Be Passionate Challengers

CORPORATE REPORT 2022

Year ended March 31, 2022

ONO PHARMACEUTICAL CO.,LTD.

Corporate Philosophy

Dedicated to the 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

Contents

Editorial Policy

In this report, ONO Pharmaceutical (ONO) reports on the Group's efforts to create value in line with the material issues we have newly identified as important management issues. We introduce key financial and non-financial initiatives centered on the value we should provide as a pharmaceutical company to achieve sustainable growth for the company and society. We publish this report as a communication tool to help stakeholders 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, 2021 through March 31, 2022

* The report is based on activities in FY2021, 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 2022 are also covered.

Reference Guidelines

ONO refers to the International Integrated Reporting Framework issued by the International Integrated Reporting Council (IIRC), Guidance for Integrated Corporate Disclosure and Company-Investor Dialogue for Collaborative Value Creation compiled by the Ministry of Economy, Trade and Industry of Japan, Environmental Reporting Guidelines 2018 by the Ministry of the Environment of Japan, and the Final Report on Recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). The GRI Standards are also referred to. Comparative tables are on the Sustainability pages of our website.
https://sustainability.ono-pharma.com/en

Publication Date:

September 2022

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.

Related Information

Corporate site
https://www.ono-pharma.com/

Information on ONO's Sustainability Initiatives
https://sustainability.ono-pharma.com/en

Financial Report
https://www.ono-pharma.com/ir/library/financial_results.html

Corporate Governance Report
https://www.ono-pharma.com/sites/default/files/en/ir/corporate_governance_report_en.pdf

External ESG Assessment of ONO PHARMACEUTICAL

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

Member of
Dow Jones Sustainability Indices
Powered by the S&P Global CSA

Dow Jones Sustainability Indices (DJSI)
Jointly developed by S&P Dow Jones Indices (US) and RobecoSAM (Switzerland) to evaluate companies based on an analysis of those companies' economic, environmental and social performance

2021 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX

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

FTSE4Good

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

FTSE Blossom Japan

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

Recognition of ONO's environmental performance

CDP A LIST 2021 CLIMATE WATER

CDP2021
[Climate Change]
[Water Security]
A List

Global accreditation by international environmental NGO CDP to name the world's top-rate businesses leading on environmental performance in climate change and water security

Recognition of ONO's safety & health performance

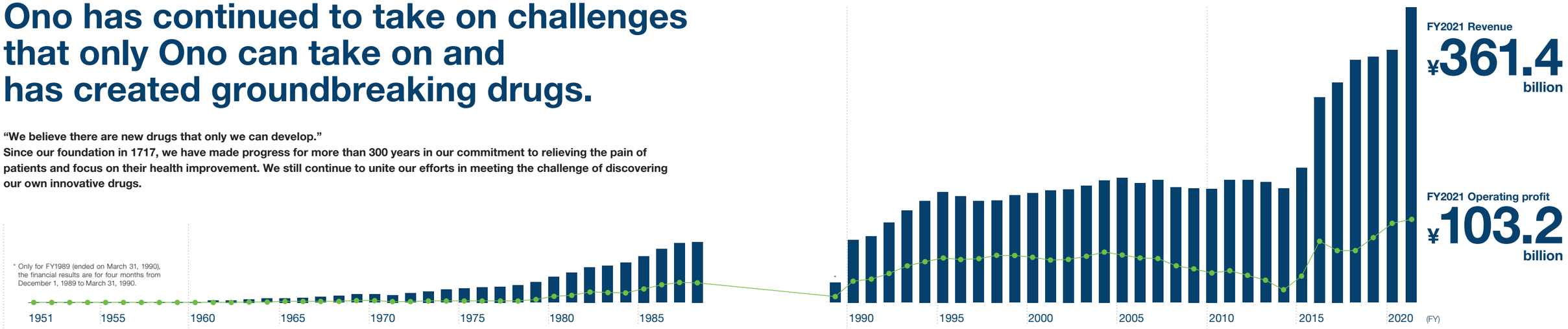
2022 健康経営優良法人 Health and productivity ホワイト500

2022 Certified Health & Productivity Management Outstanding Organization Recognition Program "White 500"

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

Ono has continued to take on challenges that only Ono can take on and has created groundbreaking drugs.

"We believe there are new drugs that only we can develop."
Since our foundation in 1717, we have made progress for more than 300 years in our commitment to relieving the pain of patients and focus on their health improvement. We still continue to unite our efforts in meeting the challenge of discovering our own innovative drugs.



Pursuing value creation from our inception

1717
Ichibei Fushimiya I founded the apothecary Fushimiya Ichibei Shoten in Doshomachi, Osaka.

1934
Ichibei Ono VIII changed the name of the business from Fushimiya Ichibei, which had been used since its foundation, to Ono Ichibei Shoten (Ono-Ichi) and reorganized operations to modernize management.


Ichibei Ono VIII

1947
Ono PHARMACEUTICAL CO., LTD. was established and it became a pharmaceutical manufacturer dedicated to developing ethical pharmaceuticals.

Contributes to a wide range of treatments through the development of innovative ethical pharmaceuticals

1960's
Transformed to a prescription drug manufacturer

1970's–1980's
Successfully developed and launched new innovative drugs on the market


PROSTARMON-F Injection (1974)


PROSTANDIN Injection (1979)


FOIPAN Tablets (1985)

1968
Became the world's first company to succeed in the total chemical synthesis of prostaglandins

World's First

Spreading drugs to Alleviate More People's Pain

1990's–
In addition to in-house drug discovery, strengthen licensing activities


ONON Capsules (1995)


ONOACT for Intravenous Infusion (2002)


STAYBLA Tablets (2007)


RECALBON Tablets (2009)


GLACTIV Tablets (2009)


RIVASTACH Patches (2011)

Creating Hope for Cancer Treatment

2010's
Full-scale entry into the oncology field

2014
Launched the world's first anti-PD-1 antibody: OPDIVO

World's First

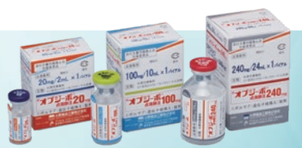
Tackling an Impossible Challenge: The Road to Launching PG Drugs on the Market

After World War II, ONO made a full-fledged entry into the OTC drug market. With the economy fluctuating and a universal health insurance system introduced in 1961, however, the OTC drug market environment became increasingly severe. Under such circumstances, prostaglandins (PGs) came to ONO's knowledge through the special lecture of Professor Sune K. Bergström of Sweden's Lund University in 1965, when ONO was still a small company with 20 researchers. With little development experience of prescription drugs, ONO started research on the then unidentified compounds. No method for the chemical synthesis of PGs had yet been established, and the only method available was biosynthesis, requiring a considerable amount of effort to produce even small quantities. Following the success by Professor Elias J. Corey (Harvard University, US) in total chemical synthesis of PGs, ONO immediately sent its researchers to the professor to have them learn about the method. Finally, in 1968, ONO succeeded in the total chemical synthesis of PGs on a commercial basis for the first time in the world.

> "To put it exaggeratedly, I feel like Columbus sailing on the Santa Maria westward across the Atlantic Ocean in search of the New World."
>
> Excerpted from Yuzo Ono's remarks at the first PG Study Meeting


Yuzo Ono standing in front of the stone monument on which ONO's corporate philosophy is engraved

A Game-Changing Cancer Immunotherapy Approach That Has Contributed to Drug Development Leading to Receipt of the Nobel Prize in Physiology or Medicine



The 2018 Nobel Prize in Physiology or Medicine was awarded jointly to Distinguished Professor Tasuku Honjo of Kyoto University and Professor James P. Allison of the University of Texas "for their discovery of cancer therapy by inhibition of negative immune regulation," which was handled by ONO. In 1992, PD-1 was discovered at the Honjo laboratory of Kyoto University, but its functions had long been unknown. It was in 2002, 10 years after the identification of PD-1, that the researchers found it plays a role in the immune evasion mechanism of cancer. However, because treating cancer by boosting the immune system was an unprecedented concept, ONO faced great difficulty in finding a co-developer with human antibody production technology and was turned down by a succession of companies. In 2005, ONO finally found and reached a collaborative research agreement with the American bioventure company Medarex (which was acquired by Bristol-Myers Squibb in 2009). As for clinical trials of OPDIVO, which started in Japan in 2008, ONO also saw reluctance among clinical healthcare professionals in accepting the therapy. Overcoming many difficulties, ONO obtained marketing approval for OPDIVO as the world's first anti-PD-1 antibody in July 2014, 22 years after the discovery of PD-1. Currently, OPDIVO is approved for 11 cancers and offers a new treatment option to clinical healthcare professionals.

An R&D-based Pharmaceutical Company Taking on the Challenge of Creating Original and Innovative in Prescription Drugs

To realize our corporate philosophy, "Dedicated to the Fight against Disease and Pain," we focus our finite management resources on drug discovery and development, creating innovative drugs, such as the cancer immunotherapy OPDIVO.

Feature 1

Continuing Vigorous Investment in Drug Development

R&D costs
(FY2021)
¥75.9 billion

R&D cost-to-revenue ratio
(FY2021)
21.0 %

Feature 2

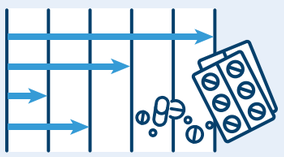
R&D Capabilities Combining In-house Drug Discovery and Open Innovation

Number of joint research projects with universities, biopharmaceutical companies, etc.
(As of end of March 2022)
About 200

Number of approvals obtained
(FY2021)
7 approvals

Feature 3

A Pipeline that Continuously Markets New Drugs

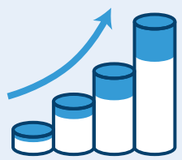


Number of clinical trials conducted
(FY2021)
82 trials

Number of new products launched and additional indications approved
(FY2017 to FY2021)
31 products

Feature 4

High Profit Margins Making Investing in Growth Possible



Revenue
(FY2021)
¥361.4 billion

Operating income to revenue ratio
(FY2021)
28.6 %

Main Products

ONCOLOGY	• **OPDIVO Intravenous Infusion** for the Treatment of Malignant Tumors • **KYPROLIS for Intravenous Injection** for the Treatment of Malignant Tumors • **EMEND Capsules** / **PROEMEND for Intravenous Injection** for the Treatment of Chemotherapy-induced Nausea and Vomiting • **DEMSER Capsules** for the Improvement of Status of Catecholamine Excess Secretion in Pheochromocytoma • **BRAFTOVI Capsules** and **MEKTOVI Tablets** for the Treatment of Malignant Tumors • **VELEXBRU Tablets** for the Treatment of Malignant Tumors • **ADLUMIZ Tablets** for the Treatment of Cancer Cachexia
DIABETES	• **GLACTIV Tablets** for the Treatment of Type 2 Diabetes • **FORXIGA Tablets** for the Treatment of Diabetes (Also approved for indications for chronic heart failure and chronic kidney disease)
CARDIOVASCULAR DISEASE	• **ONOACT for Intravenous Infusion** for the Treatment of Tachyarrhythmia • **OPALMON Tablets** for the Treatment of Peripheral Circulatory Disorder • **CORALAN Tablets** for the Treatment of Chronic Heart Failure
IMMUNE SYSTEM DISEASE	• **ORENCIA for Subcutaneous Injection** for the Treatment of Rheumatoid Arthritis
NEUROLOGICAL DISEASE	• **RIVASTACH Patch** for the Treatment of Alzheimer's Disease • **ONGENTYS Tablets** for the Treatment of Parkinson's Disease
Others	• **PARSABIV Intravenous Infusion for Dialysis** for the Treatment of Secondary Hyperparathyroidism in Patients on Hemodialysis • **STAYBLA Tablets** for the Treatment of Overactive Bladder (OAB) • **RECALBON Tablets** for the Treatment of Osteoporosis • **ONON Capsules** and **ONON Dry Syrup** for the Treatment of Bronchial Asthma and Allergic Rhinitis • **JOYCLU Intra-articular Injection** for the Improvement of Joint Function

Sales of Main Products in FY2021

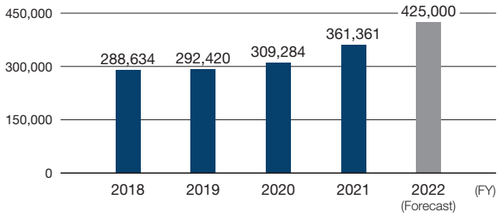
OPDIVO Intravenous Infusion	¥112.4 billion
FORXIGA Tablets	¥36.7 billion
GLACTIV Tablets	¥24.5 billion
ORENCIA for Subcutaneous Injection	¥22.9 billion
PARSABIV Intravenous Infusion for Dialysis	¥8.9 billion
KYPROLIS for Intravenous Injection	¥8.4 billion
VELEXBRU Tablets	¥6.3 billion

ONOACT for Intravenous Infusion	¥4.9 billion
OPALMON Tablets	¥4.7 billion
ONON Capsules	¥3.6 billion
ONGENTYS Tablets	¥2.9 billion
RIVASTACH Patch	¥2.9 billion
BRAFTOVI Capsules	¥2.7 billion
MEKTOVI Tablets	¥2.2 billion

Note: Revenue based on purchase price (shipment price)

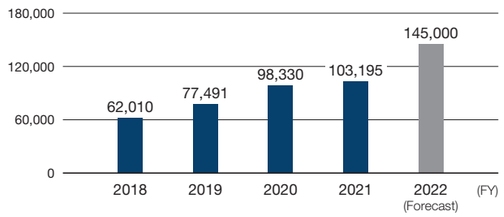
Financial Information

Revenue (Millions of yen)



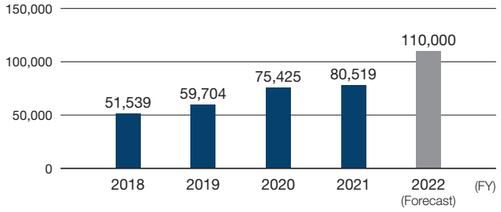
Sales from new flagship products OPDIVO Intravenous Infusion, FORXIGA Tablets, and ORENCIA Subcutaneous Injection rose and royalty revenue increased so revenue rose by 16.8% year-on-year to 361.4 billion yen.

Operating profit (Millions of yen)



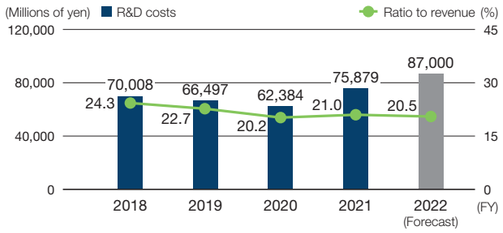
Although Cost of sales, Research and development costs, Selling, general and administrative expenses all increased, and also Other expenses increased significantly due to a one-time expense, revenue also increased significantly, resulting in a 4.9% increase year-on-year to 103.2 billion yen.

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



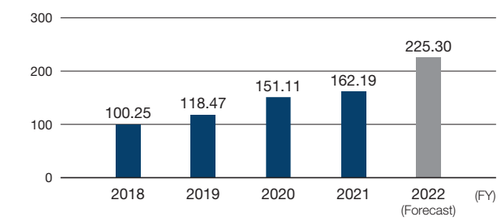
Current net income rose by 6.8% year-on-year, to 80.5 billion yen due to a decrease in corporate income tax in addition to to higher pre-tax net income.

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

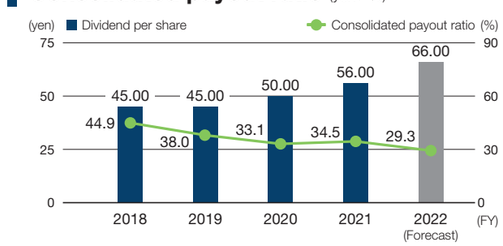


Aggressive R&D investment is necessary for sustainable growth, and in recent years we have invested 20-25% of sales revenue in R&D.

Basic earnings per share (yen)



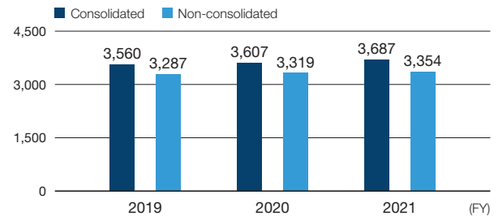
Dividend per share / Consolidated payout ratio (yen / %)



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

Non-Financial Information

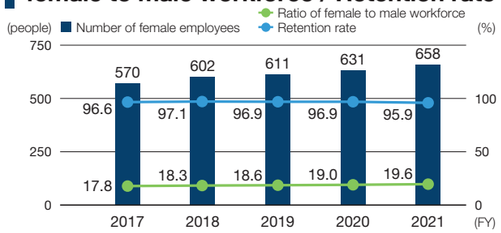
Number of employees (people)



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

▶Expansion of human capital, p.47

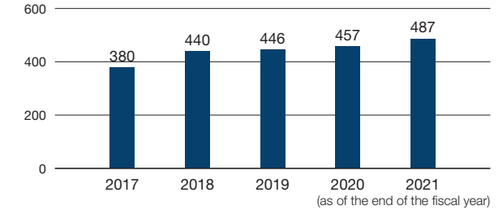
Number of female employees / Ratio of female to male workforce / Retention rate



As part of initiatives for promoting diversity, we have made efforts to promote women's participation and advancement in the workplace.

▶Expansion of human capital, p.47

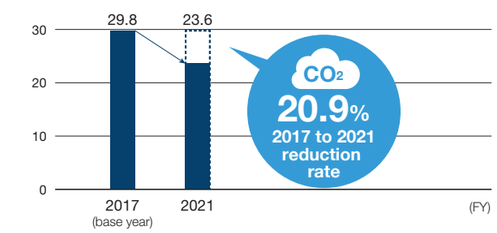
Number of mid-career hire employees (people)



We focus on hiring people with the skills, knowledge, and experience necessary for our company.

▶Expansion of human capital, p.47

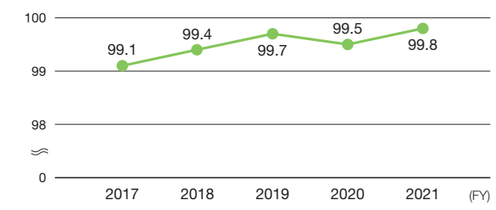
CO_2 emissions (thousand tons-CO_2)



In accordance with our environmental policy, we have set numerical targets and are working to achieve them.

▶Protection of environment, p.65

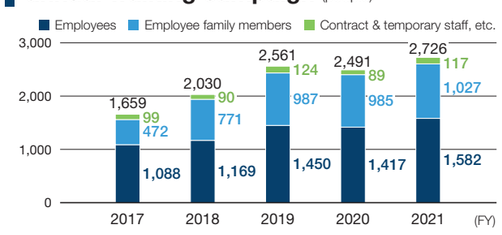
Comprehensive medical examination rate (%)



We take an approach to actively maintaining and improving the health of employees and their families. We have a support system in place for disease prevention, early detection, and treatment. Eligibility: Insured employees aged 35 and over and their dependent spouses

▶Expansion of human capital, p.47

No. of participants in ONO's annual walking campaign (people)



Each year, ONO hosts a walking campaign at the company. The event is growing in popularity each year, and encourages ONO employees and their family members to take up walking.

▶Expansion of human capital, p.47

Gyo Sagara
President,
Representative Director,
and CEO

We are steering through the increasingly uncertain conditions with concrete strategies and steadfast determination to produce sustainable growth for the company and society.

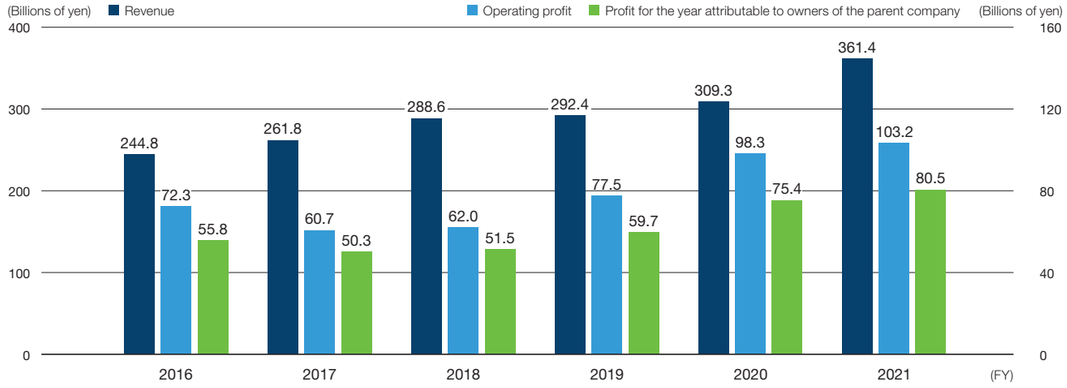
FY2021 Review

Steady progress with the growth strategy and a fourth consecutive year of growing sales and profits

The unsettled social conditions continued in fiscal 2021 as the ongoing coronavirus pandemic was joined by military conflict that rocked the global economy. Like companies around the world, the conditions deeply affected our business operations. Nevertheless, demand continued strong for our main products, including the OPDIVO intravenous infusion anticancer drug and FORXIGA Tablets for the treatment of diabetes and chronic heart failure and kidney disease. Our efforts during the year extended our business growth to four straight years with sales reaching 361.4 billion yen and operating profit 103.2 billion yen.
I believe these results reflect the steady implementation of the four strategies we initiated in 2017 to establish a growth track through the long term. The strategies are designed to maximize product value, enhance our R&D capabilities, globalize our business, and strengthen our corporate infrastructure.

We took a significant step forward in fiscal 2021with the first strategy of maximizing product value by winning approval of OPDIVO for first-line treatment of gastric cancer in Japan, South Korea, and Taiwan. OPDIVO was also approved in those countries as an adjuvant therapy for esophageal cancer, which increased the treatment lines. We also received approval for additional indications in Japan and South Korea, including for use of OPDIVO for as an adjuvant therapy for urothelial cancer.
We also made concrete progress advancing the other core strategies. We strengthened our R&D activities by initiating clinical trials for five new drug candidate compounds. We put more blocks in place to globalize our business by laying the groundwork for a direct sales system as we took another important step toward full-scale business operations in the United States. We are also strengthening our corporate foundation by enhancing our IT and digital infrastructure and cultivating talents to drive our globalization.
These growth strategies produced strong results in fiscal 2021, and we will continue actively advancing them to maintain the momentum in our performance results.

