	264
Property, plant, and equipment	21,918	—	21,918	(949)	—	20,969
Intangible assets	1,999	—	1,999	(1,601)	—	399
Retirement benefit liabilities	28,300	—	28,300	979	3,536	32,815
Long-term advances received	14,045	(14,045)	—	—	—	—
Other accounts payable	19,162	(566)	18,597	(2,998)	—	15,599
Provision for patent royalties	29,945	—	29,945	17,488	—	47,433
Other	39,263	(1,782)	37,481	6,273	—	43,753
Total	$ 441,821	$ (16,393)	$ 425,428	$ 83,473	$ 3,536	$ 512,437
Deferred tax liabilities						
Property, plant, and equipment	$ (33,019)	$ —	$ (33,019)	$ (3,330)	$ —	$ (36,349)
Intangible assets	(33,293)	—	(33,293)	1,904	—	(31,389)
Investment securities	(292,839)	—	(292,839)	227	28,330	(264,283)
Total	$ (359,150)	$ —	$ (359,150)	$ (1,200)	$ 28,330	$ (332,020)
Net	$ 82,670	$ (16,393)	$ 66,277	$ 82,273	$ 31,866	$ 180,417

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 deferred tax liabilities as of March 31, 2018 and 2019 in Japan is 30.6%.
3. Taxable temporary differences associated with investments in subsidiaries, for which deferred tax liabilities were not recognized, amounted to ¥2,357 million and ¥2,858 million ($25,750 thousand) as of March 31, 2018 and 2019, respectively. This is because the Group is able to control the timing of the reversal of the temporary differences, and it is certain that the temporary differences will not reverse in the foreseeable future.
4. The Group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "2. Basis of Preparation (4) Changes in Accounting Policies." Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

(2) Income Tax Expense

Details of income tax expense are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Current tax expense	¥ 19,840	¥ 22,601	$ 203,613
Deferred tax expense	(6,315)	(9,139)	(82,331)
Total	¥ 13,525	¥ 13,462	$ 121,282

Note: 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 30.8% for the year ended March 31, 2018 and 30.6% for the year ended March 31, 2019. Overseas subsidiaries use the income tax rates of the countries in which they are located.

(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, 2018	For the year ended March 31, 2019
Applicable tax rates	30.8 %	30.6 %
Permanent non-deductible items	0.6	0.5
Non-taxable dividends	(0.3)	(0.3)
Tax credit for research and other	(11.5)	(11.0)
Other	1.5	0.9
Average actual tax rates	21.2 %	20.7 %

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.

Note 17

Trade and Other Payables

Details of trade and other payables are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Notes payable	¥ 485	¥ 503	$ 4,534
Trade accounts payable	5,137	5,794	52,194
Other accounts payable	28,392	28,846	259,873
Refund liabilities	—	1,690	15,228
Total	¥ 34,015	¥ 36,833	$ 331,828

Note: The Group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "2. Basis of Preparation (4) Changes in Accounting Policies." Along with applying IFRS 15, "Refund liabilities" are recognized and measured based on future refund some or all of that consideration to the customer or third parties. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

Note 18

Borrowings

Details of borrowings are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Current liabilities			
Short-term borrowings	¥ 84	¥ —	$ —
Short-term lease obligations	308	435	3,918
Total	¥ 392	¥ 435	$ 3,918
Non-current liabilities			
Long-term lease obligations	¥ 320	¥ 1,765	$ 15,900
Total	¥ 320	¥ 1,765	$ 15,900

Note: The average interest rate of 2.17% is calculated based on the balance of lease obligations at March 31, 2019.

Note 19

Other Financial Liabilities

Details of other financial liabilities are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Current liabilities			
Dividends payable	¥ 110	¥ 114	$ 1,026
Deposits received	3,645	316	2,844
Other	1	86	772
Total	¥ 3,756	¥ 515	$ 4,641
Non-current liabilities			
Other	¥ 8	¥ 5	$ 47
Total	¥ 8	¥ 5	$ 47

Note 20

Assets Pledged as Collateral

Assets pledged as collateral are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Other current assets	¥ 4,000	¥ 4,000	$ 36,036
Total	¥ 4,000	¥ 4,000	$ 36,036

Note: These 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 the 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 of Yen		Thousands of U.S. Dollars	Millions of Yen		Thousands of U.S. Dollars
	Minimum lease payments			Present value of minimum lease payments		
	March 31, 2018	March 31, 2019	March 31, 2019	March 31, 2018	March 31, 2019	March 31, 2019
One year or less	¥ 317	¥ 438	$ 3,947	¥ 308	¥ 435	$ 3,918
More than one year to five years	240	1,046	9,425	215	993	8,942
More than five years	115	1,034	9,315	104	772	6,958
Total	¥ 672	¥ 2,518	$ 22,687	¥ 627	¥ 2,200	$ 19,818

Note: 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) Operating Leases

Lessee

§1 Non-cancelable Operating Lease Contracts

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

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
One year or less	¥ 211	¥ 213	$ 1,918
More than one year to five years	499	286	2,579
More than five years	—	—	—
Total	¥ 710	¥ 499	4,497

Note: The Group engages in office rental, etc., classified as operating leases. 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:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Minimum lease payments	¥ 132	¥ 174	$ 1,570

Lessor

§1 Non-cancelable Operating Lease Contracts

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

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
One year or less	¥ 18	¥ 19	$ 171
More than one year to five years	33	17	152
More than five years	7	5	48
Total	¥ 58	¥ 41	$ 371

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

Note 22

Other Liabilities

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

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Other current liabilities			
Accrued consumption taxes	¥ 19	¥ 1,729	$ 15,581
Accrued salary and bonus	5,244	5,800	52,256
Accrued compensated vacation	2,594	3,130	28,199
Accrued expenses	1,307	1,505	13,558
Other	704	16	142
Total	¥ 9,869	¥ 12,181	$ 109,736
Other non-current liabilities			
Compensated long-service benefit obligations	¥ 596	¥ 620	$ 5,588
Other	218	212	1,911
Total	¥ 814	¥ 832	$ 7,499

Note: The Group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "2. Basis of Preparation (4) Changes in Accounting Policies." Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

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 tax-qualified pension plan, and granted employees the option to select a defined contribution plan for certain lump-sum payment plans. In addition, the Company has set up a retirement benefit trust in order to supplement funding deficits in benefit obligations.
Further, three overseas subsidiaries have defined contribution plans, one overseas subsidiary has a lump-sum payment plan, and two domestic subsidiaries participate in corporate 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, 2018	March 31, 2019	March 31, 2019
Contributory			
Defined benefit obligations	¥ 47,324	¥ 49,967	$ 450,150
Fair value of plan assets (including retirement benefit trust)	(44,249)	(45,249)	(407,652)
Subtotal	3,076	4,717	42,498
Non-contributory			
Defined benefit obligations	780	798	7,189
Subtotal	780	798	7,189
Net defined benefit liability	¥ 3,856	¥ 5,515	$ 49,687
Retirement benefit liabilities stated in the consolidated statement of financial position	¥ 3,856	¥ 5,515	$ 49,687

§2 Obligations under Defined Benefit Plans

Movements in the defined benefit obligations are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Opening balance of defined benefit obligations	¥ 45,671	¥ 48,105	$ 433,376
Service cost	2,207	2,368	21,332
Interest cost	380	366	3,298
Remeasurements			
Actuarial losses (gains) due to changes in financial assumptions	737	1,383	12,464
Other	567	72	652
Benefits paid	(1,458)	(1,530)	(13,782)
Closing balance of defined benefit obligations	¥ 48,105	¥ 50,765	$ 457,339

Notes: 1. The weighted-average payment years for the defined benefit obligations as of March 31, 2018 and 2019, were 18.1 years and 18.2 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:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Opening balance of fair value of plan assets	¥ 42,866	¥ 44,249	$ 398,637
Interest income	365	345	3,105
Remeasurements			
Return on plan assets	615	173	1,559
Contributions from employers	1,474	1,526	13,744
Benefits paid	(1,072)	(1,043)	(9,392)
Closing balance of fair value of plan assets	¥ 44,249	¥ 45,249	$ 407,652

Note: The Group expected to make contributions of ¥1,491 million and ¥1,550 million ($13,967 thousand) to the defined benefit corporate pension plans in the year subsequent to March 31, 2018 and 2019, respectively.

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

	Millions of Yen						Thousands of U.S. Dollars		
	March 31, 2018			March 31, 2019			March 31, 2019		
	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	¥ 2,518	¥ —	¥ 2,518	¥ 2,315	¥ —	¥ 2,315	$ 20,854	$ —	$ 20,854
Overseas equity instruments	1,903	—	1,903	2,067	—	2,067	18,619	—	18,619
Debt instruments									
Domestic debt instruments	—	4,883	4,883	—	4,033	4,033	—	36,332	36,332
Overseas debt instruments	—	1,776	1,776	—	1,513	1,513	—	13,633	13,633
General accounts at life insurance companies	—	28,920	28,920	—	29,715	29,715	—	267,701	267,701
Other	—	4,249	4,249	—	5,607	5,607	—	50,513	50,513
Total	¥ 4,421	¥ 39,828	¥ 44,249	¥ 4,382	¥ 40,868	¥ 45,249	$ 39,473	$ 368,179	$ 407,652

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:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Service costs	¥ 2,207	¥ 2,368	$ 21,332
Net interest	15	21	193
Expenses recognized in the consolidated statement of income	¥ 2,222	¥ 2,389	$ 21,525

Note: Among the above expenses, service costs are included in "Cost of sales," "Selling, general, and administrative expenses," and "Research and development costs," and net interest is included in "Finance income" or "Finance 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, 2018	March 31, 2019
Discount rate (%)	0.8	0.6
Expected rate of salary increase (%)	2.8	2.8
Expected average remaining lives of current pensioners at age 60 at year-end (years)	25.2	25.2
Expected average remaining lives, from age 60, of future pensioners at age 40 at year-end (years)	26.7	26.8

§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 effects of any changes in assumptions used for measuring defined benefit obligations are as follows:

	Changes in principal assumptions	Millions of Yen				Thousands of U.S. Dollars	
		March 31, 2018		March 31, 2019		March 31, 2019	
		Increase	Decrease	Increase	Decrease	Increase	Decrease
Defined benefit obligations							
Discount rate	0.5% increase/ decrease	¥ (4,116)	¥ 4,526	¥ (4,369)	¥ 4,807	$ (39,362)	$ 43,306
Expected average remaining lives	1 year increase/ decrease	857	(890)	953	(987)	8,582	(8,889)

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

(2) Multiemployer Pension Plans

Two domestic consolidated subsidiaries have joined corporate pension funds (multiemployer pension plans). The funds were established as a successor for employees' pension funds (multiemployer pension plans) and the subsidiaries transferred in March 28, 2018, resulted from obtaining approval of dissolution of the employees' pension plan from the Minister of Health, Labour, and Welfare on the same day. These 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 postemployment expenses in the same manner as defined contribution plans.

(3) Defined Contribution Plans

The Group recognized ¥2,885 million and ¥3,052 million ($27,493 thousand) as expenses for defined contribution plans for the years ended March 31, 2018 and 2019, respectively.

Note 24

Provisions

(1) Details

Details of provisions are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	March 31, 2018	March 31, 2019	March 31, 2019
Provision for patent royalties	¥ 10,862	¥ 17,206	$ 155,012
Others	864	—	—
Total	¥ 11,726	¥ 17,206	$ 155,012
Current liabilities	¥ 11,696	¥ 17,206	$ 155,012
Non-current liabilities	30	—	—

(2) Schedule of Movements

The movements in provisions are as follows:

	Millions of Yen		
	Provision for patent royalties	Others	Total
Balance at March 31, 2018	¥ 10,862	¥ 864	¥ 11,726
Changes in Accounting Policies	—	(823)	(823)
Balance at April 1, 2018	10,862	41	10,903
Added to provisions	6,344	—	6,344
Settled	—	(41)	(41)
Balance at March 31, 2019	¥ 17,206	¥ —	¥ 17,206

	Thousands of U.S. Dollars		
	Provision for patent royalties	Others	Total
Balance at March 31, 2018	$ 97,860	$ 7,780	$ 105,640
Changes in Accounting Policies	—	(7,414)	(7,414)
Balance at April 1, 2018	97,860	366	98,226
Added to provisions	57,152	—	57,152
Settled	—	(366)	(366)
Balance at March 31, 2019	$ 155,012	$ —	$ 155,012

Notes: 1. Provision for patent royalties is recognized and measured based on estimated royalty payment to third parties. The information required in IAS 37, "Provisions, Contingent Liabilities and Contingent Assets," is disclosed according to IAS 37. 92., instead of disclosing the respective figures, because such information may have some effects on the results of future discussion, etc.

2. The Group has applied IFRS 15 from the fiscal year ended March 31, 2019 as described in "2. Basis of Preparation (4) Changes in Accounting Policies." The items listed in "Others" in the previous year, are listed as refund liabilities. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the fiscal year ended March 31, 2019 according to the transitional option, the amount for the fiscal year ended March 31, 2018 is not restated.