Business Performance



Industry Environment and Long-term Challenges

Aggressive R&D investment for further growth

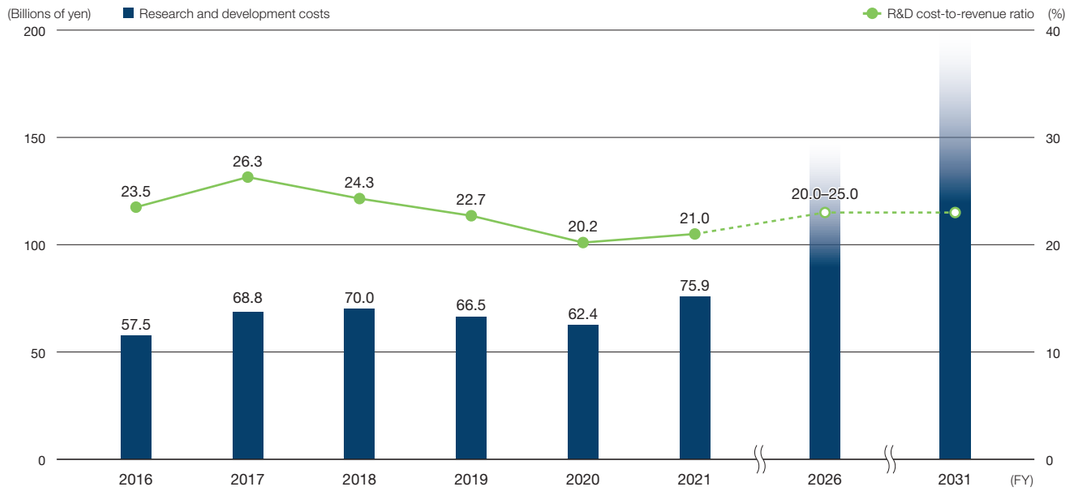
The hurdles for new drug discovery in the pharmaceutical industry are extremely high. Some maladies, like hypertension and diabetes, have received much attention and many therapeutic agents employing various mechanisms of action have become available. However, effective therapies have proven elusive for many other ailments, notably cancer, diseases of the nervous system like Alzheimer's disease, and for still incurable infectious and immunological diseases. These are complicated diseases that will require highly targeted research to develop effective therapies, and their growing complexity means research will need more sophisticated technology, human resources, time, and cost while success becomes even more difficult to achieve.
At the same time, the social conditions in Japan are making it increasingly difficult to recover R&D costs. Downward pressure on drug prices is growing as the government moves to counter the rising social security costs by controlling the costs of medicines and medical care. Lower prescription prices under the National Health Insurance system would reduce our revenue flow from existing products in Japan while constricting our ability to recover R&D costs when new products are released.
Strengthening our drug development pipeline is essential to growing our business in these conditions. We do not have the expansive resources of a mega pharmaceuticals conglomerate. What we do have is the imagination and the ability to apply highly refined selectivity, plus the flexibility to fully incorporate open innovation. In the past, we have sought to maximize our resources by pursuing the research principle that quality is the ideal, and quantity or scale is secondary. We now understand that a certain degree of scale is necessary to maintain a minimum standard of quality. Scale also helps accelerate product development. We are therefore revising our approach and are planning to allocate funds to be even more aggressive with R&D investment.
Even in the severe business environment, new methods are emerging that will help streamline and improve the efficiency of clinical trials at the development stage. One promising innovation comes from applying big data. Clinical trials are often conducted by comparing drug efficacy and safety from among two groups of participants, one group that takes the medicine being tested and a separate group that receives a placebo. We are learning how to use big data to mine information that will make the placebo group unnecessary, which has the potential to effectively cut the number of necessary clinical trial participants in half.
One impending issue is the patent cliff for our core OPDIVO product in 10 years. We were facing a similar situation when I was appointed president in 2008. At the time, 90% of the patents on our main products were due to expire within three or four years, and our research laboratories were not going to be able to produce new drugs in time to replace them. Our only choice was to look outside our organization and license drugs from outside. By mobilizing the whole company, we successfully licensed several drugs that provided a bridge until our own pipeline could reestablish our product flow.
The in-licensed new drugs we developed and launched held our sales steady until we gained real traction in 2014 with the approval of OPDIVO. Originally approved as a therapeutic agent for skin cancer, we have steadily developed and expanded its approval as a treatment for lung cancer, kidney cancer, and to 12 indications in total. Domestic sales of OPDIVO amounted to 112.4 billion yen in fiscal 2021, and we expect domestic sales to reach 155 billion yen in fiscal 2022. In addition, we expect fiscal 2022 sales of our second biggest seller, FORXIGA, which in 2021 was also approved as an indication for chronic kidney disease, to reach 47 billion yen. With our sales continuing to grow each year, we plan to use the increasing cash flow for aggressive and effective investment and set a path for ongoing business growth.

Strategies for Sustainable Growth

Applying resources to licensing and in-house drug discovery to lead us to our long-term growth vision

In the current business environment, we believe that only companies that can maintain R&D investment above a certain threshold will continue to thrive. In recent years, our R&D investment has been near 70 billion yen annually. Comparatively, major Japanese pharmaceuticals companies spend over 200 billion yen and global mega pharmaceutical firms closer to 1 trillion yen. In the current conditions, we simply will not be competitive at our present level of R&D investment. There is no clear answer for how much investment will enable us to continue growing, innovating, and discovering new drugs; nor for what society will need from a pharmaceuticals company. The only sure way forward is through R&D, and we plan to incrementally raise annual R&D spending to 100 billion yen and then to 200 billion yen, matching the level of a leading Japanese pharmaceuticals company. Aggressive R&D now is essential to extending our 300-year history another century.
The medium-term plan launched in 2017 was the first of three five-year plans that will guide our growth to 2031 when we plan to be investing 200 billion yen annually on R&D. The first R&D objective will be for the research laboratories to develop multiple new drugs that will be our next generation of products after OPDIVO.
However, building up the development pipeline will take more than in-house drug discovery. We are therefore also actively engaging in joint research and drug discovery collaborations, stepping up our drug licensing activities, and seeking to broaden our coverage to markets beyond Japan and Asia.
The drug market in Europe is double and the United States market is five times the size of the Japan drug market. That means a product with sales of 30 billion yen in Japan has the potential for sales of 60 billion yen in Europe and 150 billion yen in the United States. In other words, a single successful product in those two major markets has the potential to generate 200 billion yen in sales. Imagine two products generating 400 billion yen, or three generating 600 billion yen. Although optimistic, these projections are significant considering that successful products in just those two markets could exceed the combined total sales and royalty income from OPDIVO in Japan, South Korea, and Taiwan.
That potential for that scale of sales revenue is why we are preparing to launch our own direct sales system in the United States and Europe. Extending our reach to those major markets from our focus on Japan will open opportunities for substantial growth.

R&D Investment

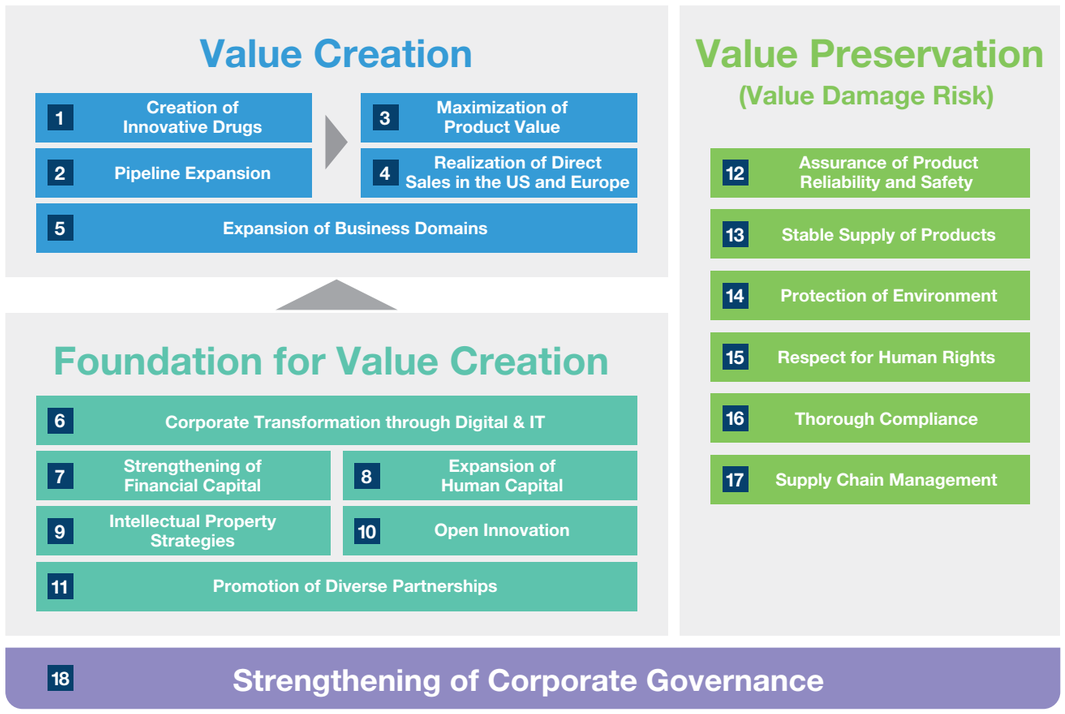


Identifying New Materiality Issues

Value creation and social contribution driven by our growth strategy and non-financial assets

We believe recognizing material issues not just for our CSR but also from a broader perspective will make us better able to advance our growth strategies, pursue wide-ranging value creation, and contribute to society. We have therefore combined our financial and non-financial issues into a single category of management materiality.
We are also focusing management assets on digital transformation and strengthening and cultivating our talents. Together, these are the foundation for the four growth strategies that we redefined in 2022: to maximize product value from the patient perspective, reinforce our pipelines and accelerate global development, establish direct sales system in the United States and Europe, and broaden our business domains.
In January 2022, we created the Digital & IT Strategy Division to serve as the IT headquarters for our enterprise infrastructure. With the mandate to dramatically improve our management efficiency and innovation capabilities, the division will implement and support digital and IT systems that will dramatically improve work productivity and efficiency in the Discovery & Research, Clinical Development, CMC & Production, Sales and Marketing, and all departments.
Cultivating talents has always been a priority at Ono Pharmaceutical. Now more than ever, we need talented individuals who are highly skilled and motivated to pursue innovation for our growth strategies of new drug discovery and expansion into the global market. In May 2021, we created the Ono Innovation Platform to foster employee innovation capability and encourage all employees to take on new challenges and develop their talents as innovators.
Another major theme is increasing the diversity of our staff. In the past, we followed a practice of building our ranks primarily with new college graduates. That served us well until about 10 years ago when we had the breakthrough with OPDIVO, our first oncology drug. Although we had experienced drug development staff and medical representatives (MRs) in the diabetes field, we knew it would take years to gain similar experience in the cancer field. The solution was to open our hiring practices to bring in experienced mid-career professionals and then to bring in staff with wide-ranging expertise to accelerate development of the business.
We are now eagerly seeking to increase the diversity of our employees. In Japanese society, the first step to increasing diversity is to hire and promote the careers of women.
We are also bringing in new employees with various backgrounds and personalities to stimulate innovation. We see the ultimate outcome of these initiatives as enhancing our ability to provide products that improve the lives of patients. If we can do that, we will generate the funds needed to continue advancing R&D and growing our business.
Diversity is also important to corporate governance. In 2020, the Board of Directors was invigorated by the appointment of our first female board member as an outside director. In 2022, we have taken it one step further by fortifying the external oversight and management expertise with the appointment of outside directors to serve as the chairs of the committees overseeing executive appointments and compensation.
We are also establishing Ono Pharmaceutical as an environmental leader in the pharmaceutical industry by aiming to achieve high standards for environmental protection and seeking to do more than our part to protect the natural environment. We declared our support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) in October 2019, which we apply to our information disclosure and to the evaluation and management of risks and opportunities.
In June 2020, we became the first Japanese pharmaceutical company to join the RE100, an international initiative of businesses committed to using 100% renewable energy.
As a company with a history going back three centuries, we believe we have a special obligation to actively participate in social movements, and we are stepping up our initiatives to contribute to the social good.

New Material Issues (Priority Management Issues)



Future Prospects and Aspirations

Major opportunity and strong determination

We want to be considered a vital element to a flourishing society. That is the fundamental goal of our business and our management and will be the source of our continuing success and growth. To achieve that, we will need to have a strong spirit of taking on challenges.
I envision a company where employees openly talk about their dreams because they know they have a chance to fulfill them. That spirit will be the driving force in our pursuit to discover and develop new drugs.
The tasks for management and myself are to envision the direction forward, map out how to get there, and guide employees in the work that must be done. As president, I will be leading our efforts. Our jobs take up a large portion of the working day, and a fulfilling job is a cornerstone to a happy life. I intend to do everything in my power to make our company a place where every employee has the opportunity to take on challenges and grow.
Ono Pharmaceutical has been a relatively small successful company for 300 years. We are now on the cusp of a major opportunity to grow. The opportunities may come at different times for different companies, and I want all of us to be ready to take the opportunity when it presents itself. Every mega pharmaceutical company started small. Our time to grow begins now. Our determination is strong, and we will make it happen.
We would like to thank all our stakeholders for your continued support.

Gyo Sagara

Be a Global Specialty Pharma, competing in the global arena with original and innovative new drugs

Issues and Awareness of Business Environment

Issues Facing Healthcare

- Complex and advanced healthcare needs
- Aging population
- Improvement in access to healthcare

Issues Facing Society

- Harmonious coexistence of society and businesses
- Mutual prosperity of employees and businesses
- Diversity enhancement

Business Environment

- Progression of healthcare cost reduction measures around the world
- Tighter regulatory controls stemming from fundamental review of the NHI drug pricing system in Japan
- Increasing complexity of target diseases for drug discovery
- Decreased success rates of drug discovery
- Prolonged period/rising costs of new drug development
- Globally increasing competition
- Increasing opportunity to achieve drug discovery innovations
- Expansion into the global market

Relevant SDGs

Capital to be Input

(2022.3)

Financial capital

A strong financial base that supports sustained drug discovery

Total capital: ¥661.6 billion

Ratio of equity attributable to owners of the parent company: 88.7%

Manufacturing capital

A manufacturing base that ensures stable supply of high-quality pharmaceutical products

Capital investment: ¥9.3 billion

Manufacturing centers: 2

Intellectual capital

R&D abilities based on ONO's unique drug discovery approach and open innovation

R&D costs: ¥75.8 billion

R&D cost-to-revenue ratio: 21%

Human capital

Providing a challenger culture and opportunities for personal growth

Number of employees (consolidated): 3,687

Total training time: 187,357 hours

Social capital

Various forms of partnership to create sustainable society

Number of drug discovery alliances and joint research projects with universities, biopharmaceutical companies, etc.

More than 200 (Japan and overseas)

Natural capital

ECO VISION 2050 and environmental management

Energy consumption: 99,438 MWh

Water resource consumption (water intake): 185 thousand m³

Corporate Philosophy

Dedicated to the Fight against Disease and Pain

Focusing limited management resources into drug discovery and development

In-house Drug Discovery

We focus on unique bioactivity, finding diseases against which drug candidates are most potentially effective, and taking up the challenge of discovering innovative drugs

Licensing Activities

We are promoting expansion of our development pipeline and global marketing of new drugs we develop

Four Growth Strategies

- Maximization of product value – From a patient-centered perspective –
- Reinforcement of pipelines and acceleration of global development
- Realization of direct sales in the US and Europe
- Expansion of business domains

Providing Products to a Broad Range of Areas

Expansion of indicated tumors: OPDIVO Intravenous Infusion

Multiple global development products

Start of clinical trials in the US : Tirabrutinib

Expansion of our business domain: Sleep supplement REMWELL

Material Issues (Important CSR Issues) ➡ P25-

Value Creation ➡ P25-

- Creation of Innovative Drugs
- Pipeline Expansion
- Maximization of Product Value
- Realization of Direct Sales in the US and Europe
- Expansion of Business Domains

Foundation for Value Creation ➡ P39-

- Corporate Transformation through Digital & IT
- Strengthening of Financial Capital
- Expansion of Human Capital
- Intellectual Property Strategies
- Open Innovation
- Promotion of Diverse Partnerships

Value Preservation ➡ P61-

- Assurance of Product Reliability and Safety
- Stable Supply of Products
- Protection of Environment
- Respect for Human Rights
- Thorough Compliance
- Supply Chain Management

Strengthening of Corporate Governance ➡ P91-

Policy for Sustainable Management Contributing to People's Health

(FY2021 results)

Economic Value

- Stable revenue from new drug creation and additional indications (revenue from sales: 361.4 billion yen)
- Stable return of profits to shareholders through sustainable growth (Cash dividend per share: 56.00 yen, payout ratio: 34.5%)

Societal Value

- Creation of innovative drugs
- Stable supply of high-quality drugs
- Increasing access to medical care
- Employment of people with disabilities at 2.38% (0.21% increase over the previous year)
- Cooperation with the local community (e.g., through a cooperation agreement with the Osaka Prefectural Government)
- Diverse talents
  95.9% retention rate of female employees, 487 employees hired mid-career (up 107 from FY2017)

Environmental Value

- Reduction of greenhouse gas emissions (20.9% for Scope 1 + 2 and 33.7% for Scope 3, both compared to FY2017)
- Increase in renewable energy use as a percentage of total electricity consumption: 17% (previous FY was 13.2%)
- Reduction of water consumption (reduction of water intake vs. FY2020: 10.7%)
- Maintained 1% or less for the final landfill disposal of industrial waste as a percentage of all industrial waste (0.04%)
- Use of environmentally friendly packaging (ex. Change from plastic to paper)

We Formulated a New Management Policy to Realize a Sustainable Society for the Next 100 Years.

Sustainable Management Policy

For more than 300 years since our founding, we have walked hand in hand with society. To help people who are suffering from disease, we have created a series of innovative new medicines that had been thought to be impossible. We will continue to contribute to people's health by practicing our Corporate Philosophy and taking on the challenge of realizing a sustainable society through responsible business activities.

Contributing to People's Health

- In addition to our own drug discovery, we will take on the challenge of drug research and development in collaboration with the world's top scientists, and bring more hope to patients and their families around the world by providing them with original and innovative medicines that are safe, secure, and appropriate.
- We will contribute to the realization of a society in which people can live healthier lives through our evidence- based, next-generation healthcare business.

Relevant SDGs

Preserving a rich global environment for future generations

We are deeply aware of our social responsibility to the environment, and will actively adopt eco-friendly technologies and work together with our suppliers and partners to pass on a prosperous and sustainable global environment to future generations.

Realizing a society in which everyone can play an active role

Through our business activities, we will contribute to the realization of a society in which the human rights and diversity of all people are respected and everyone can play an active role.

Establishing a highly transparent and robust management foundation

We will build a strong foundation through corporate governance and conduct highly transparent business activities by strengthening compliance and risk management.

Basic Approach to Our Sustainable Management Policy

We have walked hand in hand with society for more than 300 years since Fushimiya Ichibei first founded a drug wholesaler in Doshomachi, Osaka in 1717.
In the transition from Edo to Reiwa periods (the 18th Century to the 21st Century), in order to realize the desire "To help people who are suffering from disease," we have contributed to people's health all over the world by practicing our Corporate Philosophy of being Dedicated to the Fight against Disease and Pain.
We have continued to challenge ourselves. We succeeded in the total synthesis of prostaglandin with an original drug discovery approach in 1968, which had been thought to be impossible.

We created many medicines, and launched an innovative new medicine, anti PD-1 antibody, in the field of cancer immunotherapy in 2014, the first in the world.
Furthermore, even before the term "open innovation" became popular, we had been actively promoting collaboration with others.
In addition to in-house drug discovery, we will continue to create innovative medicines by making the most of open innovation.
We will continue to think of the significance of our position as a member of society, and take on the challenge of realizing a sustainable society through responsible business activities, keeping the desire of continuing to be a company needed by society in mind.

Contributing to People's Health

We will contribute to people's health through the development of medicines that truly benefit patients.

We aim to create original and innovative medicines by working on the diseases that have not yet been overcome and the diseases for which patients have low treatment satisfaction and medical needs are high.
We have set the areas of oncology, immunology, neurology, and specialty domains as priority areas, accumulated disease know-how in each area, appropriately grasped medical needs, and created therapeutic medicines for diseases for which patients have low treatment satisfaction and medical needs are high. In addition, by promoting open innovation with the world's top scientists, we will acquire original drug discovery seeds and introduce the latest technologies, aiming to create innovative new medicines with positive social impact.
We will also work with external partners to improve people's access to medical care, such as expanding indications to rare diseases and for children; providing safe, secure and appropriate medicines; and improving the medical infrastructure.
Furthermore, in the future as in the present, based on the knowledge cultivated in past research and development, we will take on the challenge to develop a next-generation healthcare business using various solutions and contribute to the realization of a society in which people can live healthier lives. By taking on these challenges, we will bring more hope to patients and their families around the world.

Maintaining a Prosperous Global Environment for Future Generations

We will take on the challenge of creating innovative medicines and strive to maintain a prosperous and sustainable global environment for future generations.

In advancing our business activities, we are deeply aware of our social responsibility to maintain the environment, and carry out eco-friendly activities at all stages of the value chain. Under our group's environmental management system, we set goals and activity plans and disclose information appropriately. We will actively incorporate eco-friendly science and technology and strive to reduce the burden on the environment. Furthermore, we will promote communication with all stakeholders inside and outside the company, such as our suppliers and partners, and work together to develop eco-friendly manufacturing processes.
Through these efforts, we will strive to pass on a prosperous and sustainable global environment to future generations.

Realizing a Society Where Everyone is Active

We will take on the challenge of creating innovative medicines and strive to realize a society in which everyone can play an active role.

We respect the human rights and diversity of all people in all our business activities.
Based on the idea that a company is its people, we will strengthen our internal environment so that diverse human resources can maximize their individual abilities, and bring their abilities together as a team, and continue to innovate.
To that end, we will promote efforts for the physical and mental health and safety of our employees.

Establishing Highly Transparent and Robust Management

We will take on the challenge of creating innovative medicines and strive to establish highly transparent and robust management.

We will build a strong foundation through corporate governance in order to earn the trust of all stakeholders and improve our corporate value.
In addition to legal compliance, we will raise employees' awareness of compliance and conduct appropriate management so that that each employee can identify compliance risks with creativity.
Furthermore, we will contribute to the realization of a sustainable society by disclosing information to stakeholders and holding extensive dialogue.
Also, with a view to global expansion, we will further strengthen our management foundation.

Growth Strategy for Continual Growth of the Company and Society

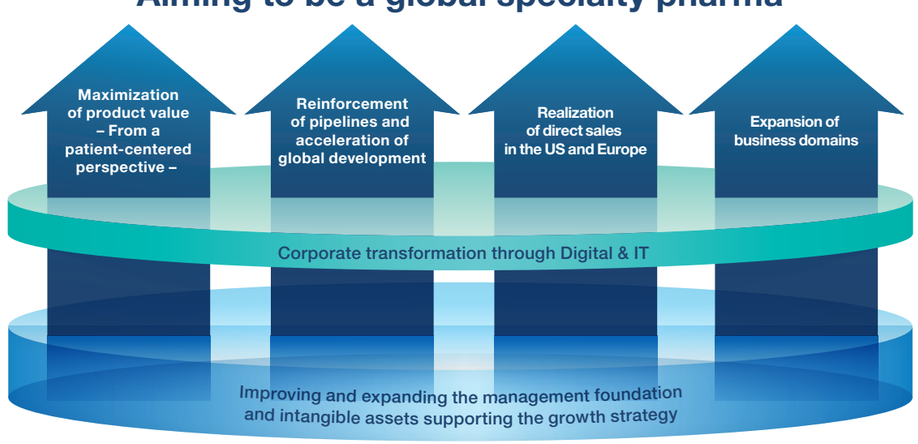
For Sustainable Development of the Company and Society

As a pharmaceutical company oriented to the development of new drugs, we clarify management issues and focus management resources on research and development to bring about sustainable development of the company and society, and promote business activities to create economic value as well as to provide value that only we can offer to patients and society.
In addition, this fiscal year, we integrated management issues and CSR material issues and re-identified them as material issues for management.

Growth Strategy Aimed at Becoming a World-Class Company

Although the environment surrounding the pharmaceutical industry is changing at a dizzying pace on a daily basis, there are still various opportunities for growth in new drug development, such as the creation of new value through active open innovation and cross-industrial collaboration centered on digital technology, and the growing importance of self-medication. In order to become a world-class company that can flexibly and swiftly respond to any situation, we have established four growth strategies: Maximization of product value - From a patient-centered perspective, Reinforcement of pipelines and acceleration of global development, Realization of direct sales in the US and Europe, and Expansion of business domains. In addition, we will strive to improve and expand our intangible assets such as human resources, corporate brand, and digital and IT infrastructure, which are the management foundation supporting these growth strategies.

The Four Growth Strategies and Our Management Foundation



Growth Strategy

Maximization of product value – From a patient-centered perspective –

We will work together with healthcare professionals to realize the wellbeing of patients and their families (a state of fulfillment in terms of physical, mental, social, and life satisfaction), and as a result, we will strive for speedy and effective development, competitive marketing, and the provision and collection of sophisticated information to achieve the rapid penetration of new drugs.
In marketing and the provision and collection of information, we cultivate specialty human resources who engage in their activities from the patient's perspective with healthcare professionals in response to medical issues. We are also working to maximize the potential of our products by utilizing digital technology to provide and collect information effectively and efficiently. In development, we are currently working on approximately 100 clinical trials in our key strategic area of oncology.
With OPDIVO, our flagship product in the area of oncology, we will work with our partner Bristol-Myers Squibb Company of the U.S. to maximize product value by expanding the number of indicated tumors and treatment lines, and developing combination therapies.
With FORXIGA, one of our main products in the diabetes area, we will work with our partner, AstraZeneca of the U.K., to deliver it not only to patients with diabetes, but also to patients with chronic heart failure and chronic kidney disease, for which the indication has been expanded, thereby taking on the challenge of extending healthy life expectancy.