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 authorized shares (Shares)	Number of issued shares (Shares)	Millions of Yen	
			Share capital	Capital reserves
Balance at April 1, 2017	1,500,000,000	589,237,500	¥ 17,358	¥ 17,144
Increase (decrease)	—	(45,896,100)	—	30
Balance at March 31, 2018	1,500,000,000	543,341,400	¥ 17,358	¥ 17,175
Increase (decrease)	—	—	—	27
Balance at March 31, 2019	1,500,000,000	543,341,400	¥ 17,358	¥ 17,202

	Thousands of U.S. Dollars	
	Share capital	Capital reserves
Balance at March 31, 2018	$ 156,381	$ 154,726
Increase (decrease)	—	245
Balance at March 31, 2019	$ 156,381	$ 154,971

Notes: 1. All shares issued by the Company are fully paid-up ordinary shares with no par value.
2. Increases and decreases in the number of issued shares for the year ended March 31, 2018 are due to retirement of treasury shares.

(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, 2017	59,218,371	¥ 59,382
Increase (decrease)	(29,998,584)	(21,234)
Balance at March 31, 2018	29,219,787	¥ 38,148
Increase (decrease)	1,073	3
Balance at March 31, 2019	29,220,860	¥ 38,151

	Amount (Thousands of U.S. Dollars)
Balance at March 31, 2018	$ 343,673
Increase (decrease)	26
Balance at March 31, 2019	$ 343,699

Notes: 1. Increases and decreases in the number and amount of treasury shares for the year ended March 31, 2018 are due to purchases under Article 156 of the Companies Act, applied by the reading of terms pursuant to the provisions of Paragraph 3, Article 165 of the Companies Act, retirement of treasury shares, and purchases of fractional unit shares. Those for the year ended March 31, 2019 are due to purchases of fractional unit shares.
2. Treasury shares held by associates as of March 31, 2018 and 2019, are ¥25 million and ¥27 million ($245 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 loss on derivatives under hedge accounting	Net gain (loss) on financial assets measured at FVOCI	Remeasurement of defined benefit plans	Total
Balance at April 1, 2017	¥ 716	¥ —	¥ 51,035	¥ —	¥ 51,752
Increase (decrease)					
Other comprehensive income	(112)	—	17,783	(478)	17,193
Transfer to retained earnings	—	—	(1,403)	478	(924)
Balance at March 31, 2018	¥ 605	¥ —	¥ 67,416	¥ —	¥ 68,021
Increase (decrease)					
Other comprehensive income	78	—	(68)	(890)	(881)
Transfer to retained earnings	—	—	(6,178)	890	(5,288)
Balance at March 31, 2019	¥ 682	¥ —	¥ 61,170	¥ —	¥ 61,852

	Thousands of U.S. Dollars				
	Exchange differences on translation of foreign operations	Net fair value loss on derivatives under hedge accounting	Net gain (loss) on financial assets measured at FVOCI	Remeasurement of defined benefit plans	Total
Balance at March 31, 2018	$ 5,448	$ —	$ 607,349	$ —	$ 612,797
Increase (decrease)					
Other comprehensive income	698	—	(613)	(8,020)	(7,935)
Transfer to retained earnings	—	—	(55,657)	8,020	(47,637)
Balance at March 31, 2019	$ 6,146	$ —	$ 551,079	$ —	$ 557,225

Notes: 1. Exchange differences on translation of foreign operations are the differences arising from consolidating the financial statements of overseas subsidiaries, which were prepared in foreign currencies.
2. Net fair value loss on derivatives under hedge accounting is the effective portion 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 is 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, 2018

Date of resolution	Share type	Total dividends (Millions of Yen)	Dividends per share (Yen)	Record date	Effective date
General shareholders' meeting held on June 29, 2017	Ordinary shares	¥ 10,600	¥ 20	March 31, 2017	June 30, 2017
Board of Directors' meeting held on November 6, 2017	Ordinary shares	¥ 12,853	¥ 25	September 30, 2017	December 1, 2017

Note: The dividends per share resolved at the Board of Directors' meeting held on November 6, 2017 includes the 300th anniversary commemorative dividend of ¥5 per share.

For the year ended March 31, 2019

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 22, 2018	Ordinary shares	¥ 10,282	¥ 20	$ 92,635	$ 0.18	March 31, 2018	June 25, 2018
Board of Directors' meeting held on November 1, 2018	Ordinary shares	¥ 11,568	¥ 22.5	$ 104,214	$ 0.20	September 30, 2018	December 3, 2018

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

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

For the year ended March 31, 2018

Date of resolution	Share type	Total dividends (Millions of Yen)	Dividends per share (Yen)	Record date	Effective date
General shareholders' meeting held on June 22, 2018	Ordinary shares	¥ 10,282	¥ 20	March 31, 2018	June 25, 2018

For the year ended March 31, 2019

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 20, 2019	Ordinary shares	¥ 11,568	¥ 22.5	$ 104,214	$ 0.20	March 31, 2019	June 21, 2019

Note 27

Revenue

(1) Disaggregation of revenue

The Group disaggregated revenue by type of goods or services and by geographic area.

§1 Details of revenue by type of goods or services

	Millions of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2019	For the year ended March 31, 2019
Revenue of goods and products	¥ 208,947	$ 1,882,406
Royalty and others		
Opdivo Intravenous Infusion	58,504	527,059
Keytruda® from Merck & Co., Inc.	12,813	115,434
Others	8,370	75,406
Sub total	79,687	717,900
Total	¥ 288,634	$ 2,600,305

§2 Details of revenue by geographic area

Details of revenue by geographic area are included in “6. Segment Information (3) Revenue by geographic area.”

(2) Contract balances

Receivables and contract liabilities from contracts with customers are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	April 1, 2018	March 31, 2019	March 31, 2019
Receivables from contracts with customers			
Trade accounts receivable	¥ 70,398	¥ 67,868	$ 611,422
Notes receivable	2,315	2,885	25,990

Notes: 1. There were no material contract liabilities.

2. Revenue recognized relating to performance obligations satisfied in previous periods was ¥71,715 million ($646,085 thousand) for the year ended March 31, 2019; it was mainly due to milestone revenue and royalty revenue.

(3) Transaction price allocated to the remaining performance obligations

There was no transaction price allocated to the remaining performance obligations.

(4) Assets recognized from the costs to obtain or fulfil a contract with a customer

There were no costs to obtain or fulfil a contract with a customer that should be recognized as assets.