Reinforcement of pipelines and acceleration of global development

Because there are many people in the world suffering from diseases for which there is no cure even today, we aim to become a Global Specialty Pharma that can respond to unmet medical needs. We have designated oncology, immunological diseases, central nervous system diseases, and specialty areas with high medical needs as priority areas, and we will accumulate disease know-how in each area to create new drugs that will bring innovation to medicine on-site.
To this end, we will strengthen and expand research and drug discovery alliances with world-leading universities, research institutions, and biopharmaceutical companies, and aim to enhance a highly original pipeline that can aim for first-in-class status. In addition, we will continue to take on the challenge of creating highly original in-house drugs by utilizing a variety of drug discovery modalities according to the theme of drug discovery, and strive to improve the certainty of R&D by actively using data from patients-derived samples to verify drug targets and strengthen translational research. Additionally, we will actively pursue the in-licensing of innovative compounds and the acquisition of new technologies in areas of high medical need.

Realization of direct sales in the US and Europe

In order to provide new drugs to patients all over the world, we are promoting efforts for our own sales organizations overseas. We have already established local subsidiaries in South Korea and Taiwan to begin marketing our own products. In Europe and the U.S., we are also working on the development of several projects, most notably the development of ONO-4059 (VELEXBRU tablets), a Bruton's tyrosine kinase inhibitor, in the U.S., and we are working to develop a sales structure with an eye on doing our own sales.

Expansion of business domains

We are working to expand our business domains to meet the needs of the expanding healthcare sector and continue to provide new value. In 2021, we established Ono Pharma Healthcare Co., Ltd. to focus on the development of foods with function claims. In March 2022, we launched REMWELL, which is a sleep supplement that has been approved in Japan as foods with function claims, that takes full advantage of the assets we have accumulated through research and development of prescription drugs. As a pioneer in lipid research, we will further work to solve various health issues in the future.
We will also take on the challenge of creating new value by utilizing digital technology to address unresolved issues faced by our customers. In parallel with these activities, we aim to create and expand new businesses through investment in biopharmaceutical companies in the healthcare field.

Improvement and Expansion of the Management Foundation and Intangible Assets that Support the Growth Strategy

To support our four growth strategies and achieve dramatic growth, we will work to improve and expand our intangible assets: talent, corporate brand, and digital and IT infrastructure. In the area of talent development, we will focus on nurturing the next generation of management personnel, globally competent employees capable of doing business on the world stage, digitally competent employees to drive corporate transformation, and innovative employees to drive the next level of growth.
In addition, with respect to raising corporate recognition, which is a major issue, especially when expanding into Europe and the U.S., we will strive to enhance corporate value by working to spread the corporate brand in order to be recognized as a company that is needed by society as a pharmaceutical company that creates innovative drugs. In addition, the entire company will work on corporate transformation through digital and IT, and will renew its IT infrastructure to be simply structured with an eye toward globalization, and promote digital transformation, including the transformation of the drug discovery value chain.

Creating Economic Value

In order to grow sustainably for the Company and society , it is important to provide patients and society with the value that only the Company can provide, while also creating economic value, and the Company aims to expand its revenue over the five-year period from 2022 to 2026 at a compound annual growth rate in the high single digits. In addition, we aim to maintain an operating margin of 25% or higher while investing about 20-25% of revenue in R&D.

Creation of Economic Value from FY2022 to FY2026

Indicator	Target
CAGR for revenue	High single digits
R&D cost-to-revenue ratio	20-25%
Operating income to revenue ratio	Maintain at least 25%

We Have Redefined Our Material Issues to Realize a Sustainable Company and Society

From Important CSR Issues to Important Management Issues

ONO has striven to develop our CSR by defining important areas of focus based on ISO 26000. In FY2018, we redefined our material issues as “important CSR issues” to clarify CSR activity themes that we should emphasize. ONO actively engaged in CSR in accordance with the material issues that we established.
In FY2021, based on the newly established sustainable management policy, we changed the material issues from “important CSR issues” to “important management issues” to analyze and manage financial and non-financial management issues in a more integrated way. The material issues thus defined have been clearly linked to the strategy of the mid-term management plan and have been developed into a more dynamic management system.
We believe that the disclosure of integrated financial and non-financial information and dialogues will be possible so that stakeholders outside of ONO can understand our sustainability initiatives.

Steps in Material Issue Analysis

Step 1
Extract the issues

Extract management issues

Analyze the external and internal environmentals
- Analyze in conjunction with the formulation of the mid-term management plan
- Organize the expectations of stakeholders
- Refer to ISO 26000, ESG disclosure criteria, etc. for CSR issues

Extract issues to realize the long-term vision
- Analyze gaps between the vision and current state

Step 2
Define material issues

Defining priority issues

Classify and analyze the importance of issues to stakeholders and business from the following perspectives:
- Opportunity for value creation
- Foundation for value creation
- Value preservation (erosion risks)

Deliberation structure
- Deliberated by the Board of Directors, at Management Meetings, and by all division managers (e.g., Research and Development, Sales and Marketing, Quality Assurance, Manufacturing, and Administration)
- Managed by the secretariat of the mid-term management plan (Corporate Planning Department) and the secretariat of the CSR Committee (CSR Promotion Department) as a company-wide cross-departmental project during the period from June 2021 to March 2022

Stakeholder issues
- Opinions of stakeholders are extracted from the issues confirmed by each division in the course of business activities, dialogues with investors, evaluations by the ESG-rating agencies, etc.

Step 1
Extract the Issues

In the material issue analysis conducted in FY2021, we analyzed the management environment in conjunction with the formulation of the mid-term management plan to extract potential management issues. This analysis identified important opportunities and risks for creating value and achieving sustainable growth of our company. Our directors, executive officers, and senior management from all divisions participated in the analysis of the external and internal management environment, which included analysis of the management environment surrounding the business and analysis of gaps between our long-term vision and current status. In addition, management issues were extracted based on requests and expectations of stakeholders that were confirmed by each division in its daily business activities. As for non-financial issues, we extracted issues related to intangible assets, such as human capital and intellectual capital, that are needed to realize our growth strategies.
Non-financial issues were updated based on ISO 26000, the GRI Standards, the SASB Standards, the Ten Principles of the United Nations Global Compact, evaluations by ESG-rating agencies, dialogues with investors, etc. Analysis of issues was conducted while the progress of deliberation was reported to and confirmed by the Board of Directors.

Step 2
Define the Material Issues

In defining material issues, we first classified the issues extracted in Step 1 into “value creation,” “foundation for value creation,” or “value preservation (erosion risks).” “Value creation” and “foundation for value creation” are opportunities and “value preservation” is a risk for our company. Furthermore, at the Management Meeting and other occasions, 18 material issues were defined as the most important issues from the perspective of importance to stakeholders and business. Material issues were deliberated and finalized by the Board of Directors.

New Material Issues (Priority Management Issues)

Value Creation
- 1 Creation of Innovative Drugs
- 2 Pipeline Expansion
- 3 Maximization of Product Value
- 4 Realization of Direct Sales in the US and Europe
- 5 Expansion of Business Domains

Foundation for Value Creation
- 6 Corporate Transformation through Digital & IT
- 7 Strengthening of Financial Capital
- 8 Expansion of Human Capital
- 9 Intellectual Property Strategies
- 10 Open Innovation
- 11 Promotion of Diverse Partnerships

Value Preservation (Erosion risks)
- 12 Assurance of Product Reliability and Safety
- 13 Stable Supply of Products
- 14 Protection of Environment
- 15 Respect for Human Rights
- 16 Thorough Compliance
- 17 Supply Chain Management

18 Strengthening of Corporate Governance

Actions for Material Issues

For each material issue that was redefined in FY2021, we established medium-term targets and plans, and confirmed the progress. Furthermore, in conjunction with the mid-term management plan, each issue is linked to a corresponding division, organization, and committee, and a company-wide PDCA management cycle has been established and is managed by the Board of Directors and via Management Meetings. Please see pp. 25-99 for targets and actions for each material issue.
Progress toward the targets will be disclosed every fiscal year starting with the results in FY2022.

Value Creation

**Our mission is to provide new value to patients through the creation of innovative drugs.
To achieve this, we need to focus on strengthening R&D and expanding our pipeline.
In addition, building a system to deliver medicines to more patients and further expanding our business domain will also be important values for the company and society.
In this section, we introduce some of the key initiatives for such value creation.**

Material Issue 1

Creation of Innovative Drugs

Management of Priority Issues

Reason for being a priority issue	The creation of innovative drugs is the practice of our corporate philosophy, “Dedicated to the Fight against Disease and Pain,” and is the core value we provide to society. To sustainably create this value, drug discovery research using the latest scientific knowledge and cutting-edge technologies is crucial, and strengthening our competitiveness in drug discovery research will lead to our growth.
Vision over the medium to long term	Cooperate with top scientists and accelerate the creation of new drugs that can change the world.
Indicators	• The number of new products going to clinical trials
Major initiatives	• Explore unique breakthrough drug seeds and creation of new drug candidate compounds through open innovation • Improve the speed of creation of new drug candidate compounds by selecting optimal modalities, utilizing artificial intelligence (AI), etc. • Promote drug discovery research based on human disease biology using the latest technologies, such as AI and informatics, as well as patient-derived samples • Promote translational research by searching for biomarkers based on the mechanism of action

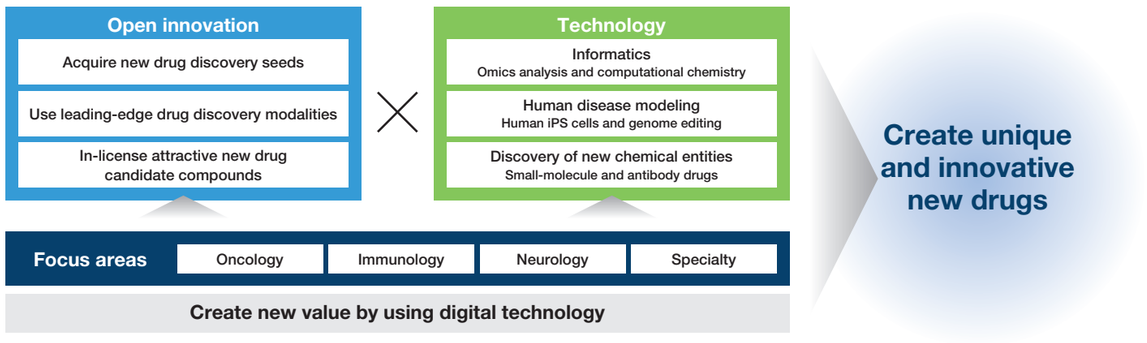
Our Mission in Research and Development

ONO’s R&D mission is “contribute to society by developing pharmaceutical products that bring true benefit to patients”. We are striving to create original and groundbreaking drugs by taking on the challenges of diseases that have not yet been conquered and areas of high medical need where patient satisfaction with treatment is still low.

Drug Discovery Strategy

ONO focuses on the areas of oncology, immunology, neurology and specialties; all of which include diseases with high medical needs. In each of these areas, we are working to strengthen our drug discovery capabilities by delving into the biology of human disease with the aim of discovering new drugs that can satisfy medical needs. In particular, by actively promoting open innovation, which is one of our strengths, we aim to discover original drug discovery seeds and create breakthrough new drugs with medical impact by utilizing a variety of cutting-edge internal and external technologies, such as informatics, human disease modeling, and the discovery of new drug candidate compounds. In addition, we are working to improve the quality and speed of drug discovery research through the use of digital technology.
As of June 2022, a total of 8 new drug candidates in our priority therapeutic areas have proceeded to the clinical stage, and we are also continuing to bolster our efforts in translational research bridging the gap between basic and clinical research to accelerate drug discovery timelines and boost success rates. By organically leveraging informatics and research tools, such as human genome data and human iPS cells in the early stages of research, we are working to analyze the relationship between target molecules and diseases to find biomarkers that can more accurately predict and evaluate the efficacy of new drug candidate compounds in humans.

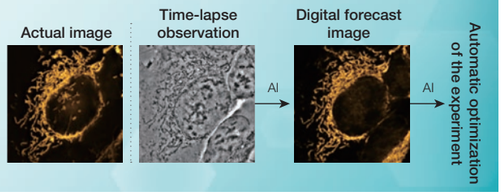
Drug Discovery Strategy



TOPICS A human-type robot for general-purpose experiments “Maholo” and digital technology

ONO has been pursuing applications for human iPS cells as a means of predicting the efficacy of drug compounds in humans. However, the handling of iPS cells requires excellent techniques and huge amounts of time to study the experimental conditions. To address these challenges, ONO is using a human-type robot for general-purpose experiments called “Maholo” at the Minase Research Institute. Maholo is not only capable of automating experiment-based tasks, but can also quantify the skills and tacit knowledge of skilled research scientists and then systematize them into “technology.”
Currently, we are evolving Maholo to be a next-generation technology platform that contributes to highly original drug discovery research, with an eye toward biodigital transformation, such as the creation of a digital prediction system for cellular changes over time and autonomous automatic experiment optimization.

Human-type robot for general-purpose experiments “Maholo”



The Drug Discovery System and Major Initiative(s) in Each of the Four Priority Areas

Priority Area	Organization	Major Initiative(s)	Major New Drug Candidates under Development	Target Diseases
Oncology	Research Center of Oncology	As a pioneer in cancer immunotherapy, the Center works toward discovering innovative drugs for cancer patients with the experience, expertise, and know-how we nurtured through R&D of the immune checkpoint inhibitor OPDIVO. The Center is pursuing original and unique drug seeds and new drug modalities not only through open innovation with academia and bio-pharmaceutical companies around the world with cutting edge technologies, but also through promoting translational research.	ONO-4578	Colorectal cancer, Pancreatic cancer, Non-small-cell lung cancer, Solid tumor, Gastric cancer
			ONO-7475	Acute leukemia, Solid tumor, EGFR-mutated non-small cell lung cancer
			ONO-7914	Solid tumor
Immunology	Research Center of Immunology	Based on many years of its experiences in immunology research, which contributed to creating OPDIVO, the Center is working toward drug discovery in both fields of cancer immunotherapy and autoimmune & allergy therapy by having a research structure with main focus on biopharmaceutical development in immunology. The Center is operated in accordance with the policy of advancing unique research with strong awareness of serendipity and the insight not to miss it.	ONO-4685	Autoimmune disease T cell Lymphoma
Neurology	Research Center of Neurology	The Center focuses on not only neurons as major components of the nervous system, but also glial cells, which maintain and support the environment necessary for the survival and function of neurons. Through its intensive analysis of patient-derived tissues and iPS cells, the Center is dedicated to discovering innovative drugs to provide disease-modifying therapies, as well as symptomatic treatments, to patients with neurodegenerative diseases, which are becoming serious problems in the aging society, and those with mental disorders or chronic pain, which are quite detrimental to society.	ONO-2808	Neurodegenerative diseases
			ONO-2910	Diabetic polyneuropathy
			ONO-2909	Narcolepsy
Specialty	Research Center of Specialty	The Center is working toward discovery of clinically valuable pharmaceutical products for diseases for which treatment is high in unmet needs, regardless of the disease indication. The Center has taken up the challenge of accurately identifying those needs in patients, medical professionals, and society, and then leveraging this knowledge to discover and develop highly original new drugs.	ONO-7684	Thrombosis

Message from the Director in Charge

Creating new drugs that change the world through open innovation x technology

We are committed to the discovery of innovative drugs that will change the world. We value the ideas of each and every one of our researchers and work with the world’s top scientists through open innovation to discover unique drug targets, while making full use of technologies such as digital and AI technologies, and promoting drug discovery alliances with bio-pharmaceutical companies engaged in cutting-edge technologies. We are also working to elucidate biology and create new drug candidate compounds. To this end, it is important to raise the level and engagement of each and every researcher, and we are promoting the creation of an environment in which drug discovery research can be conducted with an expanded perspective, including study abroad programs in academia where we conduct joint research and assignments to the US and European bases to explore opportunities for joint research and drug discovery alliances.

Toichi Takino
Executive Director,
Discovery & Research
Senior Executive Officer
Member of the Board of Directors

Material Issue 2

Pipeline Expansion

Management of Priority Issues

Reason for being a priority issue	Our pipeline is the source of our sustainable growth. We continue enriching our pipeline to constantly provide innovative drugs to patients.
Vision over the medium to long term	The speed and accuracy of establishing PoC* for new drug candidates are improving, and the pipeline is enriched through licensing activities. * PoC (Proof of Concept): PoC studies are an early stage of clinical drug development to confirm whether the drug candidates demonstrate the clinical safety and efficacy expected during the drug discovery phase.
Indicators	• The number of products in the clinical development stage • The number of newly introduced products

Major initiatives	• Establish PoC on multiple projects and conduct global clinical trials
	  • Continue system development for early establishment of PoC
	  • Further enhance activities for translational research (TR) and reverse translational research (rTR)
	  • Increase the speed and accuracy of establishing PoC by using state-of-the-art technologies and methodologies
	• Strengthen licensing activities to obtain global rights

Early establishment of PoC

ONO is working to expedite clinical development and improve the success rate of drug candidates in order to fast-track the delivery of our in-house and in-licensed compounds to patients suffering from diseases around the world. We are flexibly utilizing our clinical development functions in Japan, the US and Europe to quickly establish PoC to expediently identify the potential product value of candidate compounds. To do this, we formulate appropriate clinical development plans, including target disease selection, propose study plans to accurately evaluate efficacy, and promote studies according to the plan. Also, while advancing the search for clinical markers through TR, we launch new discovery research projects using results obtained from clinical trials, creating an R&D virtuous cycle. We are also building a system to conduct global confirmatory studies after establishing PoC.

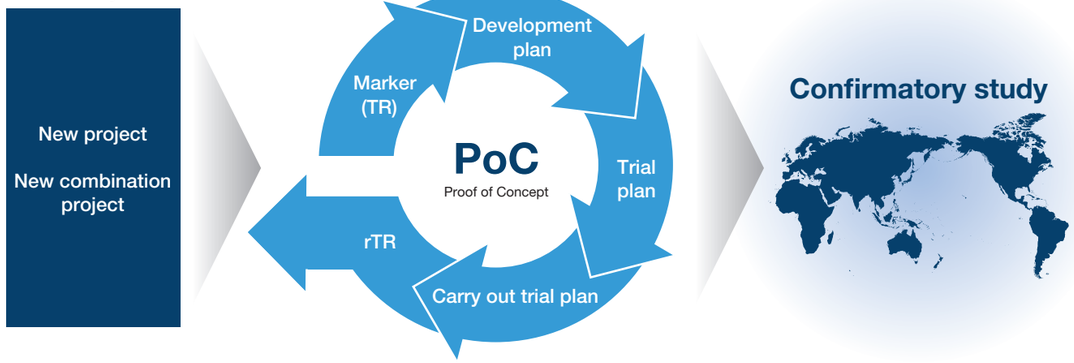
Licensing Activities

In addition to expanding our pipeline through in-house research, we are also actively pursuing licensing activities with the aim of in-licensing new candidates under development by pharmaceutical or bio-tech companies around the world. To do this, we are acquiring the global rights of new candidates with characteristics that can be of use to a global specialty pharmaceutical company, taking into consideration the areas targeted by our own products, with a view to global development in the U.S. and other countries.

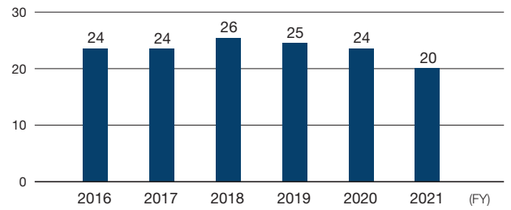
Number of products in the clinical development stage

We are also proceeding with clinical development of existing products to maximize product value. For Opdivo, we are conducting clinical trials aimed at expanding the range of cancer types, using the drug at earlier lines of treatment, and establishing combination therapies to enhance therapeutic efficacy. We are also focusing on expanding our pipeline beyond Opdivo, maintaining the number of products in the clinical development stage at more than 20 over the past several years. To improve the speed and quality of our clinical trials, we are digitizing our operations.
We will continue to aggressively pursue clinical development not only in Japan but also worldwide for the benefit of patients awaiting new therapeutic agents.

The R&D Cycle



Number of Products in the Clinical Development Stage



Global Pipeline and In-licensed Products

Among new in-house drug candidates that we are developing globally are VELEXBRU Tablets (BTK inhibitor) that are already marketed in Japan, as well as ONO-7475 (Axl / Mer inhibitor), ONO-4685 (PD-1×CD3 bispecific antibody), ONO-2808 (S1P5 receptor agonist), and ONO-7684 (FXIa inhibitor). The in-licensed product ONO-7018 (MALT1 inhibitor: in-licensed from Cordia), for which we obtained global development and marketing rights, is being prepared for overseas development. In addition, ONO-7913 (anti-CD47 antibody) and ONO-2017 (voltage-dependent sodium current inhibition/$GABA_A$ ion channel function enhancer), which are in late-stage development and were obtained through licensing activities, are being developed for approval (launch) in Japan.
In the future, we will further promote our own drug discovery as well as licensing activities to acquire global rights and engage in further enrichment of our pipeline.

Global pipeline

Product (Development code)	Mechanism of Action	Target Disease	Development Stage (Japan)	Development Stage (Overseas)	In-house/ in-license
VELEXBRU Tablets (ONO-4059)	BTK inhibitor	Primary central nervous system lymphoma	Launched	US: Phase 2	In-house
ONO-7475	Axl / Mer inhibitor	Acute leukemia	—	US: Phase 1/2	In-house
		EGFR-mutated non-small cell lung cancer	Phase 1	—	
		Solid tumors	Phase 1	—	
ONO-4685	PD-1×CD3 Bispecific antibody	Autoimmune disease	Phase 1	EU: Phase 1	In-house
		T-cell lymphoma	—	US: Phase 2	
ONO-2808	S1P5 receptor agonist	Neurodegenerative disease	Phase 1	EU: Phase 1	In-house
ONO-7684	FXIa inhibitor	Thrombosis	—	EU: Phase 1	In-house

In-licensed products (Phase 2 or later)

Product (Development code)	Mechanism of Action	Target Disease	Development Stage (Japan)	In-license
ONO-7913	Anti-CD47 antibody	TP53-mutated acute myeloid leukemia	Phase 3	Gilead Sciences, Inc.
ONO-2017	Inhibition of voltage-gated sodium currents / positive allosteric modulator of $GABA_A$ ion channel	Primary generalized tonic-clonic seizures	Phase 3	SK Biopharmaceuticals
		Partial-onset seizures	Phase 3	
Braftovi Capsules	BRAF inhibitor	Thyroid cancer	Phase 2	Pfizer Inc.
Mektovi Tablets	MEK inhibitor	Thyroid cancer	Phase 2	Pfizer Inc.

Message from the Director in Charge

To Deliver Innovative New Drugs to Patients Around the World

We continue increasing the number of new drug candidates by reinforcement of our in-house research and licensing activities, and we will quickly confirm whether these compounds demonstrate the expected clinical safety and efficacy (establish PoC). To this end, we use the data we have accumulated to date and the results of translational research to improve the accuracy of efficacy and safety prediction. Furthermore, we take a broad view of potential indications and determine the potential value of compounds as early as possible by conducting clinical trials for multiple target diseases. We conduct clinical trials flexibly in Japan, the U.S. and Europe, and are in the process of establishing a system to obtain approval on our own to deliver as many innovative new drugs as possible to patients around the world as early as possible.

Kiyoaki Idemitsu
Member of the Board of Directors, Corporate Executive Officer
Executive Director, Clinical Development

Status of Development Pipeline

(As of July 29, 2022)

Main Status of Development Pipelines (Oncology)

Product Name or Development Code (Generic Name)	Mechanism of Action, etc.	Target Disease	Development Stage I	II	III	Filed	Area	In-house / In-license
OPDIVO Intravenous Infusion (Nivolumab)	Anti-PD-1 antibody	Hepatocellular carcinoma	→	→	→		JP·KR	In-house (Co-development with Bristol-Myers Squibb)
		Ovarian cancer	→	→	→		JP·KR·TW	
		Bladder cancer	→	→	→		JP·KR·TW	
		Prostate cancer	→	→	→		JP·KR·TW	
		Pancreatic cancer	→	→			JP·KR·TW	
		Virus positive / negative solid carcinoma	→	→			JP·KR·TW	
YERVOY Injection* (Ipilimumab)	Anti-CTLA-4 antibody	Gastric cancer	→	→	→		JP·KR·TW	Co-development with Bristol-Myers Squibb
		Urothelial carcinoma	→	→	→		JP·KR·TW	
		Hepatocellular carcinoma	→	→	→		JP·KR·TW	
		Esophageal cancer	→	→	→		KR	
ONO-7913 (Magrolimab)	Anti-CD47 antibody	TP53-mutant acute myeloid leukemia	→	→	→		JP	Gilead Sciences
		Pancreatic cancer*	→				JP	
		Colorectal cancer*	→				JP	
		Solid tumor	→				JP	
		Myelodysplastic syndrome	→				JP	
		Acute myeloid leukemia	→	→	→		KR·TW	
BRAFTOVI Capsules (Encorafenib)	BRAF inhibitor	Thyroid cancer	→	→			JP	Pfizer
MEKTOVI Tablets (Binimetinib)	MEK inhibitor	Thyroid cancer	→	→			JP	Pfizer
ONO-4686*	Anti-TIGIT antibody	Solid tumor	→	→			JP	Co-development with Bristol-Myers Squibb
ONO-4482* (Relatlimab)	Anti-LAG-3 antibody	Melanoma	→	→			JP	Co-development with Bristol-Myers Squibb
ONO-7475	Axl / Mer inhibitor	Solid tumor*	→				JP	In-house
		EGFR-mutated non-small cell lung cancer	→				JP	
		Acute leukemia	→	→			US	
ONO-4059 (Tirabrutinib Hydrochloride)	Bruton's tyrosine kinase (BTK) inhibitor	Primary central nervous system lymphoma	→	→			US	In-house
ONO-4578	PG receptor (EP4) antagonist	Colorectal cancer*	→				JP	In-house
		Pancreatic cancer*	→				JP	
		Non-small cell lung cancer*	→				JP	
		Solid tumor, Gastric cancer*	→				JP	
		Hormone receptor-positive, HER2-negative breast cancer	→				JP	
ONO-7119• (Atamparib)	PARP7 inhibitor	Solid tumor	→				JP	Ribon
ONO-7122•	TGF-β inhibitor	Solid tumor	→				JP	Co-development with Bristol-Myers Squibb
ONO-7914•	STING agonist	Solid tumor	→				JP	In-house
ONO-4685	PD-1×CD3 bispecific antibody	T-cell lymphoma	→				US	In-house

* In combination with OPDIVO.

Main Status of Development Pipelines (Other than Oncology)

Product Name or Development Code (Generic Name)	Mechanism of Action, etc.	Target Disease	Development Stage I	II	III	Filed	Area	In-house / In-license
Onoact for Intravenous Infusion (Landiolol Hydrochloride)	Short-active selective β_1 blocker	Tachyarrhythmia in low cardiac function (Pediatric)	→	→	→		JP	In-house
Velexbru Tablets (Tirabrutinib Hydrochloride)	Bruton's tyrosine kinase (BTK) inhibitor	Pemphigus	→	→	→		JP	In-house
		Generalized scleroderma	→				JP	
ONO-2017 (Cenobamate)	Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel	Primary generalized tonic-clonic seizures	→	→	→		JP	SKBP
		Partial-onset seizures	→	→	→		JP	
ONO-2910	Schwann cell differentiation promoter	Diabetic polyneuropathy	→	→			JP	In-house
ONO-2808	S1P5 receptor agonist	Neurodegenerative disease	→				JP·EU	In-house
ONO-4685	PD-1×CD3 bispecific antibody	Autoimmune disease	→				JP·EU	In-house
ONO-2909	PG receptor (DP1) antagonist	Narcolepsy	→				JP	In-house
ONO-7684	FXIa inhibitor	Thrombosis	→				EU	In-house
ONO-2020	Epigenetic Regulation	Neurodegenerative disease	→				US	In-house

Material Issue 3

Maximization of Product Value

Management of Priority Issues

Reason for being a priority issue	Our mission is to contribute to people's health through our products. To achieve this mission, it is essential to maximize the potential of our products and promptly deliver drugs to patients in need. At the same time, we aim to enrich our resources for continued research and development through the maximization of product value.
Vision over the medium to long term	We have addressed our goal of achieving the well-being* of patients and their families in cooperation with healthcare professionals, and as a result, our new drugs are spreading promptly. * "Well-being" refers to a state in which satisfaction in mental, physical, social, and life conditions are achieved.
Indicators	• Number of patients to whom our new drugs are delivered • Sales by major product • Number of approvals received in Japan, Korea, and Taiwan
Major initiatives	• Engaging in effective marketing activities, using digital communications to provide information, and improving the expertise of MRs • Obtaining approvals for drugs with indications and usage, dosage and administration that maximize the potential of developed compounds • Identifying needs of patients and healthcare professionals and designing products to meet them • Generating evidence focused on extension of the healthy life span (efficacy, safety, and QoL)

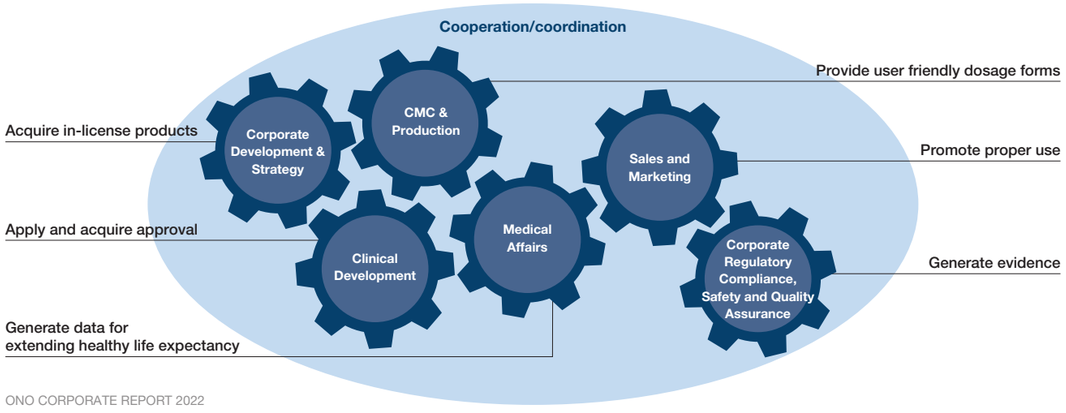
Concept of Product Value Maximization

We aim to maximize product value by working with healthcare professionals to realize the wellbeing of patients and their families, resulting in the rapid penetration of our new drugs.
Each department works to strengthen cooperation and linkages to maximize product value and engage in activities from the patient's perspective.

Bringing New Drugs to New Patients

We have a number of products that have been newly launched or had indications added in recent years, and we will continue to contribute to patients' wellbeing by promptly delivering medicines to patients who need them.
To this end, the Sales and Marketing will promote the development of specialty personnel who can communicate with healthcare professionals from their perspective, and promote the use of digital technology to not only promote appropriate use, but also to work with healthcare professionals to solve medical issues from the patient's perspective.
There are many patients with unmet medical needs to which our drugs can contribute, such as those with chronic kidney disease, cancer cachexia, and cancer of unknown primary origin. We aim to maximize product value by working with healthcare professionals to spread disease awareness, diagnosis, and treatment, and by reaching as many patients as possible.

Activities to Maximize Product Value - From a Patient-Centered Perspective -



Promotion of Information Dissemination Activities Using Digital Technology

Gathering accurate information and providing appropriate information are important to enhance the product value. Due in part to the spread of COVID-19, the channels through which healthcare professionals obtain information are becoming increasingly diverse. In particular, information is increasingly being obtained via the Internet, and we have enhanced our own websites, such as "ONO Medical Navi" and "ONO Oncology." In addition, since October 2020, Remote Communication MRs have been providing and collecting information to, healthcare professionals via remote interviews or emails.
Going forward, it will take the lead in promoting seamless and hybrid activities that integrate physical and digital information dissemination based on accumulated data through information provision activities. A system is under construction that will deliver appropriate information to healthcare professionals at appropriate times, in appropriate places, and by appropriate methods.

Division Cooperation from the Patient's Perspective

The goal of Maximization of product value is not only to increase the number of patients using the product but also to realize the wellbeing of patients. The related divisions cooperate and work together to pursue the optimal dosage forms for patients, enhance the value by generating evidence, and collect and disseminate information on side effects.

Product Design That Reflects the Needs of Patients and Healthcare Professionals

We enhance the value of our products by delivering easy-to-use pharmaceuticals to patients and healthcare professionals. We strive to design products from the perspective of patients and healthcare professionals, and to understand the actual usage and needs of pharmaceutical products in Japan and overseas, in order to develop easy-to-use products and make improvements.
In terms of surveying the actual usage of pharmaceuticals in the medical field and collecting needs, our product designers work directly with medical professionals to accurately understand and analyze the needs of the medical field. Such activities lead to prompt initiation of product lifecycle management activities, such as product improvement. For example, barcodes that show product information on each pill in a PTP sheet, and product information tags that can be easily removed from individual packaging boxes are examples of innovations that have been developed as a result of these efforts.
In the future, we will continue to develop new methods of analyzing medical needs with the aim of applying the results obtained from the above activities, the vast amount of information accumulated in-house from patients and healthcare professionals, and real-world data, to product design from the perspective of patients and healthcare professionals.

Maximizing OPDIVO's Product Value

To maximize OPDIVO's product value, we are working with our partner
Bristol-Myers Squibb (US) and focusing on the four perspectives of 1: Adding indicated tumors; 2: Adding treatment lines; 3: Developing combination therapies; and 4: Searching for biomarkers.

Generating Evidence Focused on Extending Healthy Life Expectancy

As part of our efforts to generate evidence (efficacy, safety, QoL) focused on extending healthy life expectancy, we are conducting clinical research from the patients' perspective, including surveys of patients and medical professionals. Specifically, we are collecting the opinions of many patients regarding their concerns after cancer surgery, issues they face in post-operative treatment, and their preferences in treatment choices. We plan to publish the collected data as scientifically objective data by using multiple statistical methods, such as sensitivity analysis, rather than simply tabulating patient questionnaires.
Each healthcare professional listens to the patient in front of him or her, but providing the opportunity to recognize this as objective data obtained from many patients across Japan reinforces the experience of the healthcare professional and we expect that sometimes it will lead to new insights, which will help the practice to deliver better medical care to patients and improve the product value. In addition, by identifying medical issues that have received little attention in the past through large-scale data on patients' comments, the project will uncover new unmet needs and lead to multifaceted activities aimed at solving them.

Activities to Maximize the Value of OPDIVO through Cooperation with Bristol Myers Squibb

	Activities
Adding indicated tumors	We have already obtained approval for 11 cancers in Japan and are continuing to work on development to obtain approval for additional cancer indications. In FY2021, the drug received its first approval in the world for cancer of unknown primary in Japan. We are working to apply for approval of adjuvant therapy for hepatocellular carcinoma by the end of FY2022.
Adding treatment lines	We are moving ahead with clinical trials to enable OPDIVO to be used at earlier stages in patients with advanced or recurrent cancer, and in FY2021, we received approval for first line treatment of gastric cancer in Japan, South Korea, and Taiwan. We are also developing the drug for adjuvant therapy given before or after primary treatments, such as surgery, to reduce the chance of cancer recurrence. In fiscal 2021, the drug was approved for adjuvant therapy for esophageal cancer in Japan, Korea and Taiwan, and for adjuvant therapy for urothelial carcinoma in Japan and Korea, respectively. We are working to apply for approval of adjuvant therapy for gastric cancer by the end of FY2022.
Developing combination therapies	We are proceeding with development, searching for combinations with other drugs or treatments that boost OPDIVO's therapeutic effects. In May 2022, the drug was approved for use in combination with chemotherapy, the existing standard of care for first-line treatment of esophageal cancer, as well as in combination with Ipilimumab.
Searching for biomarkers	We are advancing the search for optimal biomarkers that will predict which patients are more likely to be expected to exhibit the therapeutic effects of OPDIVO.

Material Issue 4

Realization of Direct Sales in the US and Europe

Management of Priority Issues

Reason for being a priority issue	We are committed to bringing medicines to patients around the world with our own hands. And to achieve sustainable growth, we will develop business in the U.S. and Europe, which have large markets.
Vision over the medium to long term	Aiming to become a globally competitive specialty pharmaceutical company, we are marketing new drugs in the U.S. and Europe.
Indicators	• Obtain approval and start our own sales in the U.S. and Europe
Major initiatives	• Establish a sales structure for the launch of ONO-4059 in the U.S. • Carry out development in Europe and establish a sales structure according to the progress of the development

Ono Pharmaceutical's Global Business

In order to deliver pharmaceuticals discovered and developed by our company to patients around the world, we are building a system that enables us to develop and market our own products on a global basis. In recent years, we have been strengthening our global pipeline not only for our own products but also for globally in-licensed products.
First, we are working on products in niche areas that do not require a large sales organization, with the aim of selling them ourselves overseas.

Steps for Growing as a Global Company

We are taking the following three steps to become a global company that can compete on the world stage, and we are currently in Step 2 of realizing our own marketing in the U.S. and Europe.

Step1: Globalizing Our Marketing Organizations

We started business expansion in Asia. We established two wholly owned subsidiaries: ONO PHARMA KOREA CO., LTD. in South Korea in 2013, and ONO PHARMA TAIWAN CO., LTD. in Taiwan in 2014. Then, the subsidiaries established their own sales organizations, and we started our own sales operations for OPDIVO in South Korea in 2015 and in Taiwan in 2016, respectively. To date, OPDIVO has been approved for 10 cancers in South Korea and 11 cancers in Taiwan (as of the end of June 2022). In addition, VELEXBRU received approval and began our own marketing in South Korea in 2021 and in Taiwan in 2022 for the indication of relapsed or refractory primary B-cell CNS lymphoma. Furthermore, BRAFTOVI will be marketed by our own sales organization in South Korea in 2021 for the indication of advanced or relapsed colorectal cancer with BRAFV600E mutation, and the Company is steadily increasing its presence in Asia.

Step2: Realization of Our Own Sales organizations in the U.S. and Europe

To solve various issues that arise when expanding our business in the U.S., our U.S. subsidiary, Ono Pharma USA, Inc., and Corporate Development & Strategy play a central role in strengthening cooperation with Clinical Development, Corporate Regulatory Compliance, Safety and Quality Assurance, Corporate Strategy & Planning, Sales and Marketing, CMC & Production, Medical Affairs, and other divisions.
ONO Pharma USA, Inc. is taking the opportunity of its office relocation to Cambridge, Massachusetts in April 2021 to acquire talented human resources with extensive experience in the pharmaceutical industry and create a competitive organizational structure. In addition to expanding the development system for new compounds, such as ONO-4059, they hired executives for the marketing and sales organizations, the pharmacovigilance division, and the medical affairs division in FY2021, and they are working to strengthen our own sales organization and infrastructure for the launch of new products. We plan to increase the size of the organization from the current approximately 60 employees to more than 120 in five years.

In the U.S. and Europe we are currently conducting clinical trials for 5 products and are aiming to establish a PoC for development products following ONO-4059. In Europe, we currently have an organization of about 50 people, mainly in development, but we will continue to improve and strengthen the organization, including development, to build a development structure so we will be able to do the work from late-stage clinical trials to regulatory filings, in-house. In addition, in light of the status of ongoing clinical trials, we are also moving forward with the establishment of our own sales organization.

Step3: Becoming a True Global Company

In the regions where we established sales bases by proceeding up to Step 2, we will continue to introduce new drugs that satisfy further unmet needs, and we will consider expanding our sales network to China, ASEAN, and other regions.

Steps for Growing as a Global Company

Establish Our Own Sales System in the U.S. and Europe

Accelerate the construction of a self-sales organization in the US taking the launch of VELEXBRU into account
Promote development and establish a self-sales organization in Europe

ONO PHARMA USA

Approx. 60 people at present → After 5 years, expand to more than 120 people having a self-sales organization

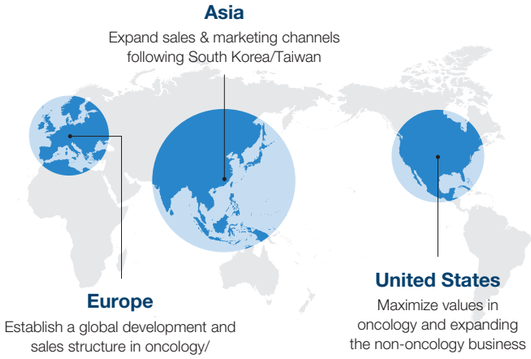
Clinical Development	Marketing	Sales	Market Access	Medical
PV	QA	CMC・Production	Company Infrastructure	

ONO PHARMA UK

Approx. 50 people at present. Consider establishing a self-sales organization including marketing and sales etc. under the progress of development in Europe

Clinical Development	PV	QA	Company Infrastructure

ONO's Vision



Continued expansion of global pipeline

		Global Development (Medium- and Long-term)
Oncology	VELEXBRU	(BTK inhibitor / PCNSL)
	ONO-7475	(Axl / Mer inhibitor / Acute leukemia, etc)
	ONO-4685	(PD-1×CD3 bispecific antibody / T cell Lymphoma)
	ONO-4578	(EP4 antagonist / Solid tumor, Gastric cancer, etc)
Neurology	ONO-2808	(S1P5 receptor agonist / Neurodegenerative disease)
	ONO-2909	(DP1 antagonist / Narcolepsy)
	ONO-2910	(Schwann cell differentiation promoter / Diabetic polyneuropathy)
Immunology	ONO-4685	(PD-1×CD3 bispecific antibody / Autoimmune disease)
Specialty	ONO-7684	(FXIa inhibitor / Thrombosis)
		New drug candidates created by Discovery & Research
		Newly in-licensed drug candidates for global development

Material Issue 5

Expansion of Business Domains

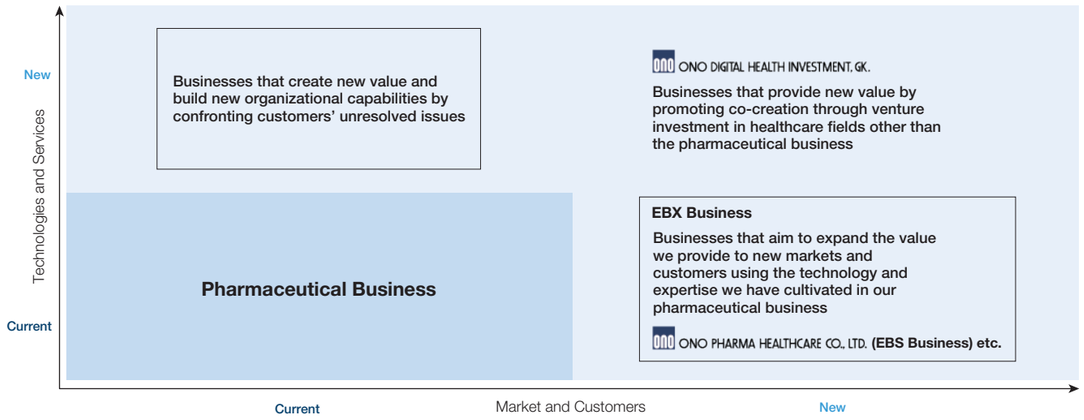
Management of Priority Issues

Reason for being a priority issue	To solve society's healthcare issues and realize a society where people can live healthier lives, we are expanding our business beyond the new drug business to new business domains. We believe that we can develop unique businesses by leveraging the knowledge and strengths we have cultivated in our history of drug discovery.
Vision over the medium to long term	Contributing to solving social issues and realizing next-generation healthcare by leveraging digital technologies and our strengths.
Indicators	• The number of new businesses started • The number of new products and services provided
Major initiatives	• Creating and promoting new businesses utilizing digital technology, starting from customers' unresolved issues (needs) • Develop and commercialize evidence-based products and services to solve social issues in the healthcare sector (Ono Pharma Healthcare Co., Ltd.) • Invest in and create business for venture companies engaged in businesses aimed at solving healthcare issues (Ono Digital health Investment, GK)

For Sustainable Growth

The business environment in the pharmaceutical industry is becoming increasingly severe, as the probability of success in new drug discovery is declining and drug prices are being lowered to curb social security costs. In order to achieve sustainable growth, we will continue to focus not only on the creation of innovative new drugs, but also on increasing the number of our business domains by developing new businesses and investing in the growth of venture companies. We aim to make our revenue base strong and at the same time become a company that is even more useful to society.
In developing new businesses, we will focus on whether we can leverage our uniqueness and superiority as a company and whether those new businesses are useful to society. The needs in the healthcare field are growing, and we will continue to search for businesses with solid evidence, starting from our assets, such as research results and know-how cultivated in the pharmaceutical business.
In creating new businesses, it is essential for us to utilize the open innovation that is deeply rooted in our company. In particular, we will actively invest in venture companies that possess technologies and ideas that we do not have, such as in the fields of digital technology and new services, and form alliances with them. In the future, we intend to develop these businesses into pillars of business, comparable to the pharmaceutical business, and link them to human health, and innovation in next-generation healthcare.

Discovery of New Businesses



Expanding the Scope of Value Provided

The scope of our new businesses is not limited to pharmaceutical treatment, but also includes businesses that can contribute to disease prevention and post-treatment. Through this, we hope to contribute not only during the period from the creation of a pharmaceutical product until it reaches the patient and demonstrates its value, but also over an even longer period of time to the improvement of quality of life.
By making more effective use of our assets and diversifying our business portfolio through the creation of new businesses, we will expand the scope of our contribution to people's health and lives. We are also looking to develop businesses other than the pharmaceutical business that will contribute to the stability of our operations.

Major Initiatives

Promoting Evidence-based X (EBX) Business

To address social issues in the healthcare field, such as the aging of society and the extension of healthy life expectancy, we are promoting the development and commercialization of products and services (=X) based on solid evidence, such as clinical trial results, by effectively utilizing knowledge obtained through pharmaceutical R&D.
In March 2022, as the first product of our Evidence-based Supplement (EBS) business, our wholly owned subsidiary Ono Pharma Healthcare Co., Ltd. launched REMWELL, a functional food sleep supplement made from functional lipids. With the mission of "Getting closer to your health with the power of lipids," the EBS business launched the "Lipid-supply" brand of supplements that contribute to health by providing high-quality lipids, which are often lacking in the diets of modern people. We intend to continue to develop supplements that make the most of our research findings.

Web Ono Pharma Healthcare Co., Ltd.
https://www.ono-hc.co.jp/

Increasing Investment in Healthcare-related Venture Businesses

In March 2022, we established Ono Digital health Investment, GK, a corporate venture capital, to increase investments in venture healthcare businesses other than pharmaceuticals.* Ono Digital health Investment, GK invests in venture companies that work to solve healthcare issues.
As of March 2022, our investments include Xenoma Inc. (healthcare services using smart apparel technology), Rehab for JAPAN Corporation (development and provision of rehabilitation support SaaS for caregiving office), and BMG Incorporated (medical biomaterial products). Going forward, we will work to increase our business domains and support entrepreneurs through collaboration with our investment partners, aiming to extend healthy life expectancy and realize a sustainable society.

* A CVC (Ono Venture Investment Inc.) established in the US in 2020, invests in bio-venture companies related to drug discovery.

Web Ono Digital health Investment, GK
https://www.onodigitalhealth.com/en/

Business development that addresses unresolved issues of customers

In developing new business, we look at various healthcare issues surrounding patients, their families, and society. For example, alleviating pain is a major theme. Cancer patients suffer not only physically, but also mentally, socially such as with regard to work, and spiritually, as they struggle with the meaning of their lives. To alleviate various types of suffering that cannot be reached by pharmaceuticals, we aim to achieve this by utilizing digital technologies and external resources, as well as by promoting mid-career recruitment.
In January 2022, we participated in the Osaka Smart Senior Life Demonstration Project Promotion Council, which aims to solve issues faced by senior citizens in Osaka Prefecture through the use of Information and Communication Technology, together with the venture company K-three Inc. K-three provides a personalized public notification service aiming to promote cancer screening and other medical examinations, and link this to various private services after the examinations. We also aim to contribute to the maintenance and promotion of health of cancer patients by providing value to them through digital products.