Note 28

Selling, General, and Administrative Expenses

Major details of selling, general, and administrative expenses are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Business planning expenses	¥ 5,533	¥ 4,814	$ 43,373
Sales promotion expenses	3,714	4,719	42,515
Employee benefit expenses	25,961	26,713	240,659
Depreciation and amortization	1,702	2,033	18,316
Business consignment expenses	9,609	10,005	90,136

Note 29

Employee Benefit Expenses

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

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Salary and bonus	¥ 33,488	¥ 34,935	$ 314,732
Retirement benefit expenses (defined benefit plans)	2,207	2,368	21,332
Retirement benefit expenses (multiemployer pension plans)	23	20	178
Retirement benefit expenses (defined contribution plans)	2,885	3,052	27,493
Legal welfare expenses	1,851	1,982	17,860
Other welfare expenses	2,014	1,900	17,122
Other employee benefit expenses	3,531	3,733	33,628
Total	¥ 45,999	¥ 47,990	$ 432,345

Notes: 1. Employee benefit expenses are included in "Cost of sales," "Selling, general, and administrative expenses," and "Research and development costs" in the consolidated statement of income.
2. The employee benefit expenses above include remuneration of key management personnel. Remuneration of key management personnel is described in "37. Related Parties."

Note 30

Other Income and Other Expenses

Details of other income and other expenses are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Other income			
Gain on sale of non-current assets	¥ 2,857	¥ 149	$ 1,345
Insurance proceeds	224	270	2,432
Others	174	227	2,045
Total	¥ 3,255	¥ 646	$ 5,822
Other expenses			
Impairment losses	¥ 306	¥ 209	$ 1,885
Loss on disposal of non-current assets	41	7	68
Donations	1,564	1,609	14,495
Litigation costs, etc.	162	1,502	13,530
Others	66	72	651
Total	¥ 2,139	¥ 3,400	$ 30,630

Note: “Litigation costs, etc.” in other expenses include the payment of the settlement with Pfizer for patent-related litigation for the year ended March 31, 2019.

Note 31

Finance Income and Finance Costs

Details of finance income and finance costs are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
(Finance income)			
Interest income			
Financial assets measured at amortized cost	¥ 89	¥ 74	$ 664
Dividend income			
Financial assets measured at FVPL	—	18	158
Financial assets measured at FVOCI	2,901	3,073	27,684
Gains on marketable securities			
Financial assets measured at FVPL	57	—	—
Exchange gains	120	25	225
Others	111	93	842
Total	¥ 3,277	¥ 3,282	$ 29,572
(Finance costs)			
Interest expenses			
Financial liabilities measured at amortized cost	¥ 14	¥ 27	$ 241
Losses on marketable securities			
Financial assets measured at FVPL	—	83	746
Net interest on employee benefits	15	21	193
Others	7	19	171
Total	¥ 36	¥ 150	$ 1,351

Note 32

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, 2018

	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 (loss) gain on financial assets measured at FVOCI	¥ 25,668	¥ —	¥ 25,668	¥ (7,870)	¥ 17,797
Remeasurement of defined benefit plans	(689)	—	(689)	211	(478)
Share of net (loss) gain on financial assets measured at FVOCI of associates	3	—	3	(1)	2
Total	24,982	—	24,982	(7,660)	17,321
Items that may be reclassified subsequently to profit or loss					
Exchange differences on translation of foreign operations	(112)	—	(112)	—	(112)
Net fair value (loss) gain on cash flow hedges	112	(112)	—	—	—
Total	0	(112)	(112)	—	(112)
Total other comprehensive income	¥ 24,982	¥ (112)	¥ 24,870	¥ (7,660)	¥ 17,210

For the year ended March 31, 2019

	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 (loss) gain on financial assets measured at FVOCI	¥ (59)	¥ —	¥ (59)	¥ 16	¥ (43)
Remeasurement of defined benefit plans	(1,283)	—	(1,283)	393	(890)
Share of net (loss) gain on financial assets measured at FVOCI of associates	(2)	—	(2)	1	(1)
Total	(1,343)	—	(1,343)	409	(935)
Items that may be reclassified subsequently to profit or loss					
Exchange differences on translation of foreign operations	78	—	78	—	78
Net fair value (loss) gain on cash flow hedges	53	(53)	—	—	—
Total	131	(53)	78	—	78
Total other comprehensive income	¥ (1,213)	¥ (53)	¥ (1,266)	¥ 409	¥ (857)

	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 (loss) gain on financial assets measured at FVOCI	$ (529)	$ —	$ (529)	$ 141	$ (389)
Remeasurement of defined benefit plans	(11,556)	—	(11,556)	3,536	(8,020)
Share of net (loss) gain on financial assets measured at FVOCI of associates	(18)	—	(18)	5	(12)
Total	(12,103)	—	(12,103)	3,682	(8,421)
Items that may be reclassified subsequently to profit or loss					
Exchange differences on translation of foreign operations	698	—	698	—	698
Net fair value (loss) gain on cash flow hedges	480	(480)	—	—	—
Total	1,178	(480)	698	—	698
Total other comprehensive income	$ (10,925)	$ (480)	$ (11,405)	$ 3,682	$ (7,723)

Note 33

Earnings per Share

(1) Basic Earnings per Share

§1 Basic earnings per share are as follows:

	Yen		U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Basic earnings per share	¥ 97.00	¥ 100.25	$ 0.90

§2 Basis of Calculation of Basic Earnings per Share

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

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Profit for the year attributable to owners of the parent company	¥ 50,284	¥ 51,539	$ 464,316
Weighted-average number of ordinary shares outstanding (Thousands of shares)	518,390	514,121	

(2) Diluted Earnings per Share

§1 Diluted earnings per share are as follows:

	Yen		U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Diluted earnings per share	¥ 96.99	¥ 100.24	$ 0.90

§2 Basis of Calculation of Diluted Earnings per Share

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

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Profit for the year attributable to owners of the parent company	¥ 50,284	¥ 51,539	$ 464,316
Weighted-average number of ordinary shares outstanding (Thousands of shares)	518,390	514,121	
Increased number of ordinary shares under subscription rights to share (Thousands of shares)	36	50	
Weighted-average number of diluted ordinary shares outstanding (Thousands of shares)	518,426	514,171	

Note 34

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 interest-bearing 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 bio-ventures, and additionally the introduction of pipelines 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.

(2) Financial Risk Management

The Group is constantly exposed in its operating activities to various financial risks, including credit, liquidity, market, and others (e.g., foreign exchange and price fluctuation). 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

Credit risks are risks that result in financial losses incurred by the Group when a customer goes into default for contractual obligations. When full or partial collection of trade receivables, etc., is considered impossible, or extremely difficult, it is deemed to be a default.