TOPICS EBS Business: sleep supplement REMWELL goes on sale

REMWELL is Japan's first* sleep supplement containing DHA, EPA, and DAGE (diacylglyceryl ether) and has been confirmed to improve sleep quality. This is the product of cooperative development between ONO, with our more than 50 years of lipid research and development of many prostaglandin formulations, and Maruha Nichiro Corporation, which excels in the research and development of functional materials derived from marine products. We have confirmed that it significantly increases the amount of deep sleep and REM sleep, and significantly improves negative mood state scores (depression, tension, and anxiety) and vitality/vigor scores based on clinical trials conducted during development of the product.

* The first clinically tested functional food in Japan (as of April 2022, according to TPC Marketing Research Inc.)

Details about REMWELL are available here:
https://www.ono-hc.co.jp/remwell_lpC-03-0003/

Foundation for Value Creation

The use of digital technology and information technology, which have become indispensable for corporate activities, as well as the strengthening and expansion of financial and human capital, are also important elements for sustainable corporate growth.
Intellectual property strategies unique to drug discovery companies and partnerships with external parties, particularly open innovation, are also important foundations.
This section introduces important initiatives related to these foundations for value creation.

Material Issue 6

Corporate Transformation through Digital & IT

Management of Priority Issues

Reason for being a priority issue	We aim to grow into a company capable of accelerating our growth strategy, innovating business processes, and creating new value (digital transformation) by leveraging digital and IT cross functionally.
Vision over the medium to long term	A global IT infrastructure is being implemented to support corporate transformation.
Indicators	• Completion of the IT blueprint of the (big picture for IT infrastructure and related systems) Implementation of a data utilization platform. • Establishment of a cross-functional DX promotion system • Number of participants in the Digital Talent Development Training Program: 500 • Of these, the number capable of planning, managing and executing DX projects: 100
Major initiatives	• Implement cross-functional IT infrastructure based on the IT blueprint • Implement a data utilization platform including internal and external data for important decision-making • Improve robust information security management capabilities • Develop the talent to plan and lead DX

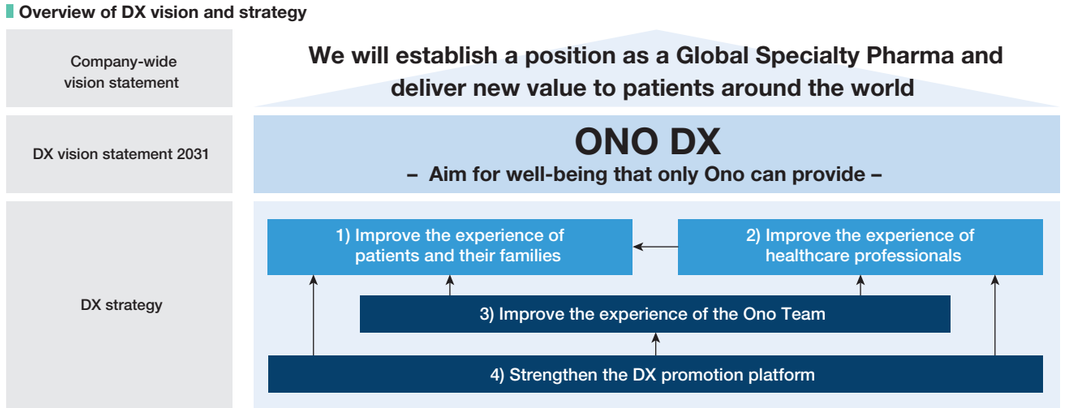
Overview of Corporate Transformation by leveraging Digital and IT

In the midst of a drastically changing business environment, we are transforming the company to have high dynamic capability by leveraging digital and IT.
This requires a flexible IT infrastructure supported by the latest technologies, a data utilization platform including internal and external data, and the capability of data analysis from company-specific perspectives. This foundation enables us to detect and assess business issues and new opportunities accurately and timely, and turn them into business transformation initiatives. All activities related to every value creation process with the foundation leads us to a global specialty pharma.

Global IT Infrastructure

IT infrastructure has two important roles which are supporting business efficiency and providing up-to-date data with consistency for digital transformation. Our approach is to implement an IT infrastructure based on the big picture that includes future Ono global business activities, which do not rely solely on a demand focused approach We utilize systems and services that are widely used throughout the world, without company-specific customization.
This allows us not only to enjoy the latest functionalities, but also maintain the flexibility for future changes including collaboration with other companies related to business innovation.

Overview of DX vision and strategy



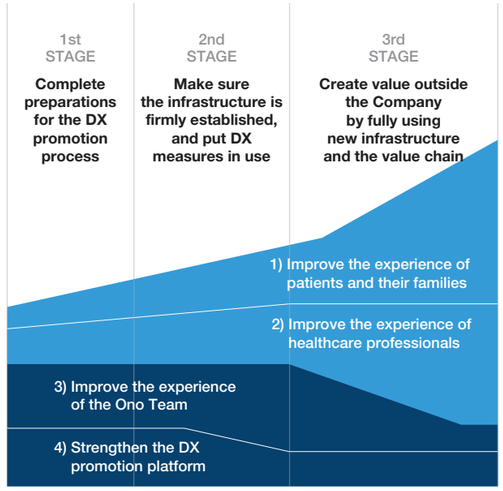
ONO's DX Promotion Strategy

While DX is generally viewed as technology-centric, at ONO we think it is people-centric. To realize our corporate philosophy and accelerate the work that is unique to our company, it is important to deliver value not only to patients and their families, but also to healthcare professionals, employees, and our diverse partners. We believe that this will enhance the vitality of people and improve the productivity and creativity of the company.
The environment surrounding the pharmaceutical industry has two completely different aspects. On the one hand, it is a heavy industry with large companies requiring huge amounts of time and funds for research and development, and on the other hand, it is an innovation-oriented industry with a forest of startups and a high degree of uncertainty where new modalities are born one after another. To address both of these aspects, we are implementing a DX strategy that focuses on the human experience by rethinking our company from the perspective of providing value, rather than from the conventional perspective of positioning and competence, which is based on the stability of the environment.
Specifically, while maintaining the efficient operational value chain organization that we have refined over the years, we will work to promote DX in a horizontal manner centered on people, the people to whom value is delivered. With digital technology, DX will bring about business transformation, it will cover a very wide range of areas, from existing businesses to new ones, and from operational efficiency to new business models.

Development of DX talent

Talent development is at the core of DX activities. Our goal is to be a company that continues to transform itself on a daily basis, rather than to make one-off major changes with the help of external forces. To achieve this, each and every employee, from the management team to the front lines of the workplace, must be able to direct and execute change as needed.
We then clarified the DX promotion process and the DX talent needed to implement it. Based on this, we considered which human resources should be external and which should be developed internally, and formulated an internal talent development program, defining three layers: talent who plans and drives DX, talent who can participate in projects and play an active role, and employees who have a DX background.

DX promotion process



Status of Data Use

The use of real-world data (RWD), which began three years ago, has spread throughout the company. Simple analysis is performed by each division using tools, while detailed analysis is performed by specialists in statistical analysis using programming, allowing for both speed and quality. RWD is now used on a daily basis by everyone from R&D to sales. To cite one example, in the cost-effectiveness evaluation system introduced in April 2019 by the Ministry of Health, Labour and Welfare, our chronic heart failure drug Coralan was judged to be very cost-effective after being evaluated using RWD and other methods.
OASIS, which was built as an integrated data utilization platform, started operation in August 2022, enabling cross-divisional analysis on a single platform of data owned by each department, commercial RWD, and open data. OASIS has enabled us to manage data centrally and realize a stronger data governance system better than before. OASIS is also a platform that can handle pseudonymized information as defined in the revised Act on the Protection of Personal Information, can do advanced AI analysis while protecting personal information and contributes to the creation of new evidence.

Message from the Officer in Charge

Digital transformation to improve the experience of all people involved in our company

What do you imagine when you hear the term "digital transformation"? Generally speaking, it is the use of digital and IT technologies to improve operational efficiency and transform business models, but the definition is ambiguous.
We have placed the wellbeing of all people involved in our company at the center of our digital transformation and the enhancement of their experience. First, through the development of IT and digital infrastructure and talent development, we will foster an environment in which employees can think about and implement change on a daily basis toward the realization of the future they envision.
Beyond that, we will improve the experience for patients and their families, healthcare professionals, employees, and partners. We are not interested in technology itself, but rather how we can bring our company closer to the future envisioned by all of the people involved. From this perspective, we will continue to leverage the latest digital and IT technologies.

Satoshi Numata
Corporate Executive Officer / Executive Director
Digital & IT Strategy, Global IT Strategy & Planning Dept.

Material Issue 7

Strengthening of Financial Capital:
financial strategy and policy on medium- to long-term investment

Management of Priority Issues

Reason for being a priority issue	Robust financial capital is important for continuing investment in management infrastructure that supports research and development and growth, which makes it possible for us to provide value to patients and continue increasing our corporate value.
Vision over the medium to long term	Based on our corporate philosophy, Dedicated to the Fight against Disease and Pain, we strive to maintain and expand a robust financial base that leads to drug discovery, with the aim of becoming a global specialty pharma that creates innovative new drugs that truly benefit patients, and responds to unmet medical needs.
Indicators	(FY2022 to FY2026) • Revenue CAGR: In the high single digits • Operating income to revenue ratio: Maintain 25% or higher
Major initiatives	• Enhancing operating cash flow by expanding sales revenue • Increasing asset efficiency by reducing cross-shareholdings • Maintaining and increasing profitability and ROE by maximizing return on investment

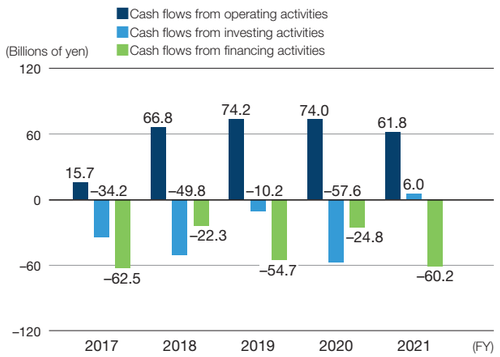
Creating Stable Investment Resources

To realize our corporate philosophy, Dedicated to the Fight against Disease and Pain, we will acquire growth capital by maximizing the value of prescription drugs we create and investing the capital intensively in the discovery and development of new drugs, thereby generating innovative drugs. We will create a virtuous cycle of capital and cash generation by using the cash generated by both the creation of new drugs and by the improvement of capital efficiency, including the reduction of cross-shareholdings, to fund the next stage of growth while ensuring financial soundness, aiming to create value for patients and society and continuously enhance corporate value. We will create a virtuous cycle of capital and cash generation to create value for patients and society and enhance our corporate value continuously.

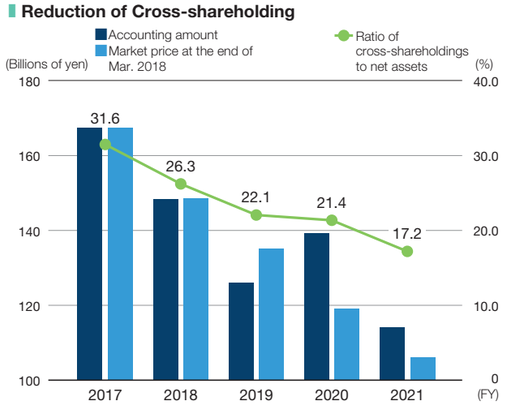
At the same time, the business environment surrounding pharmaceutical companies is becoming increasingly challenging, and the probability of success in new drug discovery remains low. By securing an appropriate level of internal funds, we will ensure the liquidity of funds necessary for smooth business activities, including prompt investment in quality projects.

We have been actively reducing our cross-shareholdings to prevent the hollowing out of voting rights, and from April 2018 to the end of March 2022, we reduced our cross-shareholdings by a total of 44 issues, amounting to 53.2 billion yen (on a balance sheet basis). In addition, from October 2021 to March 2025, we plan to generate approximately 40 billion yen in cash by reducing our cross-shareholdings (based on market value as of September 30, 2021) by 30%, which will be used for future growth investments. We will continue to reduce our cross-shareholdings from the viewpoint of capital efficiency.

Statement of Cash Flows



Reduction of Cross-shareholding

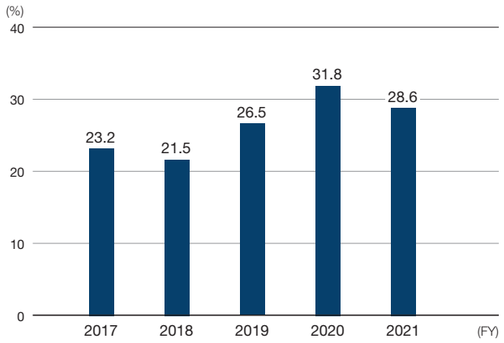


Maximizing Return on Investments and Maintaining Financial Soundness

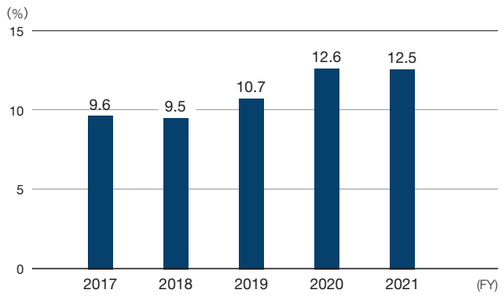
Even as we make aggressive R&D and strategic investments, we will strictly apply our investment adoption criteria to ensure value creation and profitability. For the five years from FY2022 to FY2026, we will strive to expand revenue at an revenue CAGR in the high single digits compared to FY2021. We will then aim to maintain an operating income to revenue ratio of at least 25% while investing about 20-25% of revenue in R&D. With these levels of revenue growth and expanding profits through aggressive R&D investment as targets, we believe we can achieve ROE that exceeds the cost of shareholders' equity without falling into a short-term orientation.

Regarding fund procurement, the Group will ensure the liquidity necessary for smooth business activities, and will do so effectively and flexibly, taking into consideration market conditions and other factors. The Group's current assets far exceed current liabilities, and the source of funds is allocated between funds generated from operations and internal funds.

Operating Income to Revenue Ratio

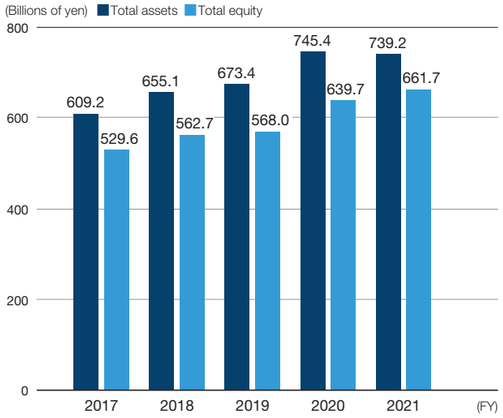


ROE*

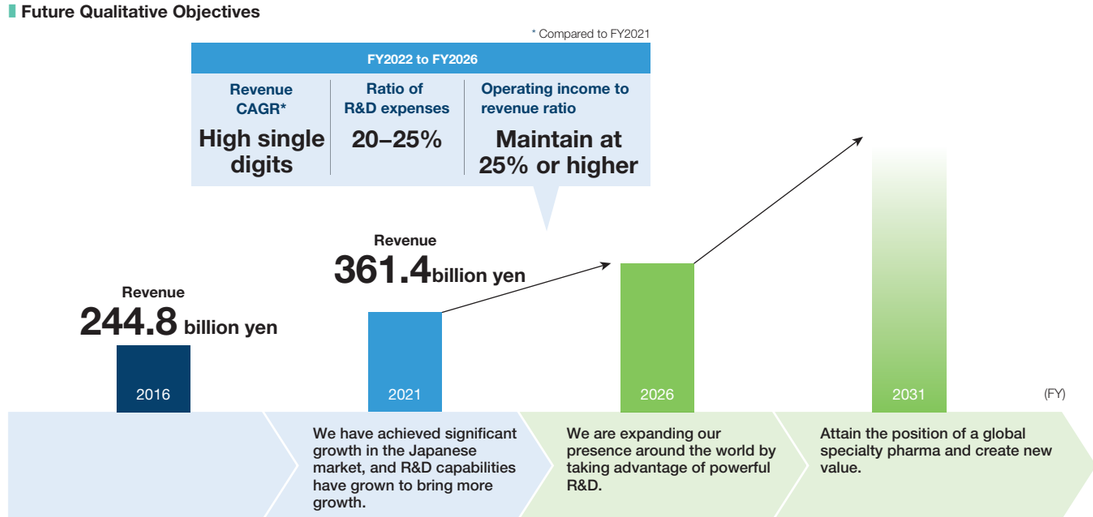


* Profit for the year attributable to owners of the parent company / Equity attributable to owners of the parent company (average of beginning and end of fiscal year)

Total Assets and Total Equity



Future Qualitative Objectives



Policy on Medium- to Long-term Investment

Strategic investments are essential for sustainable growth. Although R&D expenses will increase due to aggressive growth investments, we will raise the level of ROE by expanding profits through revenue growth. We will also maintain an appropriate level of shareholders' equity by balancing shareholder returns.

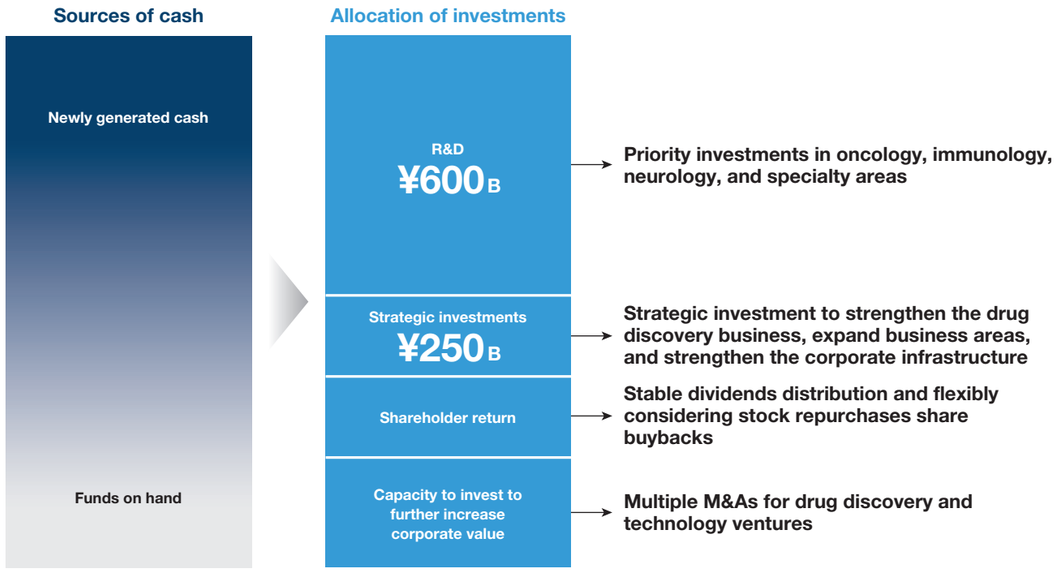
■ Research and Development Investment

We are aggressively investing in R&D to create original and innovative new drugs and expand our development pipeline. Along with the expansion of revenue, we plan to increase R&D expenditures to the 100 billion yen-level first, and then in the five years from 2022 to 2026, invest a total of 600 billion yen in R&D. Specifically, in addition to drug discovery alliances with biopharmaceutical companies that possess the world's most advanced technologies, we are actively pursuing research alliances that lead to drug discovery research with universities and other research institutions. At the end of FY2021, we were carrying out more than 200 cooperative research projects in Japan and overseas, and we plan to do even more going forward. In addition to compounds in the late development stage, which are expected to be launched within a few years, we are also strengthening our licensing activities to actively acquire attractive compounds even in the early development stage (preclinical and Phase I).
In addition, Ono Venture Investment Fund I, L.P., established in July 2020, is investing in drug discovery ventures in the seed stage.
In addition to regular R&D expenditures, we intend to invest 150-200 billion yen over the next five years to strengthen our drug discovery business by acquiring global rights to compounds with established PoC.

■ Investments to strengthen corporate infrastructure and expand business areas

We will also actively invest in IT and digital technology, and research and production facilities sufficient to maintain the latest drug discovery activities and safe and efficient production activities over the medium-to-long term.
With regard to expanding our overseas development bases and sales network, we will accelerate the establishment of our own sales organization in the U.S. in anticipation of the launch of the BTK inhibitor VELEXBRU Tablets, and in Europe, we will consider establishing an organization for our own sales, including marketing and sales, while taking into account the progress of development.
With regard to R&D and production facilities, in July 2019, we built the Yamaguchi Plant to accommodate business expansion and reduce the risk of large-scale disasters in terms of business continuity, and it began operation in March 2020. Going forward, we will continue to also make ESG-related investments on the basis of environmental and societal factors.
Furthermore, Ono Pharma Healthcare Co., Ltd., established in February 2021, and Ono Digital health Investment, GK. in March 2022, plan to invest in new healthcare businesses, DX funds, and other business domain expansion, and together with the expansion of our overseas development bases and sales network, and also the strengthening of corporate foundations, plan to invest 30 to 50 billion yen over the next five years.

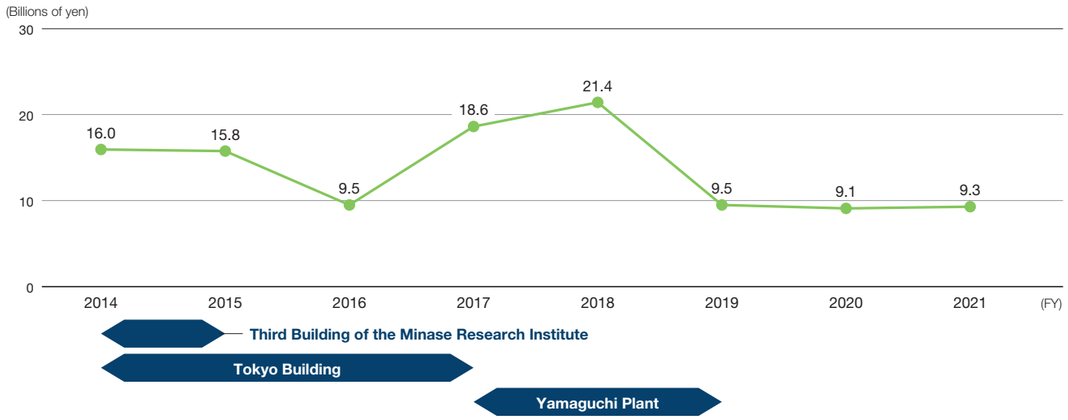
The Sources of Cash and Allocation of Investments (FY2022-FY2026)



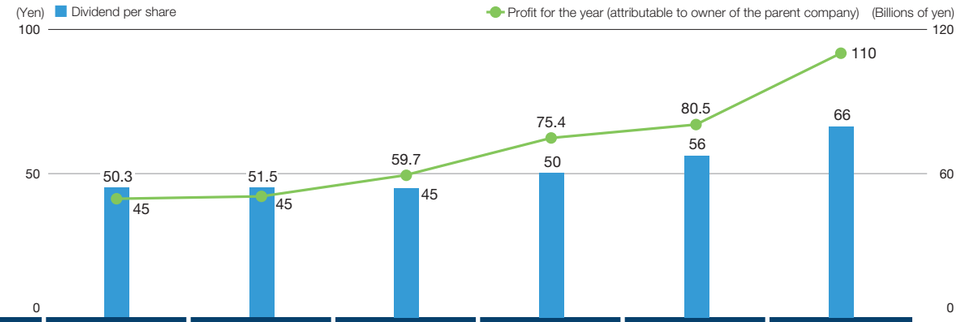
Shareholder Returns

Returning profits to all of our shareholders is one of ONO's key management policies, and we will achieve a good balance between dividends and share buybacks.
We are focused on maintaining stable dividends on a monetary basis, and also consider business performance in the current fiscal year and various indicators. ONO increased its share dividend by 6 yen in FY2021 and is planning to increase the dividend by 10 yen in FY2022. We will continue to flexibly review and execute share buybacks, positioning them as a part of measures to improve shareholder benefit and comprehensive shareholder returns.

Capital Expenditures & Major Investments



Shareholder Returns Over Time



	2018.3	2019.3	2020.3	2021.3	2022.3	2023.3 (Forecast)
Total dividends	23.1 billion yen	23.1 billion yen	22.5 billion yen	25.0 billion yen	**27.7 billion yen**	
Dividend payout ratio	46.4%	44.9%	38.0%	33.1%	**34.5%**	29.3%
Share buybacks	38.8 billion yen	–	29.6 billion yen	–	**30.0 billion yen**	
Ratio of payouts and buyouts to net profit	123.1%	44.9%	87.2%	33.1%	**71.6%**	

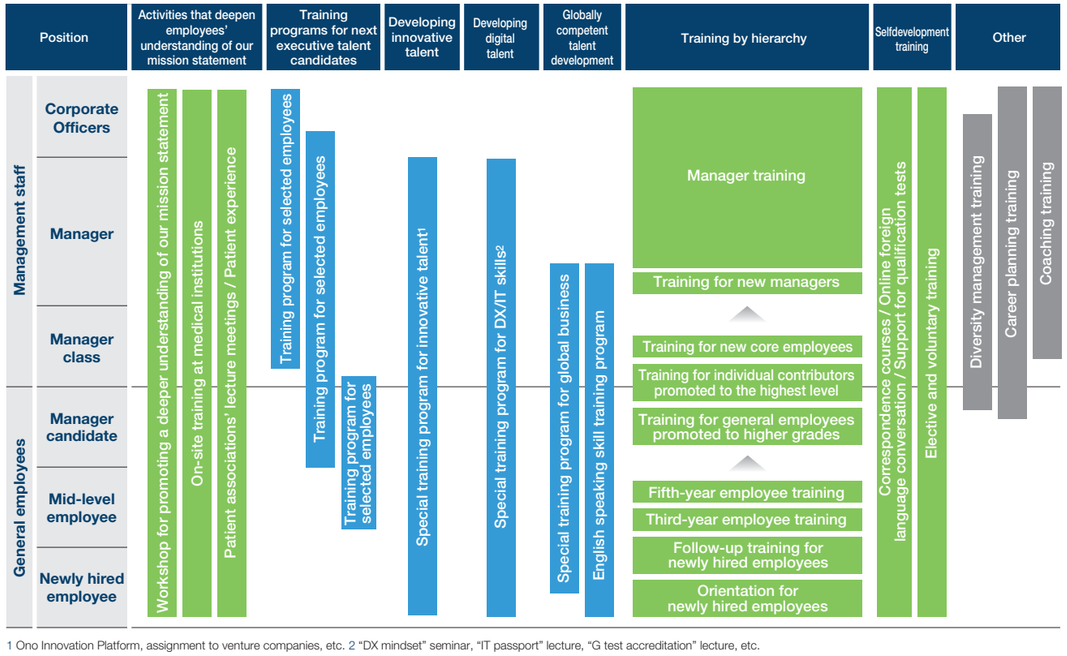
Material Issue 8

Expansion of Human Capital

Management of Priority Issues

Reason for being a priority issue	To achieve sustainable growth, it is essential to secure talent that can execute strategies as passionate challengers towards achievement of our corporate philosophy.
Vision over the medium to long term	We provide talent development programs to selected people, approximately 30% of employees of our group companies, and the creation of corporate value is driven through talent development. In particular, the enhancement of executive talent, globally competent talent, digital talent, and innovation talent have been set as important themes.
Indicators	(Total number of persons up to 2026) • In next executive talent pool: 250 or more • In globally competent talent pool: 300 or more • Persons who will have participated in digital talent development and training program: 500 or more Including those who can plan, manage, and execute the DX project: 100 or more • Core innovation talent: 150 or more
Major initiatives	• Next executive talent: Promoting the training for selected employees and the strategic personnel transfers • Globally competent talent: Promoting development plans based on global development and implementing global strategic personnel transfers • Digital talent: Developing talent to plan and lead the digital transformation, and providing training programs for them • Innovation talent: Providing programs to trigger innovations, and promoting innovation • Other: Engaging in activities to disseminate mission statements, providing voluntary-participation type training, developing a self-development learning support system, etc.

Summary of Common Education and Training Programs for All Divisions in FY2021



1 Ono Innovation Platform, assignment to venture companies, etc. 2 "DX mindset" seminar, "IT passport" lecture, "G test accreditation" lecture, etc.

Policy on Human Capital and Talent Development

We regard the increase of human capital as one of the major issues in our management foundation and focus on talent development to support our growth strategy. We also provide a variety of growth opportunities so that each employee can always take on challenges and work autonomously. Furthermore, through the development of future executive talent, global talent, digital talent, and innovative talent, we are pursuing strategic talent development initiatives that will help us make the leap to a being a "Global Specialty Pharma."

Activities to disseminate our mission statement

We have Dedicated to the Fight against Disease and Pain as our mission statement, and we aim to ensure that each and every employee thinks and acts based on a full understanding of how patients who use our pharmaceutical products, and their families, are dealing with their illnesses and undergoing treatment. To disseminate this mission statement, we are working on three main activities: a workshop for deep understanding of our mission statement, on-site training at medical institutions[1], and efforts for improving the patient perspective.

Since FY2019, we have been holding a virtual reality patient experience session. This is an opportunity for healthy people to experience the symptoms of patients with dementia and gain perspectives that they may not have been aware of. In FY2021, we introduced training in understanding the patient experience to foster a more patient-oriented mindset by understanding the values held by patients, which will lead to the creation of new drugs and the provision of other value.

The workshop for deep understanding of our mission statement aims to promote empathy with the mission statement and action. For employees of overseas subsidiaries and mid-career hires, president personally explains how the mission statement was formulated and the history of our company's taking on challenges which is the background to the formulation, after which participants share their impressions and what actions they would like to take in the future. The workshop is designed to achieve Level 3: Know specific examples and models that symbolize the philosophy, and Level 4: Can interpret the philosophy in one's own way in the 14 stages of philosophy dissemination.[2]

1 Not done for FY2021 due to COVID-19
2 Masako Tanaka, Keiei Rinen Sintou no Mekanizum, Chuokeizai-sha Holdings, Inc., 2016.

Talent Development Strategy

We are committed to developing a diverse range of human resources, such as future executive talent, global talent, digital talent, and innovative talent. We consider these talents to be valuable shared human capital that cuts across divisions, and we are working to develop them through strategic personnel transfers.

The development training program for future executive talent is designed to instill the basic principles of management, the ability to think, and the ability to involve others. Selective training for general employees is conducted for a year to develop talent who can be the next generation of leaders. Selective training for managers is conducted over a two-year period to develop talent who can be the next generation of senior directors, executive directors, and company management. After completing the selective training, personnel are strategically transferred to jobs that they should experience as future executive candidates, and this is determined through meetings where all executive managers and division directors can discuss the issues from the same perspective.

In developing global talent, we implement a Global Skill Improvement Program, which aims to develop talent who can exercise global leadership and perform their duties in appropriate cooperation with those around them. The Global Skill Improvement Program includes a self-improvement training subsidy system, voluntary training, and selective language training in stages to develop not only English language skills but also international perspectives and cross-cultural communication skills.

Digital transformation talent is defined as those who can improve the experience of patients and their families, healthcare professionals, employees, and partners through the use of digital and IT technologies. The digital skills training program is designed for each level of employees, such as those who understand and encourage digital transformation (DX), those who can actually participate in DX projects, and those who can lead DX projects at a higher level, meaning it is not only for technical skill.

We define innovative talent as those who are capable of personal growth through taking on the challenge of innovation. In developing innovative talent, we established the "Ono Innovation Platform" (OIP, see pp. 53-54) with the aim of increasing the number of employees who can take on challenges as their own personal matters and act on them, and to have this activity take root in our corporate culture.

Promotion of Diversity and Inclusion

We believe that it is important to deepen our understanding of the diversity of the attributes, values, and behavioral characteristics of the members of our organization and to recognize their personalities in order to respond quickly and flexibly to changes in the environment and improve our corporate value. Thus, we promote various related initiatives. In order to understand the significance of diversity and to utilize it for the management of various human resources, we promote understanding by incorporating the promotion of diversity, inclusion, and social integrity into both the training by year of employment and rank-based training. In addition to our own activities, we also

Development training program for the next generation of executives

	Talents capable of serving as the next generation of leaders	Talents capable of serving as the next generation of managers of a business office	Talents capable of serving as the next generation of general managers and management
Training	Selection training for general employees	Selection training I for management employees	Selection training II for managers
Length	1 Year	2 Years	2 Years

participate in study sessions and seminars that transcend the boundaries of companies, and strive to collect know-how and information on initiatives for improving diversity.

Activities to promote female employee participation in the workplace

We have focused on creating a system in which women can work actively. As a result of proactive recruitment of women and measures to prevent turnover associated with life events, the number of female employees has steadily increased, and the employment rate of female employees as of March 2022 had increased by 4.7% compared to March 2013.
We established an action plan based on the Act on Promotion of Female Participation and Career Advancement in the Workplace. In accordance with the action plan, to be implemented from April 1, 2021 to March 31, 2023, we are improving the employment environment to increase the number of female potential managers and to support the balance of working and family life.
In addition, we hold seminars called “Support Balancing Work and Child-raising after Returning from Childcare Leave” twice a year to support employees who are balancing their work and child-raising. By providing information about the seminars and opportunities to consider participation with childcare and balancing of work and child-raising, not only for women but for all employees, we are creating a friendlier working environment.

Goals and action plans for FYs 2021 to 2022

Goals	Action plan	Results for FY2021
Increase the percentage of women in the section chief level to 15% or more	• Provide opportunities to consider careers, regardless of gender, so that future careers, including management, can be envisioned • Provide systems to support the careers of subordinates in order to foster a culture for training the next generation of managers	14.0%
Increase the rate of male employees taking child-care leave to at least 75%	• Implement an approach to have the superiors of male employees encourage them to take childcare-related leave and use the support system for work-life balance after the birth of a child • Disseminate childcare-related leave and programs to support systems for balancing work and family life	79.0%

Effort made for promoting active participation of people with disabilities and employing people mid-career

We actively promote the employment of people with disabilities as part of our promotion of diversity and inclusion and are working to create an environment in which people with disabilities can work comfortably. In April 2022, we established Ono Pharma UD Co., Ltd., a wholly owned subsidiary, to provide more work opportunities for people with disabilities. We are starting with a printing business, and in the future, we plan to contribute to the promotion of a sustainable society by providing opportunities for employment that are rewarding for people with disabilities to fully demonstrate their abilities and play active roles in a wide variety of tasks.
In addition, we are also focusing on recruiting mid-career people, people with the skills, knowledge, and experience that we need and can immediately contribute to our business. Especially since FY2014, when we started to actively promote the hiring of mid-career people in view of changes in the business environment, we have been hiring them in a broad range of jobs, including MR, development, safety information management, digital / IT, and management. In FY2021, we hired about 50 mid-career recruits and they now play their respective roles, applying their experience and expertise.

TOPICS Use of UD Talk

We introduced UD Talk* for business in 2016 as a communication tool for hearing-impaired people, and use it in almost all departments that have hearing-impaired employees. Currently, subtitles are displayed in real time on the screen of the Web conferencing system, and we will support an environment where people with hearing impairments can work energetically without any inconvenience through in-house communication, even in a telework environment.

* UD Talk: It is an application used for communication mainly with hearing-impaired people, using a smartphone. It converts voice into text using automatic speech recognition.

Employees

	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022
The male-to-female ratio of new employees (%)	34	49	34	40	40	38
Retention rate of female employees (%)*	96.6	97.1	96.9	96.9	95.9	—
Employment rate of persons with disabilities (%)	2.24	2.28	2.20	2.17	2.38	—
Number of mid-career employees recruited (as of the end of the fiscal year)	380	440	446	457	487	—

* Retention rate = 100-(Turnover rate each fiscal year)

Cultivation of Employee-friendly Workplaces, and Safety and Health

We are moving ahead to create workplaces where employees can work with peace of mind. We are continually working to develop support systems and working conditions that help employees work in various styles, as well as improve 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.

Promoting Work Style Reform

We have been promoting work style reform since FY2015 to enhance productivity by simultaneously enhancing work efficiency and creating an attractive working environment. To make this a company-wide initiative, we have appointed employees from each division to be promotion committee members and are working to raise awareness, increase operational efficiency, and promote the use of paid vacation days. At the same time, we have been improving systems that make use of IT and introducing flexible working hours, telecommuting systems, and interval work systems. In FY2021, due to the impact of COVID-19, employees were required to work in a different way than before. As a result, the amount of work increased, resulting in an average of 16.3 hours of overtime per month and 62.5% of available paid vacation taken overall. From now on, we will further enhance new working styles, such as telecommuting, and enhance work efficiency. In FY2022, we aim to have average monthly overtime work hours per employee of 13 hours, and 70% or more of available paid vacation taken.

Regular feedback on employee evaluations

We have an interview system for work goals to improve employees’ motivation and develop human resources. Employees have eight interviews with their supervisors each year. All employees set goals for their work every six months and align their course of action to our corporate vision. In the middle of the fiscal year, the progress toward the goals is checked, and the course is revised in an interim meeting with the manager. At the end of the term, feedback is provided about the employee’s overall performance, strengths and weaknesses, and evaluation results, and also the next term’s work plan, development policy, and future career development are discussed. Evaluation consists of performance evaluation and behavior evaluation; the performance evaluation evaluates the degree of achievement against individual goals based on the outcomes and process each employee used, and the behavior evaluation is based on how the employees behaved compared to the required behaviors determined according to each employee’s roles; results that combine the performance evaluation and the behavior evaluation are the final evaluation. Also, as a rule multiple people do the evaluations, which ensures objectivity and fairness, and the results are reflected in employee compensation.

Childcare Support Initiatives

We believe that society as a whole should support families raising children and that creating an environment that supports childbearing and childrearing is one of the challenges that companies should address. We formulated an action plan based on the “Act on Advancement of Measures to Support Raising Next-Generation Children,” and are working to help employees balance their work and childrearing. As a result, we were certified by the Minister of Health, Labor and Welfare as a standard-compliant general company, and we were awarded the mark of certification as a childcare support company (Kurumin) five times between 2008 and 2020.
We introduced a new childcare support system in April 2017: Encouraging Leave for Childcare Participation, and as a way to promote understanding in the workplace of male employees who take childcare leave, that child-rearing is a life event for both men and women. We are also promoting the creation of an environment in which men can actively participate in childcare. Specifically, we hold seminars to support work-life balance, in which employees and their superiors can participate, to help employees balance their work and childrearing. In addition, we publish open newsletters about the experiences of men taking childcare leave. In recognition of these activities to support a balance of work and childcare and create a supportive work environment, we were awarded the Platinum Kurumin certification in November 2019.
In order to continue promoting male participation in childcare after April 2021, we have set a target of increasing the percentage of male employees taking childcare-related leave to 75% or more, and are promoting further efforts to support both male and female employees by establishing various personnel systems and conducting seminars about balancing work and childcare.

Kurumin certification mark

Various Support Systems for Creating a Pleasant Workplace

In addition to the systems stipulated in laws and regulations, we have established various other systems to create a rewarding and pleasant work environment. We continuously develop systems so that employees can have many options in working styles, by constructing systems that meet employees’ needs, or by establishing systems that exceed legal standards. The following systems are applicable to all employees, in principle.
Furthermore, we have prepared a handbook that summarizes these systems and posted it on our intranet to ensure that employees are fully aware of what they are and how to use them.

- **Expanding the Telecommuting and Flexible Working Time Systems**

The conventional telecommuting and flexible time systems were limited in terms of reasons, frequency, and working hours, but we are considering expanding their use to improve productivity and bring about flexible work styles during the COVID-19 pandemic.

- **Expanding the open recruitment system**

We have an open recruitment system to entice employees to take on challenges and increase inter-departmental transfers. In FY2021, while more than 80 employees applied, only about 10% of the applicants were transferred through the open recruitment system because the application conditions were too strict. From FY2022, we have eased conditions for applying based on the needs of employees, and greatly expanded the number of departments and positions available, renewing the system to raise awareness among more employees.

• Introduction of an internal challenge job system

Based on the needs of employees who wish to expand their horizons by learning about work in areas other than their own department, grow professionally, or deepen person-to-person exchanges across departments, we have introduced an internal challenge job system with the aim of challenging employees to work in another department for 20% of their prescribed working hours while still being in their current department, and raising employees' skills and providing career support. We plan to proceed with trial operation in limited departments in FY2022.

Support Systems

Systems that exceed the standards specified by labor-related laws	Childcare leave、shortened work hours for childcare, nursing care leave
Legally required systems	Shortened work hours for nursing care, family care leave, nursing care leave
Systems that promote flexible work styles	Flexible working hours, telecommuting system, hourly-basis annual leave, selective retirement system, support for transfer
Various leave and subsidy systems	Accumulated holidays, holidays to encourage employees to take part in child-raising, maternity protection leave, support of employee volunteer activities and bone-marrow donor leave, subsidies for day-care centers and baby-sitting, subsidies for sick child care, support for medical checkups
Other systems and benefits	Support for employees with cancer, use of company cars to pick up and drop off children, day-care center concierge (day-care center enrollment support system), re-employment for employees who have quit ONO, non-regular re-employment, etc.

TOPICS

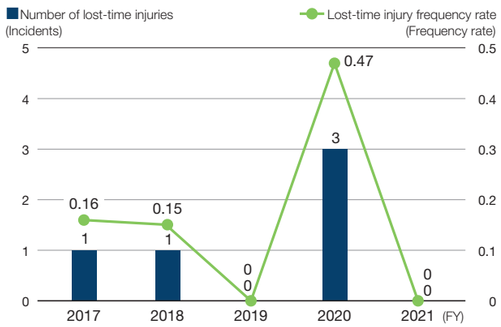
Support for Employees with Cancer

Employees who are diagnosed with cancer will work in the midst of many challenges, including regular hospital visits, side effects from various treatments, and financial problems. To support employees who wish to continue working while receiving cancer treatment, we have the following systems: a leave of absence extension system, an income guarantee system to eliminate non-earning periods, a system that allows employees to take their accumulated leave in half-day units, and a system that allows employees to work shorter hours for cancer treatment. Furthermore, we are implementing multifaceted initiatives to support employees with cancer, including the establishment of a workplace support system to ensure that employees with cancer receive adequate support in their workplace and disseminating information on this workplace support system thoroughly to our employees.

Commitment to Safety and Health

We have positioned minimizing environmental impact and ensuring the health and safety of our employees as major management objectives, and have established a basic policy for activities related to the environment, health, and safety.
Regarding health and safety at manufacturing bases and research institutes, we conduct risk assessments to identify issues regarding the risk of exposure to chemical substances handled at each site and risks that could lead to injury or accidents. The Safety and Health Committee meets regularly to address the issues identified and to continually improve the workplace environment. In addition, at manufacturing bases and research institutes, we conduct workplace inspections based on laws and regulations, such as for fire prevention measures and emergency equipment, the safe handling of machinery, the level of safe work practices, transportation work, and for organization, orderliness, and cleanliness. The findings are shared with the committee, which makes suggestions for improvement.
Health committees at the head office and other sites where they have been established, take various measures to maintain the health of employees based on the results of workplace environment measurements. At the semi-annual meetings of the Central Safety and Health Committee, the Safety and Health Committees and Health Committees from the various sites report on the status of health management initiatives, share information and exchange opinions on company-wide health issues, and discuss measures that contribute to health in a unified company-wide effort.
In FY2020, we installed AI-powered telematics (in-vehicle equipment with communication capabilities) in all our sales vehicles and have been working to improve employee awareness of safe driving and eco driving by detecting dangerous driving behavior. In addition to ensuring employee safety, we aim to reduce CO_2 emissions by decreasing traffic accidents and violations and improving fuel efficiency through eco-driving.
In addition, the Environment, Health, and Safety Promotion Office checks these activities at each business site and promotes continual improvement activities related to occupational health and safety.

Number of Lost-time Injuries and Lost-time Injury Frequency Rate



* Scope of data collection: Employees at all worksites in Japan
Lost-time injury frequency rate = (number of lost-time injuries / total number of actual working hours) × 1,000,000

Promoting Health and Productivity Management

For ONO to contribute to society through the creation of innovative drugs, it is important that all employees are mentally and physically healthy, that our worksites are places where individual abilities can be used to their utmost, and that the lives of employees and their families are satisfying. With the President, Representative Director's health up declaration we organized a Health Up Committee, and are engaging in the promotion of health and productivity management in a systematic way with our company, labor union, industrial health staff members, and health insurance society working together as a single team. These activities are being recognized, and in March 2022, we were recognized for the fourth consecutive year in the Health & Productivity Management Outstanding Organizations 2022 - White 500 (large enterprise category), promoted jointly by the Ministry of Economy, Trade and Industry (METI) and Nippon Kenko Kaigi. Also, for the second consecutive year we were in the top 50 companies among respondents (FY2021: 2,869 companies) and received high marks. We will continue to engage in health and productivity management through various activities.

2022 健康経営優良法人 Health and productivity ホワイト500

Health & Productivity Management Outstanding Organizations 2022 – White 500 (large enterprise category certification

Health Management Theme

1. Prevent Passive Smoking	• Prohibit smoking at company sites (since April 2019) • Raise awareness by conducting internal questionnaires, displaying original posters, etc. • Support employees trying to quit smoking by granting subsidies to see a doctor at a smoking cessation clinic, providing online programs for smoking cessation, etc.
2. Lifestyle-related Diseases and Cancer Measures	• Require employees to receive an annual health checkup (Employees over 35 years old undergo a complete medical checkup instead of a statutory health checkup) • Establish contract facilities for complete medical checkups in prefectures throughout Japan Percentage receiving complete medical checkups :99.8% (FY2021) • Support the cost of screening tests for each type of cancer • After the medical checkup, occupational health staff may provide health guidance, or recommend that employees visit a medical institution, or participate in specific health instructions, etc., as required
3. Mental Health Measures	• Provide internal training on mental health and have occupational health staff conduct individual consultations • Provide stress checks to all employees once a year • Establish an external free consulting service counter and have a system where employees can consult with experts via phone or e-mail in addition to face-to-face consultations
4. Develop a Self-care Environment	• Operate a portal site where employees can check the results of their complete medical checkup and regular health checkups at any time and Health Management Sites that compile information from the stress-check system and a health consultation counter • Provide healthcare application software for lifestyle correction and improvement • Conduct a walking campaign every year in the company • Conduct an annual session to measure body composition, blood vessel age, bone density, and more at major workplaces • Distribute health age notifications that are calculated based on the health checkup results and show the difference between health age and actual age

Health Management Support

In 2021, we opened a health management portal site to transmit and share information on health. We will promote efforts to encourage employees to consider self-care as their own issue by bringing together interviews of the president on health promotion and other health-related contents.
Also, we have linked the health management portal site with an existing site where employees can check the results of their annual complete medical checkups and periodic health checkups at any time via their terminals. In addition, the site includes information to help employees correctly understand checkup results and improve their lifestyle habits, and personalized advice on lifestyle according to their individual health conditions. We are working to enhance the contents of the portal site to raise employees' awareness of their health.

Message from the Director in Charge

Aiming to be a company where it is "natural" for each and every employee to take on management challenges as if they were their own.

I think Ono's goal in expanding human capital is to become a company that continues to enhance a culture that recognizes those who take on the challenge of difficult goals as their own, and don't give up if they fail, and a system that encourages them to do so.
For example, globalization, innovation, and DX are all important management issues for our company, but if they are left as big words, we will never find a solution. When each of us starts thinking and trying to make them "our own business," far-reaching issues will be brought closer to us and attempts to find solutions will begin. By continuing to support the tireless efforts of our employees, Ono hopes to become a company where it is natural for each and every employee to continue to seek challenges on a daily basis with a sense of excitement.

Toshihiro Tsujinaka
Member of the Board of Directors, Senior Executive Officer
Executive Director,
Corporate Strategy & Planning

TOPICS **Training Talent to be Innovative**

Started the Ono Innovation Platform to Nurture Talent

The Ono Innovation Platform

Supporting Employees' Taking on Challenges with a Program to Train Innovative Talent

In May 2021, we launched the Ono Innovation Platform, a program to develop innovative talent with the aim of inspiring each and every employee to challenge themselves. The program consists of three opportunities: learning, experiencing, and taking on challenges, and helps employees discover what they want to accomplish and take on challenges on their own initiative.
In order to focus our limited management resources on the creation and development of innovative new drugs, we have invested heavily in the creation of new innovations and developing the talent that will be the source of such innovations. Going forward, to dramatically grow into a global specialty pharmaceutical company, we need to develop more talent with the will and qualities to pursue innovation. In this program, we aim to create an environment where employees are excited to take on challenges and grow into innovators. In FY2021, the first year of the program, a total of 1,445 employees participated.