The Group's trade receivables 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 that this may have a severe and disadvantageous influence on the Group's financial performance.

The Group's revenue mainly consists of royalty revenue and sales of products through a small number of wholesalers, and the total revenue from the top five group companies (including the parent company and the group company) accounts for about 76% of "Revenue" in the consolidated statement of income. Trade receivables from the top five group companies as of March 31, 2018 and 2019 were ¥56,081 million and ¥55,140 million ($496,761 thousand), respectively.

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 minimize the amount of uncollectable receivables, the Group manages due dates and balances by transaction, and executes continuous credit evaluation by receiving credit updates for its main counterparties from third party rating agencies. With regard to trade receivables, etc., that do not contain significant financing components, the allowance is always measured at an amount equal to the lifetime expected credit losses, regardless of whether or not there has been a significant increase in credit risk since initial recognition, and the Group has never recorded a significant bad debt loss on its trade receivables in the past.

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 derivative transactions used to mitigate the foreign exchange risk associated with settling payments in foreign currencies. Because the Group operates funds primarily through secure debt instruments and executes transactions with highly rated financial institutions in order to prevent the emergence of credit risk in advance, credit risk is low.

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.

At the end of each fiscal year, the Group evaluates whether the credit risk on financial instruments has increased significantly since the initial recognition, and with respect to impairment of financial assets measured at amortized cost, the Group recognizes an allowance for expected credit losses on such financial assets.

The movements in allowance for doubtful accounts are as follows:

	Millions of Yen	Thousands of U.S. Dollars
	For the year ended March 31, 2019	For the year ended March 31, 2019
Balance at the beginning of the year	¥ 8	$ 74
Increase	0	0
Decrease (utilization)	—	—
Decrease (other)	—	—
Balance at the end of the year	¥ 8	$ 74

(4) Liquidity Risk Management

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 the Group's cash flow forecasts and results. Because the Group has sufficient cash and cash equivalents and other highly liquid assets and secures stable cash in flows from operating activities, this risk is low.

Financial liabilities by maturity are as follows:

March 31, 2018

	Millions of Yen			
	Carrying amount	Contractual cash flows	One year or less	More than one year
Trade and other payables	¥ 34,015	¥ 34,015	¥ 34,015	¥ —
Borrowings				
Short-term borrowings	84	84	84	—
Current portion of long-term borrowings	—	—	—	—
Short-term lease obligations	308	317	317	—
Long-term lease obligations	320	355	—	355
Other financial liabilities	3,764	3,764	3,756	8

March 31, 2019

	Millions of Yen			
	Carrying amount	Contractual cash flows	One year or less	More than one year
Trade and other payables	¥ 36,833	¥ 36,833	¥ 36,833	¥ —
Borrowings				
Short-term borrowings	—	—	—	—
Current portion of long-term borrowings	—	—	—	—
Short-term lease obligations	435	438	438	—
Long-term lease obligations	1,765	2,080	—	2,080
Other financial liabilities	520	520	515	5

	Thousands of U.S. Dollars			
	Carrying amount	Contractual cash flows	One year or less	More than one year
Trade and other payables	$ 331,828	$ 331,828	$ 331,828	$ —
Borrowings				
Short-term borrowings	—	—	—	—
Current portion of long-term borrowings	—	—	—	—
Short-term lease obligations	3,918	3,947	3,947	—
Long-term lease obligations	15,900	18,740	—	18,740
Other financial liabilities	4,688	4,688	4,641	47

(5) Market Risk Management

§1 Foreign Exchange Risk

1) Foreign Exchange Risk Management

The Group engages in business activities internationally and receives royalties or makes payment of expense in foreign currencies. Therefore, the Group is exposed to risks such as decrease in revenue, increase in cost price and development cost, and foreign exchange losses through fluctuations in foreign exchange rates. This risk primarily arises from currencies such as U.S. dollar, Euro, and British pound. In order to mitigate this risk, the Group enters into hedging instruments 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 are 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, 2018		March 31, 2019		March 31, 2019
	Contractual amount (Millions of U.S. Dollars)	Fair value (Millions of Yen)	Contractual amount (Millions of U.S. Dollars)	Fair value (Millions of Yen)	Fair value (Thousands of U.S. Dollars)
(Sell)					
U.S. Dollar	$ 29	¥ 32	$ 47	¥ (86)	$ (772)
Cash flow hedge included in the above	27	33	45	(84)	(761)

3) Foreign Exchange Sensitivity Analysis
At the end of 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 pound is as follows:

	Millions of Yen				Thousands of U.S. Dollars	
	March 31, 2018		March 31, 2019		March 31, 2019	
	Equity	Profit or (loss)	Equity	Profit or (loss)	Equity	Profit or (loss)
U.S. Dollar	¥ 287	¥ (62)	¥ 306	¥ (541)	$ 2,756	$ (4,874)
Euro	—	(58)	—	(36)	—	(323)
British Pound	107	(17)	116	(17)	1,042	(158)

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

§2 Price Fluctuation Risk
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 and the 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 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 by ¥12,767 million and ¥11,553 million ($104,078 thousand) as of March 31, 2018 and 2019, respectively, as a result of changes in fair value of the equity instruments designated as financial assets measured at FVOCI.

(6) Hedge Accounting

§1 Hedging instruments
The periods over which the Group hedges cash flow fluctuations by foreign exchange contract are within one year or less.
The carrying amounts (fair value) of the assets of hedging instruments are included in “Other financial assets,” and the carrying amounts (fair value) of the liabilities of hedging instrument are included in “Other financial liabilities.”

March 31, 2019

Type of hedge	Risk classification	Hedging instrument	Notional amount (Millions of U.S. Dollars)	Carrying amount (Fair value)				Change in fair value of the hedging instrument used as the basis for recognizing hedge ineffectiveness	
				Assets (Millions of Yen)	Liabilities (Millions of Yen)	Assets (Thousands of U.S. Dollars)	Liabilities (Thousands of U.S. Dollars)	Millions of Yen	Thousands of U.S. Dollars
Cash flow hedge	Foreign currency risk	Forward exchange contract	$ 45	¥ —	¥ 86	$ —	$ 772	¥ 54	$ 486

Note: The average foreign exchange rate in foreign exchange contracts is ¥109.10 per U.S.dollar.

§2 Hedged items

Type of hedge	Change in value of the hedged item used as the basis for recognizing hedge ineffectiveness		Balance in cash flow hedge reserve for continuing hedges	
	Millions of Yen	Thousands of U.S. Dollars	Millions of Yen	Thousands of U.S. Dollars
Cash flow hedge	¥ (53)	$ (480)	¥ —	$ —

§3 Amounts that affected the consolidated statement of comprehensive income in association with cash flow hedges

For the year ended March 31, 2019

Type of hedge	Risk classification	Hedging instrument	Gains or losses on hedges recognized in other comprehensive income		Amount transferred from cash flow hedge reserve to profit or loss		Line item in profit or loss affected by the transfer
			Millions of Yen	Thousands of U.S. Dollars	Millions of Yen	Thousands of U.S. Dollars	
Cash flow hedge	Foreign currency risk	Forward exchange contract	¥ 53	$ 480	¥ 53	$ 480	Revenue, etc.

Note: The figures represent amounts before tax effect adjustments.

The hedge ineffectiveness is immaterial. Also, there is no cash flow hedge reserve arising from hedging relationships for which hedge accounting is no longer applied.

(7) Fair Value of Financial Instruments

§1 Fair Value Measurements

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

Cash and cash equivalents, trade and other receivables, and trade and other payables

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 and other financial liabilities

- 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.
- Time deposits
  The fair values of time deposits are based on discounted future cash flows using an interest rate assumed to be applied if similar contracts were to be newly carried out.
- Others
  Since other items are settled in a short period of time, their fair values are approximately equivalent to their carrying amounts.

Borrowings

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.

§2 Fair Value and Carrying Amount

The carrying amounts and fair values of financial assets and liabilities held by the Group by account are as follows. The following table does not include financial assets and liabilities whose carrying amounts and fair values are equivalent.

	Millions of Yen				Thousands of U.S. Dollars	
	March 31, 2018		March 31, 2019		March 31, 2019	
	Carrying amounts	Fair value	Carrying amounts	Fair value	Carrying amounts	Fair value
(Financial assets)						
Financial assets measured at amortized cost						
Marketable securities and investment securities	¥ 13,959	¥ 13,940	¥ 5,234	¥ 5,223	$ 47,155	$ 47,054
Other financial assets	50,800	50,800	95,800	95,800	863,063	863,063

§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, 2018			
	Level 1	Level 2	Level 3	Total
(Financial assets)				
Financial assets measured at FVPL				
Marketable securities and investment securities	¥ 422	¥ —	¥ 125	¥ 547
Other financial assets	—	33	6,685	6,718
Financial assets measured at FVOCI				
Investment securities	181,855	—	2,112	183,967
Total	¥ 182,277	¥ 33	¥ 8,922	¥ 191,232
(Financial liabilities)				
Financial liabilities measured at FVPL				
Other financial liabilities	¥ —	¥ 1	¥ —	¥ 1
Total	¥ —	¥ 1	¥ —	¥ 1

	Millions of Yen			
	March 31, 2019			
	Level 1	Level 2	Level 3	Total
(Financial assets)				
Financial assets measured at FVPL				
Marketable securities and investment securities	¥ 350	¥ —	¥ 114	¥ 464
Other financial assets	—	—	6,672	6,672
Financial assets measured at FVOCI				
Investment securities	164,187	—	2,277	166,464
Total	¥ 164,537	¥ —	¥ 9,064	¥ 173,601
(Financial liabilities)				
Financial liabilities measured at FVPL				
Other financial liabilities	¥ —	¥ 86	¥ —	¥ 86
Total	¥ —	¥ 86	¥ —	¥ 86

	Thousands of U.S. Dollars			
	March 31, 2019			
	Level 1	Level 2	Level 3	Total
(Financial assets)				
Financial assets measured at FVPL				
Marketable securities and investment securities	$ 3,154	$ —	$ 1,031	$ 4,185
Other financial assets	—	—	60,111	60,111
Financial assets measured at FVOCI				
Investment securities	1,479,162	—	20,515	1,499,677
Total	$ 1,482,316	$ —	$ 81,657	$ 1,563,972
(Financial liabilities)				
Financial liabilities measured at FVPL				
Other financial liabilities	$ —	$ 772	$ —	$ 772
Total	$ —	$ 772	$ —	$ 772

Note: For the years ended March 31, 2018 and 2019, 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, 2018			
	Level 1	Level 2	Level 3	Total
(Financial assets)				
Financial assets measured at amortized cost				
Marketable securities and investment securities	¥ —	¥ 13,940	¥ —	¥ 13,940
Other financial assets	—	50,800	—	50,800

	Millions of Yen			
	March 31, 2019			
	Level 1	Level 2	Level 3	Total
(Financial assets)				
Financial assets measured at amortized cost				
Marketable securities and investment securities	¥ —	¥ 5,223	¥ —	¥ 5,223
Other financial assets	—	95,800	—	95,800

	Thousands of U.S. Dollars			
	March 31, 2019			
	Level 1	Level 2	Level 3	Total
(Financial assets)				
Financial assets measured at amortized cost				
Marketable securities and investment securities	$ —	$ 47,054	$ —	$ 47,054
Other financial assets	—	863,063	—	863,063

Note: For the years ended March 31, 2018 and 2019, 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:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Balance at beginning of the year	¥ 8,861	¥ 8,922	$ 80,382
Total gains or losses	308	266	2,392
Profit or loss	82	83	744
Other comprehensive income	227	183	1,648
Purchase	289	400	3,605
Sale	(1)	(18)	(158)
Settlement	(535)	(507)	(4,564)
Balance at end of the year	¥ 8,922	¥ 9,064	$ 81,657

Notes: 1. Profit or loss included in total gains or losses is related to financial assets measured at FVPL. These gains and losses are included in "Finance income" and "Finance costs," respectively.
2. Other comprehensive income included in total gains or losses is related to financial assets measured at FVOCI. 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 35

Share-based Payments

The Company has a share option plan which reflects the Board of Directors' goal of long-term improvement of corporate value to share the consciousness of the profit of the Company with shareholders.

(1) Contractual conditions of share options

	Eligible persons	Number of share options granted (Shares)	Grant date	Exercise period	Settlement method	Vesting conditions
2015 issued	The Company's directors (excluding outside directors)	2,900	July 13, 2015	From July 14, 2015 through July 13, 2055	Settled in equity	None
2016 issued	The Company's directors (excluding outside directors)	13,000	July 14, 2016	From July 15, 2016 through July 14, 2056	Settled in equity	None
2017 issued	The Company's directors (excluding outside directors)	14,500	July 14, 2017	From July 15, 2017 through July 14, 2057	Settled in equity	None
2018 issued	The Company's directors (excluding outside directors)	14,500	July 9, 2018	From July 10, 2018 through July 9, 2058	Settled in equity	None

Notes: 1. Holders of subscription rights to shares can exercise their share subscription rights only from the day following the date of resignation from their position as Director of the Company.
2. Although the Company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016, the effect of this stock split is not reflected in the above table for 2015 issued.