Overview of the Ono Innovation Platform

Opportunity for learning

Providing opportunities for knowledge, exposure, and experience

We operate the Innovation Cafe as an opportunity to learn, providing programs where it is possible to gain knowledge, be exposed to things, and experience things. We hold various seminars and workshops so employees can not only get basic knowledge, but can also learn on the job and gain practical skills. In FY2021 we held 10 programs on themes such as learning the latest trends in business and healthcare, and how to solve customers' issues with a customer-oriented approach. A total of 1,315 employees participated. In addition, we provided a full range of opportunities for learning about open innovation, which we focus on, such as by inviting outside experts to hold seminars.
Going forward, too, not only will employees gain knowledge and skills, we will provide them with opportunities where they can accomplish that which they themselves want to accomplish (WILL).

FY2021 Innovation Cafe Contents (partial)

Program	Course content	When held	No. of participants
Knowledge	Lecture by a venture capitalist, and discussion with the Executive Director of Research	June 2021	235
	Seminar on stimulating a business creation mindset	Sept. 2021	90
	Lecture by management experts on the danger of destructive innovation and countermeasures	Nov. 2021	194
	Lecture about the latest technology and digital trends	Feb. 2022	119
Exposure	Lecture and discussion with an entrepreneur in the healthcare field	June 2021	211
	Talk session by the person responsible for our company's new businesses	Aug. 2021	120
Experience	Workshop on hypothetical proposals and verification for customer issues	July to Oct. 2021 (5 days, half day each)	69

Opportunity for experience

Nurturing the capability to make decisions and act via a program to dispatch employees to venture companies

We established a relocation program called V2V (Voyage to Venture) so employees can gain experience in a way that is not possible in the company. Employees leave behind their affiliation with ONO and, while they test their own capabilities, they nurture a mind to continually take on challenges and grow by thinking on their own and acting in an environment without precedent or results, which is a venture company.
From October 2021, five employees were dispatched to venture companies for one year. At the venture companies they are contributing to developing business, and when they return to ONO, they will plow the experiences they gained at the venture businesses back into ONO, strengthening our organization.

Venture company dispatch results

Venture companies	Venture companies (business details)
NPO Japan Kodomo-Shokudo Support Center "MUSUBIE"	cooperates with businesses and supports the activities of organizations that support children's dining rooms
K-three Inc.	develops and operates products that strengthen citizen communication
General Incorporated Association Platform for Sustainable Education and Community	provides support to regional high school students for entry into higher-level schools in other prefectures
Lightblue Technology, Inc.	develops image analysis software to contribute to mechanization and automation
camelove, Inc.	provides subscriptions to camera equipment

Comment from a dispatched employee

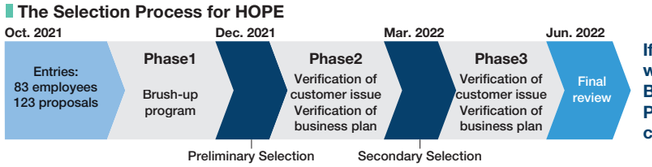
I was placed in a position where I was required to think and act on my own, which made it an opportunity for me to improve the speed of my growth. After returning to Ono, I would like to share this experience within the company and link it to my taking on new challenges at Ono.
(Business Strategy Division, 30s)

Opportunity for taking on challenges

Holding of a Business Contest as a Place for Employees to Take on Challenges

We held a "HOPE" business contest as an opportunity for employees to voluntarily take on the challenge of putting what they have learned and experienced into practice. The name HOPE reflects our belief that our innovation leads to hope for patients and their families.
For our first contest in 2021, we received 123 proposals from 83 employees. The business proposals were based on the employees' own original experiences and customer issues, such as solutions to support patients in their fight against illness, and support services for childcare. After a final review that will include top management, the selected themes will continue to be examined with the aim of commercialization and the creation of new innovations.

The Selection Process for HOPE



If the proposal passes, it will be moved to the New Business Planning and Promotion Division and continue to be verified

この挑戦は希望をつくる
HOPE
OIP Challenge Program

Comments from HOPE 2021 Participants

Participants commented such as "I started to want to make a difference in the world," "it gave me the experience of thinking as hard as I could and making decisions on my own," and "I was inspired by people who were willing to take on challenges." HOPE has become an opportunity for participants to stimulate each other, enhance their perspectives, and draw out the potential of employees. We will continue to develop talent who will proactively tackle various issues.

Online review

Material Issue 9

Intellectual Property Strategies

Management of Priority Issues

Reason for being a priority issue	**Intellectual property (IP) is one of the most important intangible assets for R&D-based pharmaceutical companies. To deliver value to patients and generate financial value, IP (inventions), which are intangible assets, must be patented and given concrete form as innovative drugs. Creating, maintaining, and utilizing IP are important issues for maximizing its value.**
Vision over the medium to long term	**In our research and development activities, we ensure that IP that leads to innovative pharmaceuticals is licensed, and we create new IP by leveraging internal and external IP to create financial value.**
Indicators	• **Products and the R&D pipeline** • **Amount of IP in use (IP landscape)**
Major initiatives	• **Creating and maintaining IP to create innovative new drugs** • **Strengthening the inventive process to lengthen the life of launched products and products in development, and filing patents effective for LCM*** • **Utilization of IP (IP landscape) through integrated analysis with market and business information to determine the appropriateness of in-licensed products, new businesses, investments, etc.** * Lifecycle management

Basic Approach to IP

IP is one of the most important intangible assets of a pharmaceutical company. As a pharmaceutical company at the forefront of rapidly changing science, the IP generated by the company is also changing daily. In order to deliver value to patients, pharmaceutical companies need to ensure that their IP (inventions) are patented and given concrete form in the form of innovative drugs. This is the only way for intangible assets to have financial value.
In addition, advances in techniques for analyzing information and the proliferation of big data have led to increasingly diverse ways of using IP. For example, by using both internal and external IP, important information can be obtained for considering M&A, the introduction of compounds and drug discovery technologies, and new businesses.
Our experience in creating many innovative drugs has given us a wealth of unique IP, such as patents and know-how related to prostaglandins and other lipid-based drug discovery, as well as cancer immunology surrounding PD-1. These are not only our core technologies themselves, but also important factors in attracting partners. We believe that new IP will emerge from open innovation based on our highly unique IP, leading to the creation of new innovative drugs.
At the same time, through company-wide IP awareness activities, employees learn the importance of respecting the IP of others, and at the same time, through extensive research tailored to the stage of each project, we take great care not to infringe on the patents of others.

Important Themes (Ideas) in Our IP Strategy

At ONO, creating, maintaining, and utilizing IP are important ideas in our IP strategy.
Regarding the creation of IP, we believe that corporate value can be enhanced by strengthening the process of inventing things such as innovative drugs and fundamental technologies, and by continuing to file appropriate patent applications.
Regarding the maintenance of IP, as our overseas business expands, we believe that we can increase the value of IP by acquiring and maintaining optimal patent and trademark rights based on the differences in systems in each country and the unique circumstances of each product or project.
Regarding the utilization of IP, we believe that analyzing internal and external IP together with market and business information can provide strategic options that contribute to management decisions and lead to the expansion of our IP.

Initiatives for Realizing the Important Themes

Our IP strategy is positioned as a concrete means to form a cycle of IP creation and value enhancement by creating a relationship and continuity among the three themes of IP. Our IP Strategy Department plays a central role in securing and maximizing the future financial value of IP generated from day-to-day research and development activities. The department is not only involved in the passive process of acquiring IP rights, but is also deeply involved in the innovation process of research and development, picking up all of our unique IP and ensuring that core technologies that lead to increased corporate value are protected and acquired as rights. We will also take a firm stand against any actions that may lead to the destruction of our IP.
Furthermore, in actively utilizing our IP to maximize its financial value, it is important to consider not only the rights aspect, but also the information aspect, including the IP of other parties. In other words, IP, which is information with financial value, must be disclosed to the public in order to obtain rights, and it is important to analyze the disclosed information of others and pick up drug discovery technologies and know-how that are useful for the Company's activities. We make strategic investments in appropriate partners and technologies to more reliably monetize and maximize the value of our IP.
In order to realize these themes and promote our growth strategy, we believe that a company-wide cooperative system is key, and our IP Strategy Department is working to create a system that allows close communication with related departments. In addition, we continually conduct educational activities tailored to the circumstances of each department to raise awareness of IP among all employees. We have also established rules providing rewards for employee inventions to provide an incentive to create IP.

Investing in IP that Goes Beyond the Realm of Pharmaceuticals

In today's society, where the boundaries between industries are blurring, the pharmaceutical industry, which used to be a relatively independent industry, is no exception, and it is now merging with devices and applications, making the industrial structure increasingly complex and sophisticated. In this era of transition from competition to collaborative creation, the creation of new value through open innovation is the key to growth.
We have long been active in open innovation and have produced a number of innovative pharmaceutical products through these efforts. We will continue to maximize the value of our IP, which protects our core technologies, and we will also strategically invest in IP obtained through collaboration with others. Furthermore, we will also actively invest in the acquisition of IP that is not limited to pharmaceuticals, but is expected to generate synergies with our IP. We will contribute to the health of mankind by giving concrete form to this IP as products that are unique and have a lot of value for mankind.

Strengthening the Management of the Product Lifecycle

Original drug manufacturers need to leverage their IP, such as patents and know-how, to ensure that their drugs are used to their fullest potential and that as many patients as possible can benefit from them. Our IP Strategy Department is involved in each project as a member of the team from the very beginning. To maximize the value of all of our products and developed compounds, we are constantly looking at creating new IP from a lifecycle management perspective as well.

IP Strategy and Branding

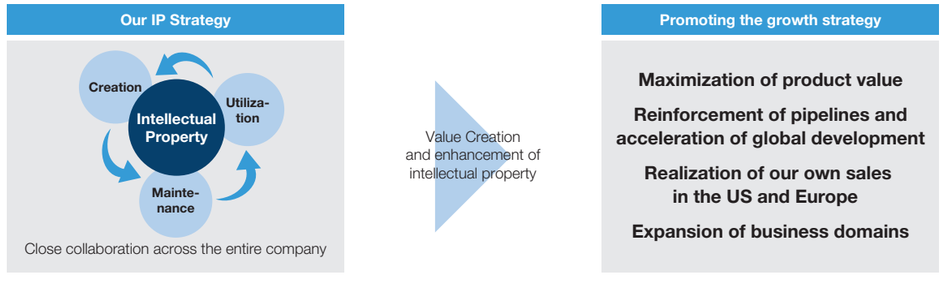
IP also plays an important role in branding activities. In addition to global trademark protection of pharmaceutical brand names and corporate/product logos, IP mix strategies that combine multiple intellectual property rights to protect products and services in new businesses other than pharmaceuticals will become even more important in the future.
Unlike pharmaceuticals, where substance patents are overwhelmingly effective, new businesses need to strategically apply for and obtain not only patents and trademarks, but also designs and utility models. We will work to acquire intellectual property rights from various perspectives, not only from the perspective of product protection, but also from the perspective of strengthening brand power.

Our Policies on Intellectual Property Rights and on Patents in Countries with Limited Access to Healthcare

To deliver our innovative drugs to more patients worldwide, we neither apply for nor enforce patent rights in Least Developed Countries defined by the United Nations[1] and Low Income Countries defined by the World Bank[2]. Also, with the exception of some countries, we do not file patent applications or enforce rights in Lower Middle Income Countries defined by the World Bank[3]. Furthermore, we continually explore the potential applications of our patented compounds in tropical diseases (NTDs) and other diseases.

*1 Least Developed Countries defined by the United Nations: https://www.un.org/development/desa/dpad/least-developed-country-category.html
*2 Low Income Countries defined by the World Bank: https://data.worldbank.org/income-level/low-income
*3 Lower middle Income Countries defined by the World Bank: https://data.worldbank.org/income-level/lower-middle-income

Implementing Growth Strategies through IP Strategies



Material Issue 10

Open Innovation

Management of Priority Issues

Reason for being a priority issue	We have been able to link the seeds of original drug discovery found through collaborative research with academia and other organizations to the creation of groundbreaking new drugs. The ability to realize open innovation is one of our core strengths and is the lifeline to continually create innovative new drugs in the future.
Vision over the medium to long term	Based on the original seeds discovered through collaborative research with world-class researchers, the company is continually creating new drug candidate compounds through drug discovery alliances with biopharmaceutical companies
Indicators	• The number of research collaborations
Major initiatives	• Promote collaborative research with world-class researchers, and drug discovery alliances and joint research with biopharmaceutical companies focusing on priority research areas • Network with world-class researchers through the research grant activities of the Ono Pharma Foundation in the U.S. • Strengthen competitiveness in drug discovery and R&D activities through strategic investments by Ono Venture Investment

The Characteristics of ONO's Open Innovation

Even before the widespread use of the term "open innovation", ONO was already involved in the discovery of new drug seeds through partnerships with universities and other research institutions, and had been using these seeds as a starting point to create innovative new drugs. The Discovery Research Alliance Department and the Business Development Department cooperating with Research Centers and Development Divisions are presently taking the lead in collaborating on research with world-class researchers and forming drug discovery alliances with biopharmaceutical companies with a focus on our priority research areas, and are actively in-licensing various drug candidates. We are working on these collaborative activities with a sense of urgency in order to obtain cutting-edge research data before our competitors and leverage this data in expedited drug discovery. We have sent Japanese researchers with practical experience in drug discovery to our locally incorporated subsidiaries in the US and UK, and they are visiting world-leading researchers and biopharmaceutical companies in Europe and the US to launch more new partnerships. Currently, more than 200 research collaborations and drug discovery alliances are in progress globally.

Collaborative research and drug discovery alliances from FY2021

- **Research Alliance Agreement with Healx of the U.K. (August 2021)**

The goal is to create innovative therapeutics to meet unmet medical needs by utilizing the company's proprietary artificial intelligence technology.

- **Drug Discovery Alliance Agreement with MiraBiologics Inc. (August 2021)**

The goal is to create next-generation biologics utilizing the company's proprietary LassoGraft Technology®, a new technology that combines the company's proprietary cyclic peptide discovery method with protein engineering.

- **Continuation of Drug Discovery Collaboration Agreement with Vanderbilt University (December 2021)**

Based on the drug discovery collaboration agreement signed with Vanderbilt University in November 2015, we are working to discover compounds to validate the hypothesis that unexplored ion channels or transporters are potential drug targets, and based on the results of this validation, create new drug candidates for the treatment of novel central nervous system diseases.

- **Drug Discovery Collaboration Agreement with Neurimmune of Switzerland (January 2022)**

The purpose of this new collaboration is to discover antibody drugs for drug targets in the neurodegenerative disease area by utilizing Neurimmune's proprietary antibody discovery approach, Reverse Translational Medicine™ (RTM™) technology. In November 2017, we entered into a drug discovery collaboration agreement with the company in this area and are working to create human monoclonal antibodies for targets different from those in this new agreement by utilizing RTM technology.

- **Drug Discovery Collaboration Agreement with Iktos of France (March 2022)**

The objective is to create innovative small molecule compounds for drug targets presented by ONO by utilizing the company's proprietary artificial intelligence (AI) drug discovery technology that designs new chemical structures.

- **Development and License Agreement with Numab, Switzerland (March 2022)**

As a result of the agreement signed in 2017 for the creation of multi-specific antibodies in the field of cancer immunology, we were able to obtain the desired antibodies, and we exercised our option rights and entered into a new development and license agreement with Numab.

- **Discovery Collaboration Agreement with Domain S.A. of France and Montréal University of Canada (April 2022)**

The objective is to apply the proprietary GPCR drug discovery platform and expertise in medicinal chemistry and pharmacology for GPCR drug discovery of Domain and Montreal University to create novel small molecule compounds targeting our selected GPCRs in the area of metabolic diseases.

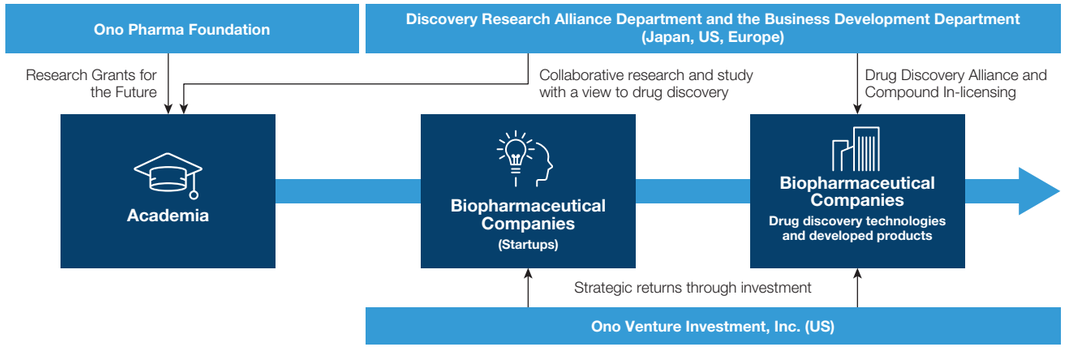
Ono Pharma Foundation

Ono Pharma Foundation in the U.S. was established in 2017. The Foundation funds academic research that will generate breakthroughs in the life sciences and promotes the creation of a community of researchers. In the four years since the foundation was established, it has supported 20 research projects and provided a forum for researchers to interact. Currently, it is focusing on the area of "chemical biology," which is of global interest as an area that integrates chemistry and life sciences and is expected to lead to the creation of innovative new drugs. In fiscal year 2021, three research projects that pave the way for new approaches to drug discovery were selected for funding.

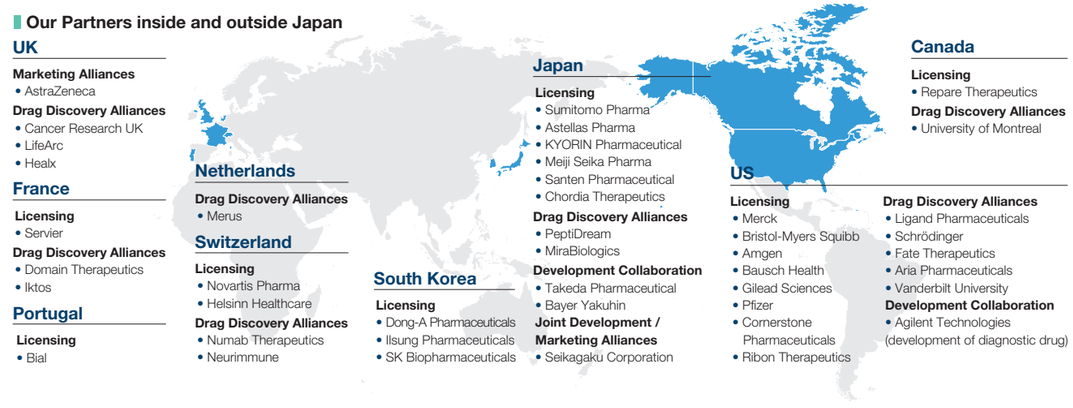
Ono Venture Investment, Inc.

In FY2020, we launched a U.S. subsidiary, Ono Venture Investment, Inc. We expect to further enhance our competitiveness in drug discovery and R&D via strategic investments in research on drug targets and advanced technologies that lead to breakthrough new drugs. In fiscal 2021, we expect to invest in the following companies: Curreio, Inc., which is developing a drug discovery business based on structural analysis using cryo-electron microscopy; Immunitas Therapeutics, a U.S. company developing novel immuno-oncology therapeutics using antibody drugs, and Arbor Biotechnologies, a U.S. company developing therapeutic drugs using novel gene editing technology.

Open innovation that supports drug discovery into the future



Our Partners inside and outside Japan



Material Issue 11

Promotion of Diverse Partnerships

Management of Priority Issues

Reason for being a priority issue	Our business is based on partnerships with diverse stakeholders. We will further strengthen networks and relationships of trust and cooperation with our partners and strengthen our brands, and thereby expand partnership opportunities and achieve growth strategies.
Vision over the medium to long term	We strengthen company brands, etc. and accelerate business activities to promote partnerships with diverse stakeholders.
Indicators	• The number of companies with which in-license and out-license agreements are concluded • Number of joint research projects • Other partnering results
Major activities	• Collaborating with partner companies in the research and development and sale of drugs • Building relationships with local communities and municipalities • Building cooperative relationships with the suppliers • Building relationships with many partners for our business

Building partnerships that are essential to our business activities

Building partnerships with diverse stakeholders is extremely important in order to aggressively and strategically pursue our business activities, such as the discovery of innovative pharmaceuticals and the promotion of new businesses. We will build stronger relationships of trust and cooperation with our current partners, which will lead to sustainable growth. Building new networks is also essential, and we will continue to expand partnership opportunities by strengthening our own brands.
In R&D, we have created many innovative new drugs through open innovation, and we will continue to collaborate with academia and many biopharmaceutical companies in our research efforts. We have also formed partnerships with many companies for the in-licensing and out-licensing of new drug candidate compounds, and we will continue to strengthen our relationships to expand our development pipeline. In the production of pharmaceuticals, too, we will continue to deliver high-quality drugs to many patients by strengthening our partnerships with many suppliers. In addition, in areas where our plants and laboratories are located, we are focusing on local activities and actively working with local communities. Furthermore, we are also working with NPOs and NGOs to contribute to improving access to healthcare overseas.
Our many activities for sustainable growth can not be completed by our company alone. We will continue to work with an increasingly diverse array of partnerships to promote our business activities.

Strengthening Our Own Brands to Expand Partnerships

We are also working to strengthen our own branding in order to expand opportunities for diverse partnerships. We believe that our history of taking on challenges and the culture of innovation we have created in the healthcare industry are among our intangible assets. By ensuring that these assets are properly understood by our stakeholders, we are expanding opportunities for global partnerships and strengthening collaboration.

Major Partnership Activities

Collaboration with Companies

We have newly entered the health food and foods with function claims business by using our knowledge in the lipid area, which was cultivated through pharmaceutical research. At the start of the business, we jointly developed and successfully commercialized a functional lipid product using functional ingredients derived from marine products with Maruha Nichiro Corporation.
By effectively using each other's knowledge and business know-how as trusted partners, the two companies will pioneer the field of prevention and pre-illness, which lies between food and pharmaceutical products, and deliver lifelong health to more people.

Press conference for the collaboration in the field of health food with Maruha Nichiro Corporation

Cooperation with Biopharmaceutical Companies

We are actively investing not only in the field of prescription pharmaceuticals, but also in the field of healthcare. Through investment and collaboration with biopharmaceutical companies, we hope to contribute to the extension of healthy life spans and the realization of a sustainable society.
In FY2021, we invested in BMG Incorporated, a biomaterials venture company originating from Kyoto University, which is developing medical adhesives that can be degraded and absorbed in vivo.
In addition, to confirm the safety and efficacy of combination therapy with OPDIVO and chemotherapy for gastric cancer patients, we collaborated with the Prime Research Institute for Medical RWD, Inc. (PRiME-R,Inc.). We are engaged in a company-led, large-scale multi-institutional clinical study utilizing CyberOncology®, PRiME-R's input support system that manages and integrates standardized and structured real-world data in routine cancer care.

Cooperation with Local Communities

We have concluded cooperative agreements with Osaka Prefecture and other local governments to promote health and wellness. In November 2021, we concluded an agreement to collaborate and cooperate with Osaka Prefecture to promote the health of Osaka residents. In February 2022, we also joined the Osaka Smart Senior Life Demonstration Project Promotion Council, which is promoted by Osaka Prefecture and 23 private companies.

Collaborating with NPOs and NGOs

As part of our efforts to support medical systems, we provide assistance to NPOs and NGOs such as Japan Committee, Vaccines for the World's Children, Japan Heart, and People's Hope Japan. We contribute to global medical care and health through activities such as delivering medicines to those who have difficulty receiving necessary medical care due to lack of medical infrastructure, poverty, etc., and supporting the education of students who aim to become medical professionals, thereby further promoting the realization of our corporate philosophy of Dedicated to the Fight against Disease and Pain.