(2) Movement of the number of share options and their weighted-average exercise price

	For the year ended March 31, 2018		For the year ended March 31, 2019		For the year ended March 31, 2019
	Number of share options (Shares)	Weighted-average exercise price (Yen)	Number of share options (Shares)	Weighted-average exercise price (Yen)	Weighted-average exercise price (Dollar)
Outstanding at the beginning of the year	27,500	1	42,000	1	0.01
Granted	14,500	1	14,500	1	0.01
Exercised	—	—	—	—	—
Forfeited	—	—	—	—	—
Outstanding at the end of the year	42,000	1	56,500	1	0.01
Options exercisable, at the end of the year	—	—	—	—	—

Note: The exercise price of unexercised share options was ¥1 ($0.01) for the year ended March 31, 2019 and the weighted-average remaining life was 37.8 years as of March 31, 2019.

(3) Fair value and fair value measurement method of share options

§1 Measurement method

Black-Scholes model

§2 Primary base assumptions and measurement method

	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Fair value	¥ 1,766	¥ 1,909	$17
Share price at the grant date	¥ 2,449	¥ 2,598.5	$23
Exercise price	¥ 1	¥ 1	$0.01
Expected volatility	33.059%	31.649%	
Option life	20 years	20 years	
Expected dividend yield	¥ 40	¥ 40	$0.36
Risk-free interest rate	0.595%	0.487%	

Note: The expected volatility is estimated based on share prices for the past 20 years.

(4) Expenses related to share-based payments

Expenses related to share-based payments are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Share-based payments	¥ 30	¥ 27	$ 245

Note 36

Non-cash Transactions

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

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Property, plant, and equipment acquired under finance leases	¥ 104	¥ 1,933	$ 17,415
Total	¥ 104	¥ 1,933	$ 17,415

Note 37

Related Parties

(1) Subsidiaries and Affiliates

Details of the Group's subsidiaries and affiliates are as follows:

Name	Primary business	Location	Proportion of voting rights held by the Group	
			March 31, 2018	March 31, 2019
			(%)	(%)
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	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. 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.

(2) Transactions with Related Parties

There were no significant transactions and balances of receivables and payables between the Group and its related parties.

(3) Remuneration of Key Management Personnel

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

	Millions of Yen		Thousands of U.S. Dollars
	For the year ended March 31, 2018	For the year ended March 31, 2019	For the year ended March 31, 2019
Fixed remuneration	¥ 247	¥ 257	$ 2,316
Bonuses	60	77	692
Share-based payments	30	27	245
Total	¥ 336	¥ 361	$ 3,253

Notes: 1. Remuneration of key management personnel comprises the remuneration for eight people for the year ended March 31, 2019 (seven people for the year ended March 31, 2018), who are key management personnel having authority and responsibility for planning, supervising, and managing business activities of the Group.

2. As for remuneration of key management personnel, remuneration of internal directors consists of fixed remuneration, bonuses and share-based payments, and remuneration of outside directors and auditors consists of only fixed remuneration. The fixed remuneration of internal directors is determined in consideration of factors such as the size of the Group's business, the nature of their duties, scope of responsibility of each management personnel, and consistency in treatment with respect to other employees with a remuneration database from major consulting companies. The bonuses and stock options as share-based payments are determined in consideration of management indicators, such as revenue and operating profit that reflect performance and qualitative indicators such as contributions to enhancement of long-term corporate value. On the other hand, in consideration of factors, such as the nature of their duties and to ensure the independence from the execution of business, the remuneration of outside directors and auditors consists of only fixed remuneration. To determine the level of remuneration of outside directors, the Company refers to a remuneration database from major consulting companies so that the Company can seek suitable persons who have significant experience and broad knowledge.

Note 38

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, 2018	March 31, 2019	March 31, 2019
Property, plant, and equipment	¥ 12,786	¥ 2,013	$ 18,131
Intangible assets	266	—	—
Total	¥ 13,052	¥ 2,013	$ 18,131

Commitments for expenditure of property, plant, and equipment for the year ended March 31, 2018 are composed of mainly expenditures relating to plant equipment under construction in Yamaguchi prefecture.

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 may potentially pay within three years are ¥19,359 million and ¥18,158 million ($163,586 thousand) as of March 31, 2018 and 2019, respectively. These milestone payment amounts are undiscounted and include all such potential payments assuming all projects currently in development are successful and specific sales targets are achievable.

Note 39

Contingent Liabilities

In September 2015, Dana-Farber Cancer Institute in the United States of America filed a suit in the U.S. District Court for Massachusetts against the Company, Bristol-Myers Squibb Company, and Professor Tasuku Honjo for addition of inventors for patent applications on anti-PD-1 antibodies and anti-PD-L1 antibodies that the Company owned.

On May 17, 2019, in the first instance, the Court ruled that Clive Wood, PhD and Dana-Farber Cancer Institute scientist, Gordon Freeman, PhD are coinventors on the patents. The Company was dissatisfied with the decision and appealed. The Group is not able to estimate the impact on its consolidated financial statements at this stage.

Note 40

Approval of Financial Statements

The consolidated financial statements for the year ended March 31, 2019, were approved by Gyo Sagara, President, Representative Director, and Chief Executive Officer, on June 20, 2019.

Note 41

Significant Subsequent Events

Acquisition and Retirement of Treasury Shares
On May 30, 2019 in accordance with Article 370 (resolution by documents instead of resolution by board meetings) of the Companies Act, the Company resolved to acquire its own shares under the provisions of Article 156 of the Companies Act, applied by the replacing terms pursuant to the provisions of Paragraph 3, Article 165 of the Companies Act, and retire its own shares pursuant to the provisions of Article 178 of the Companies Act.

1. Reasons for the Acquisition and Retirement of Treasury Shares
   The shares will be acquired and retired for the purpose of improving capital efficiency and as a part of measures for shareholder return.

2. Contents of the Acquisition
   (1) Class of shares to be acquired:
   Common stock of the Company
   (2) Total number of shares to be acquired:
   15 million shares (maximum)
   (2.92% of the total outstanding shares excluding treasury shares)
   (3) Aggregate amount of acquisition cost:
   ¥30.0 billion (maximum)
   (4) Period of acquisition:
   May 31, 2019 to September 30, 2019
   (5) Method for acquisition:
   Purchase on the Tokyo Stock Exchange
   (6) Schedule after acquisition:
   All the common stock acquired will be retired.

3. Contents of the Retirement
   (1) Class of shares to be retired:
   Common stock of the Company
   (2) Total number of shares to be retired:
   All the common stock acquired in accordance with Section 2 above
   (3) Scheduled date of retirement:
   October 31, 2019 (planned)

(Reference)
Number of treasury shares held by the Company as of March 31, 2019
- Total number of shares issued (excluding treasury shares): 514,183,401 shares
- Total number of treasury shares: 29,157,999 shares

Litigation
For litigation, refer to “39. Contingent Liabilities.”

Independent Auditor's Report

Deloitte.

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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, 2019, 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, 2019, and the consolidated results of their operations and their cash flows for the year then ended in accordance with International Financial Reporting Standards.

Emphasis of Matter

As discussed in Note 2 to the consolidated financial statements, effective April 1, 2018, the consolidated financial statements have been prepared in accordance with IFRS 15, IFRS 9 (revised in July 2014), and IFRIC 22. Our opinion is not modified in respect of this matter.

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.

Deloitte Touche Tohmatsu LLC

June 20, 2019

Member of
Deloitte Touche Tohmatsu Limited

ISO 26000 Comparison Table

ISO26000		ONO PHARMACEUTICAL Corporate Report 2019	
Core subjects	Issues	Pages	Related items
Organizational Governance		pp. 025-026 pp. 037-038 p. 038 p. 038 p. 038-039 p. 039	• ONO's Value Creation Process • Corporate Governance Structure • Corporate Governance Code • Internal Control System • Risk Management • Business Continuity Plan (BCP)
Human Rights	Due diligence	p. 045 p. 046 p. 048	• Respect for Human Rights • Enhancing the Creation of Workplace Environments with Job Satisfaction • Promotion of Diversity and Inclusion
	Human rights risk situations		
	Avoidance of complicity		
	Resolving grievances		
	Discrimination and vulnerable groups		
	Civil and political rights		
	Economic, social and cultural rights		
	Fundamental principles and rights at work		
Labor Practices	Employment and employment relationships	p. 045 p. 046 p. 047 p. 048	• Promotion of Human Resources Development • Enhancing the Creation of Workplace Environments with Job Satisfaction • Promotion of Health and Productivity Management • Promotion of Diversity and Inclusion
	Conditions of work and social protection		
	Social dialog		
	Health and safety at work		
	Human development and training in the workplace		
The Environment	Prevention of pollution	p. 051 p. 051 p. 052 p. 052 p. 052 p. 052	• Promotion of Environmental Management • Environmental Vision • Mid- and Long-Term Goals (greenhouse gas, water consumption, and waste) • Achievement of Low Carbon Society • Achievement of Water Circulation Society • Achievement of Resource Circulation Society
	Sustainable resource use		
	Climate change mitigation and adaptation		
	Protection of the environment, biodiversity and restoration of natural habitats		
Fair Operating Practices	Anti-corruption	p. 043 pp. 043-044	• ONO PHARMACEUTICAL Compliance Structure • Compliance Promotion Initiatives
	Responsible political involvement		
	Fair competition		
	Promoting social responsibility in the value chain		
	Respect for property rights		
Consumer Issues	Fair marketing, factual and unbiased information and fair contractual practices	pp. 009-010 pp. 011-014 pp. 015-016 pp. 029-031 pp. 032-034 pp. 035-036 p. 049	• History of Tackling Challenges • Key Product Profiles • Status of Development Pipeline • Game-changing R&D • Maximizing Product Value • Globalizing Business • Efforts Towards Imporvement of Medical Access
	Protecting consumers' health and safety		
	Sustainable consumption		
	Consumer service, support, and complaint and dispute resolution		
	Consumer data protection and privacy		
	Access to essential services		
	Education and awareness		
Community Involvement and Development	Community involvement	p. 049 pp. 049-050	• Efforts Towards Imporvement of Medical Access • Various Corporate Social Responsibility (CSR) Activities
	Education and culture		
	Employment creation and skills development		
	Technology development and access		
	Wealth and income creation		
	Health		
	Social investment		

Guide to Our Website

Our website provides detailed information about us in various areas, focusing around business activities.
In combination with this report, please use our website to learn more about us.

English https://www.ono.co.jp/eng/

Japanese https://www.ono.co.jp/

Research & Development
https://www.ono.co.jp/eng/rd/philosophy.html

Global Business & Alliances
https://www.ono.co.jp/eng/alliances/business_development.html

News Releases & Archives
https://www.ono.co.jp/eng/news/index.html

CSR Activities
https://ono-csr.disclosure.site/en

Investor Information
https://www.ono.co.jp/eng/investor/index.html

Corporate Information

Profile (as of March 31, 2019)

Company Name	ONO PHARMACEUTICAL CO., LTD.
Founded	1717
Date of Incorporation	1947
Paid-in Capital	¥17,358 million
Number of Shareholders	103,587
Number of Employees	3,555 (consolidated) 3,284 (unconsolidated)
Corporate Website	https://www.ono.co.jp/eng/

Minase Research Institute

Yamaguchi Plant
(due for operation in 2020)

Fukui Research Institute

Tsukuba Research Institute

JAPAN

ONO PHARMACEUTICAL CO., LTD.
Headquarters

Joto Plant

Fujiyama Plant

●Branch

KOREA
ONO PHARMA KOREA CO., LTD.

EUROPE
ONO PHARMA UK LTD.

TAIWAN
ONO PHARMA TAIWAN CO., LTD.

NORTH AMERICA
ONO PHARMA USA, INC.

Major Offices (as of March 31, 2019)

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(Registered Office)
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Tokyo Building
9-11, Nihonbashi-Honcho 4-chome, Chuo-ku,
Tokyo 103-0023, Japan

Branches in Japan
Hokkaido, Miyagi, Tokyo, Saitama, Aichi, Kyoto, Osaka, Kagawa, Hiroshima, Fukuoka, and other branches in major cities

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
Yamaguchi Plant, Yamaguchi, Japan
(due for operation in 2020)

Domestic Subsidiaries
Oriental Pharmaceutical & Synthetic Chemical Co., Ltd.
Bee Brand Medico Dental Co., Ltd.

Overseas Subsidiaries
ONO PHARMA USA, INC., New Jersey, USA
ONO PHARMA UK LTD., London, UK
ONO PHARMA KOREA CO., LTD., Seoul, Korea
ONO PHARMA TAIWAN CO., LTD., Taipei City, Taiwan

Related Party
Namicos Corporation

ONO PHARMACEUTICAL CO.,LTD.

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