Licensing Activities

In addition to strengthening our pipeline through our in-house research, we are also actively pursuing licensing activities with the aim of in-licensing new candidates under development by pharmaceutical or biopharmaceutical companies around the world. Our in-licensing efforts focus on compounds deemed to be strategic and efficient from a business perspective, and compounds deemed to be viable from the perspective of diseases with high medical needs. In FY2021, although we didn't implement any in-license or out-license partnerships, we continue to search for opportunities to in-license drug candidate compounds from around the world. Also, when in-licensing we are working to acquire development and marketing rights not only in Asia, but also globally, as the company has an eye to global expansion.

Licensing Activities

Agreement date	Licensee	Product name and development code	Licensing details	Disease*	Development status
Sept. 2011	KAI Pharmaceuticals (US) (currently Amgen)	PARSABIV	License to develop and commercialize the calcium sensing receptor agonist, generic name: Etelcalcetide, in Japan	Secondary hyperparathyroidism under hemodialysis	On sale in Japan
Apr. 2013	Bial (Portugal)	ONGENTYS	License agreement to develop and commercialize the long-acting COMT (catechol-O-methyltransferase) inhibitor, generic name: opicapone, in Japan	Diurnal variability of symptoms in Parkinson's Disease	On sale in Japan
Dec. 2013	AstraZeneca (UK)	FORXIGA	Co-promotion agreement for a sodium-glucose cotransporter 2 (SGLT-2) inhibitor, generic name: dapagliflozin, in Japan	Type 2 diabetes, type 1 diabetes, chronic heart failure, chronic kidney disease	On sale in Japan
May 2017	Array Biopharma (US) (currently Pfizer)	BRAFTOVI	License agreement to develop and commercialize MEK inhibitor Binimetinib and BRAF inhibitor Encorafenib in Japan and Korea	Malignant melanoma, colorectal cancer	On sale in Japan and Korea (in Korea, only for colorectal cancer)
		MEKTOVI		Malignant melanoma, colorectal cancer	On sale in Japan
Aug. 2017	Seikagaku Corporation (Japan)	JOYCLU	Agreement on co-development and co-marketing of a therapeutic agent for osteoarthritis, generic name: diclofenac etalhyaluronate, in Japan	Osteoarthritis	On sale in Japan
July 2019	Forty Seven (US) (currently GileadSciences)	ONO-7913	License agreement to develop and commercialize the anti-CD47 antibody ONO-7913/Magrolimab in Japan, Korea, Taiwan and ASEAN countries	Blood cancer Solid tumors	In P3 in Japan In P1 in Japan
Oct. 2020	SK Biopharmaceuticals Co., Ltd. (South Korea)	ONO-2017	License agreement granting ONO development and commercialization rights in Japan for anti-epileptic drug Cenobamate	Epileptic seizures	In P3 in Japan
Dec. 2020	Chordia Therapeutics Inc. (Japan)	ONO-7018	License agreement granting ONO global rights to develop, manufacture and commercialize mucosa-associated lymphoid tissue lymphoma translocation 1 (MALT1) inhibitor drug CTX-177 and its associated compounds	Lymphoma	Preparing for global trials
Feb. 2021	Ribon Therapeutics, Inc. (US)	ONO-7119	License agreement granting ONO rights in Japan, South Korea, Taiwan, and ASEAN nations to develop and commercialize poly-ADP-ribose polymerase 7 (PARP7) inhibitor RBN-2397	Solid tumors	In P1 in Japan

* Target diseases and indications vary.

Value Preservation

**We also believe that it is important to take initiatives that do not damage the value we have created and cultivated to date.
As a pharmaceutical company, ensuring the reliability and safety of our products and a stable supply are extremely important values.
We also recognize that the supply chain, human rights, and compliance are also matters that should be emphasized.
We are also taking the lead in the industry in protecting the global environment.
Here, we introduce some of our important initiatives regarding the protection of these values.**

Material Issue 12

Assurance of Product Reliability and Safety

Management of Priority Issues

Reason for being a priority issue	Quality assurance and safety management of pharmaceutical products are fundamental to our business. If a problem were to occur in either of these areas, it would be a serious risk that could violate our corporate philosophy, harm the health of patients, and significantly reduce our social value and raison d'être.
Vision over the medium to long term	A global specialty pharmaceutical company with established organizational systems for appropriate quality assurance and safety management.
Indicators	• Completion of quality assurance and safety management systems for global business • Zero significant findings from regulatory inspections • Zero recalls of Ono products
Major initiatives	• Create appropriate global systems for product quality and safety management • Establish an operation to study safety signals of investigational products • Establish a system to respond to inspections of products for the U.S. market in preparation for the launch of ONO-4059 in the U.S.

Initiatives for Ensuring the Stable Supply of High Quality Pharmaceutical Products

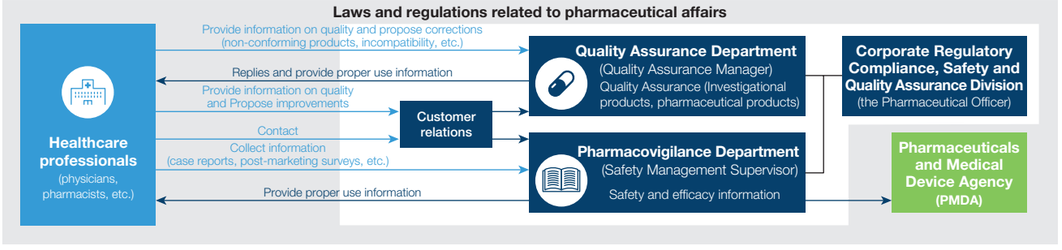
To supply high-quality pharmaceutical products, ONO manufactures all drugs under an appropriate quality assurance system both in our plants and in outsourced plants. At our plants, we established a quality assurance system complying with global regulations, such as GMP (Good Manufacturing Practice; standards for manufacturing and quality control systems) in each country and PIC/S GMP, etc. When outsourcing, we confirm that appropriate manufacturing control and quality control are implemented by conducting periodic quality audits. In quality assurance, we don't just meet the legal requirements as a manufacturer and distributor, we have established a pharmaceutical quality system. Through continuous improvement of this system, we strive to provide high quality pharmaceutical products from the perspective of patients, caregivers, and healthcare professionals.
We strive to provide high-quality products through multiple measures, e.g. training for all employees engaging in production and quality assurance, enhancing the quality system based on the ICH Q10 Pharmaceutical Quality System, and the development of risk management systems at manufacturing sites.
To ensure that these quality assurance and supply activities can be carried out throughout the entire group, including overseas, we are working to build systems and establish a global structure.

Web Quality System and Training System
https://www.ono-pharma.com/company/business_activities/manufacturing.html

Initiatives to Ensure Safety

In terms of safety management, ONO establishes a risk management plan for each drug, gathers and manages safety (adverse reaction) information. We evaluate the details of gathered information and take safety measures, such as the revision of the "Precautions for Use" text accompanying pharmaceutical products and provide information related to the proper use of drugs, etc. as necessary. After the launch of the anticancer drug OPDIVO, safety information in and outside Japan increased drastically.
We strive to use it properly by evaluating it based on the opinions of an external expert committee on proper use and other medical experts and then disseminate it through various information delivery materials, academic societies, medical journals, etc.
In safety management activities, too, we are working to build a system and develop a global structure so that the entire group, including overseas offices, can conduct these activities.

Safety Information Gathering and Management System



Material Issue 13

Stable Supply of Products

Management of Priority Issues

Reason for being a priority issue	The provision of a stable supply of our drugs to patients who need them is a basic duty of our business.
Vision over the medium to long term	Our products are supplied stably to patients throughout the world.
Indicators	• No out-of-stock incidences
Major activities	• Building a global product supply system • Implementing risk management for overall operations related to product supply, such as strengthening response to BCP, maintaining proper inventory, etc. • Examining mid- to long-term stable production systems, including increased production efficiency and the use of CMO, etc.

Management of the Supply Chain

In order to ensure a stable supply of high-quality medical products as a pharmaceutical company involved in health, ONO manufacturers all its drugs under an appropriate manufacturing and quality assurance system both in our plants and in outsourced companies. Although the manufacturing locations and suppliers of drug substances (APIs), raw materials, and formulations of pharmaceuticals are spread throughout the world and the supply chain has become increasingly complex, we are striving to supply pharmaceuticals that can be used safely by patients in compliance with the regulations and compliance requirements of each country and region.
In addition, we are working to further expand our supply chain for self-sales in Europe and the United States. We set appropriate inventory levels of APIs and products for each product according to the manufacturing lead time, delivery time, and number of manufacturing bases for APIs, raw materials, and formulations. By constantly monitoring and maintaining appropriate inventory levels, we strive to ensure a stable supply of products even when production is temporarily halted due to problems during manufacturing.

Initiatives to Keep Facilities Operating

To ensure stable production, we formulate and implement maintenance plans that combine preventive and post-maintenance for manufacturing equipment for oral and injectable drugs, air conditioning systems, pharmaceutical water systems, and analytical equipment used for various tests. Preventive maintenance involves replacing major parts of equipment and facilities and setting the frequency of periodic maintenance to avoid breakdowns due to age-related deterioration. In addition, to prepare for unexpected breakdowns, for parts that take a long time to be delivered, we keep spare parts in-house so we can quickly restore production and analytical equipment.
In addition, we have begun working on predictive maintenance of facilities, and have begun developing a system to prevent outages due to unexpected facility problems. This involves using AI to analyze the various types of electrical data, such as pressure and temperature measured during operation, and predicting failures.
If effective predictive maintenance can be established, it will lead to improved productivity by reducing the frequency of periodic inspections. We are also working to stabilize quality through the use of digital data, and are considering the use of digital data and AI in the visual inspection process of products, which requires the recruitment of a large number of inspectors.

Stable Supply of Products in Disasters

To ensure continuous supply of products even in the event of a large-scale disaster, we have formulated a crisis response and business continuity manual, and conduct periodic drills based on the manual.
From the viewpoint of stable supply, having multiple manufacturing bases is also important, and we have dispersed our own manufacturing bases to two locations: the Fujiyama Plant in Shizuoka Prefecture and the Yamaguchi Plant in Yamaguchi Prefecture. Furthermore, by actively outsourcing, we are diversifying risks in the event of a large-scale disaster. We have already established a system that enables us to produce Opdivo, our main product, at our two manufacturing bases, Fujiyama and Yamaguchi, and we are carrying out risk analysis for other products, and considering production at multiple manufacturing bases for other products as necessary.
In addition, we are working to secure multiple manufacturing bases for APIs because all APIs are outsourced. Risk assessments are also conducted for supply chains other than products and APIs, and efforts are being made to ensure a stable supply.


Fujiyama Plant


Yamaguchi Plant

Material Issue 14

Protection of Environment

Management of Priority Issues

Reason for being a priority issue	Our businesses are supported by a sound global environment. We believe that reducing the burden from our business activities on the global environment and local communities is an important corporate responsibility.
Vision over the medium to long term	Under “ECO VISION 2050,” we aim to become a leading environmentally friendly company in the pharmaceutical industry, and will strive to maintain a rich global environment for future generations so that people can have a healthy and sound society.
Indicators	Achievement of 2030 goals • Achievement of a decarbonized society • Achievement of a water-recycling society • Achievement of a resource-recycling society
Major initiatives	• Reduce greenhouse gas emissions and increase share of renewable energy in total electricity consumption • Reduce use of water resources • Reduce the final landfill rate of our industrial waste

Environmental Management

Global Environment Policy and Environmental Vision

ONO has established a Global Environment Policy as a guideline for our environmental activities. We formulated our medium- and long-term environmental vision for 2050, the “Environment Challenging Ono Vision (ECO VISION 2050),” based on this policy. We recognize our corporate social responsibility for the environment and engage in activities to realize an abundant global environment by prioritizing the environment in all business areas.

Web Global Environment Policy and Medium- and Long-term Environmental Vision
https://sustainability.ono-pharma.com/en/themes/106

Targets (Medium- and Long-term Targets and Annual Target) and Results

Key priority	Indicators	Medium- and long-term targets	Target in FY2021	FY2021 results and progress
Realization of a decarbonized society	Greenhouse gas emissions (Scopes 1 + 2) (Market-based CO_2 emissions[1])	55% reduction by FY2030 and reduction to zero by FY2050 <Compared to FY2017>	Reduce by 16.8% or more from FY2017	23.6 kt-CO_2 (Reduce by 20.9% from FY2017[2])
	Greenhouse gas emissions (Scope 3)	30% reduction by FY2030 and 60% reduction by FY2050 <Compared to FY2017>	Reduce by 6.9% from FY2017[3]	49.8 kt-CO_2 (Reduce by 33.7% from FY2017[3])
	Green energy use rate in all electricity consumption	Increase to 55% or more by FY2030 and increase to 100% by FY2050	16.8% or more	17.0%
Realization of a water recycling society	Water resource consumption (water intake)	15% reduction per production volume unit by FY2030 <Compared to FY2017>	Less than or equal to the previous year’s level (FY2020: 245.6 thousand m^3)	219.4 thousand m^3 (Increase by 25.6% per production volume unit from FY2017)
Realization of a resource recycling society	Final landfill rate of industrial waste	1% or less every year[4]	1% or less	0.04%
	Industrial waste volume	15% reduction per production volume unit by FY2030 <Compared to FY2017>	Less than or equal to the previous year’s level (FY2020: 502.7 t)	479.1 t (Increase by 20.3% per production volume unit from FY2017)
	——	Promote reductions in the environmental impact in business activities	——	Reduce environmental impact by changing product package materials and packaging form, etc.

1 Market-basis greenhouse gas emission volumes are calculated based on emissions coefficients published by each electric power company.
2 Greenhouse gas emissions (Scopes 1 + 2) do not include CO_2 offsets from voluntary credits (carbon neutral city gas purchases). If these voluntary credits are included, greenhouse gas emissions (Scopes 1 + 2) would be reduced by 22.9% compared to FY2017.
3 Scope 3 is calculated based on FY2020 emissions since the data of our major suppliers and pharmaceutical wholesalers for FY2021 had not yet been published at the time we made our calculations.
4 ONO’s ZERO Emission standard is that the percentage of non-recycling (landfill and simple incineration) is 1% or less of the total amount.

Medium- and Long-term Targets and Fiscal Year Targets

In FY2019, we set three priority items, Realization of a decarbonized society, Realization of a water recycling society, and Realization of a resource recycling society, and set specific medium- and long-term targets for greenhouse gases, water, and resource recycling, to achieve “ECO VISION 2050.” Also, each year we set annual targets based on progress. We are also promoting measures to conserve biodiversity, in consideration of society’s demands.

Promotion of Environmental Management

We have an environmental management system where the President and Representative Director has overall responsibility. Under the President and Representative Director, the Corporate Executive Officer / Head of Corporate Communications, who is the chairperson of the CSR Committee, actually handles company-wide environmental management. The Environmental Management Committee, which consists of the responsible members for environmental management in each department, engages in both identifying the actual current situation and in promoting management of the system and the CSR Promotion Section handles the operation of this Committee. In particular, regarding the three priority items of Realization of a decarbonized society, Realization of a water recycling society, and Realization of a resource recycling society, the Environmental Management Committee’s subcommittees (the climate change subcommittee, water recycling subcommittee, and resource recycling subcommittee) investigate initiatives to reduce the environmental burden, and establishes targets for each site to achieve for the fiscal year, and handle promotion.
Each of the manufacturing sites and research institutes with a large environmental burden has a subcommittee. The manufacturing sites have ISO 14001 certification and work to reduce their environmental impact. The progress of these efforts is reported at least once a year at the Executive Committee, which is chaired by the President and Representative Director.
In addition, to reduce environmental risks, employees involved in operations that could have an impact on the environment receive the necessary training on environmental management. We also have a structure to minimize environmental impact by conducting drills and providing on-site training for emergency response to accidents and by formulating various manuals.

Web Environmental Management System and Status of Acquisition of ISO 14001 Certification
https://sustainability.ono-pharma.com/en/themes/107#957

Achieving a Decarbonized Society

Medium- and Long-term Goals for Achieving a Decarbonized Society

One of our goals to realize a decarbonized society, Reduction of greenhouse gas emissions (Scopes 1 + 2) to zero by FY2050 is categorized as the most aggressive goal for the “1.5°C target” by the international initiative “Science Based Targets initiative (SBTi).” To achieve this challenging goal, we are promoting various initiatives throughout the company. Regarding the energy we use, we are increasing the use of renewable energy in line with RE100 (joined in June 2020).

SCIENCE BASED TARGETS
DRIVING AMBITIOUS CORPORATE CLIMATE ACTION

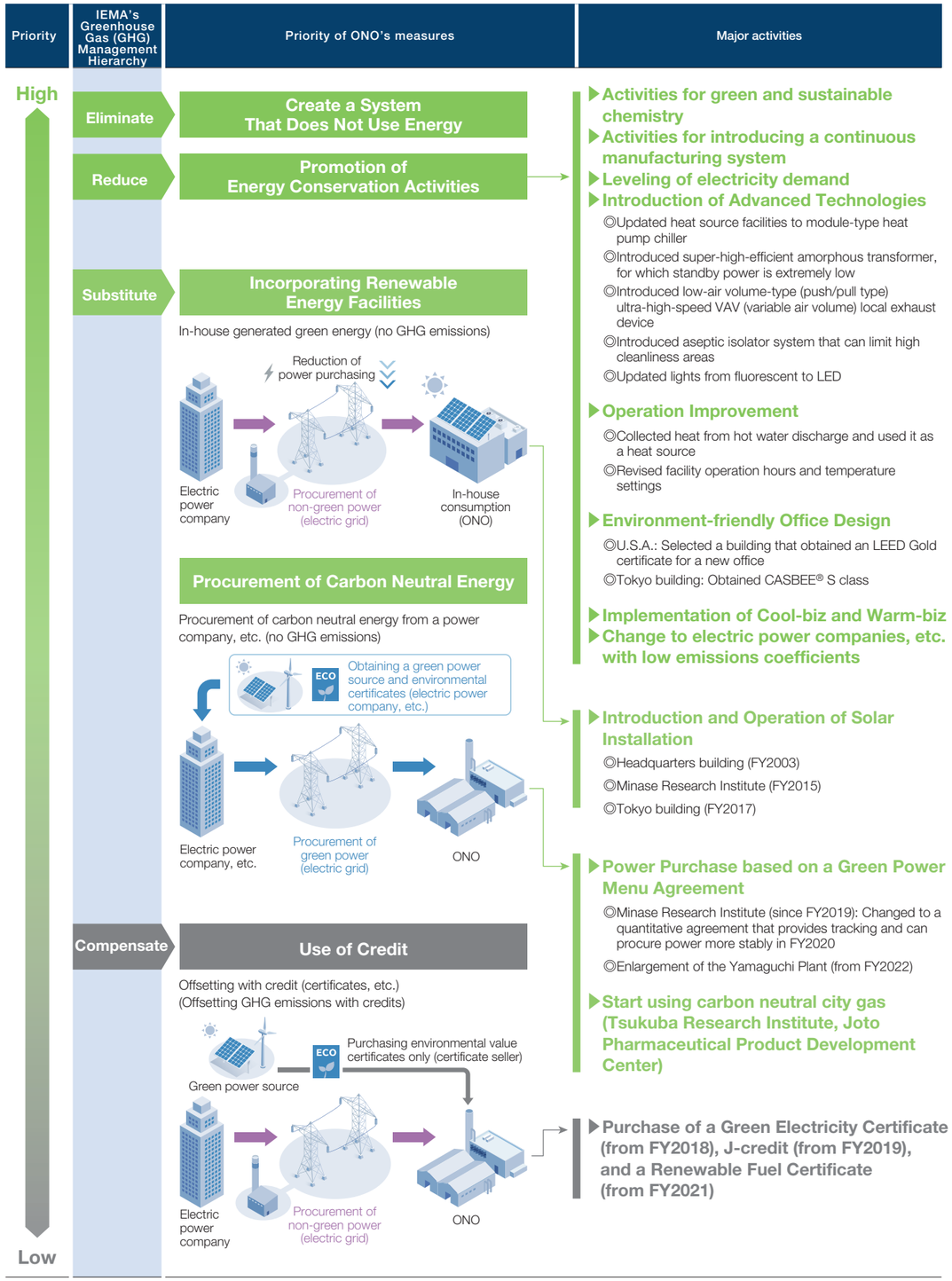
RE100
CLIMATE GROUP | CDP

International initiatives: the Science Based Targets initiative and RE100

Revised Priority of Measures in Consideration of the Latest Market Trends and Future Outlook

In FY2020, we again revised our priority on reducing greenhouse gas emissions based on the current energy market trends, costs, emission factor predictions, and other factors. We used the Institute of Environmental Management and Assessment (IEMA)’s greenhouse gas (GHG) management hierarchy, as a reference and gave Procurement of Carbon-Free Energy a higher priority than Use of Credits, for the following priority of measures: Promotion of Energy Conservation Activities > Incorporating Renewable Energy Facilities > Procurement of Carbon-Free Energy > Use of Credit.
We will implement these revisions based on changes to the business environment and the progress of our activities as needed. Going forward, we will accelerate our activities to become a leading environmental company in the pharmaceutical industry by 2050, and to achieve a decarbonized society in addition to promoting the realization of a healthy and sound society through the discovery and development of innovative pharmaceutical products for our future in 2050.

Priority of ONO's Measures for Reducing Greenhouse Gas Emissions and Major Activities



Source: Prepared by ONO based on materials from ENECHANGE Ltd.

Disclosure of Climate Change-Related Information (Disclosure based on TCFD)

ONO has expressed its support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) in October 2019. The TCFD is a task force established by the Financial Stability Board (FSB) to promote the disclosure and understanding of the financial impact of climate change on companies and published recommendations on methods of information disclosure in June 2017. Based on the recommendations, we will evaluate and manage climate change-related risks and opportunities and promote appropriate information disclosure.

TCFD TASK FORCE ON CLIMATE-RELATED FINANCIAL DISCLOSURES

Task Force on Climate-related Financial Disclosures (TCFD)

Governance of Climate Change-Related Activities

We appoint the president, representative director, and CEO as the highest responsible person on management of environmental

Risks Related to Climate Change and the Effect on Finance and Business

Factor		Value chain	Risk and impact		Financial impact*	Management approach
Society aiming for below 1.5°C	**Regulatory risk**	ONO	Increased carbon tax burden	Our burden of carbon tax levied on greenhouse gas emissions may increase due to the possible tightening of climate change-related regulations.	¥1.9 billion	Mitigation • Achieve the greenhouse gas emissions reduction target (Scope 1+2) in line with the 1.5°C target • Implement energy saving and green energy investment plans to achieve the target
		Suppliers	Carbon tax passed on to procurement prices	Suppliers' burden of the carbon tax levied on greenhouse gas emissions may increase due to the possible tightening of climate change-related regulations, and suppliers may pass on the carbon tax burden to us through higher procurement prices, potentially resulting in an increase in our materials costs.	¥0.6 billion	Mitigation • Achieve greenhouse gas emissions reduction target (Scope 3) • Strengthen engagement with suppliers to achieve the target
If the temperature rises by 4°C	**Physical risk**	ONO, manufacturing contractors, suppliers	Flood risk (acute)	Acute damage (flood) risk from typhoons, etc. may increase, and an interruption of operations caused by damage to production facilities or damage to storage facilities may potentially result in a decrease in revenue.	¥2 billion	Adaptation • Introduce emergency power generators at main bases and conduct periodic maintenance • Integrate climate risks into enterprise risk management (ERM) • Ensure cooperation with suppliers (e.g., consider floodproofing measures at product storage locations and at suppliers. Elevated storage in recognized flood risk areas will be addressed during 2022). • Secure multiple suppliers • Consider the impact of flood due to climate change in the business partner selection process
			Water shortage risk (chronic)	Since sufficient inventory is maintained, it is not likely at present that water-use restrictions due to long-term depletion of water resources will cause an interruption of our operations, resulting in a decrease in revenue.	¥0 billion	Adaptation • Secure proper inventory to avoid loss of opportunities • Maintain a cooperation system with business partners

* Financial impact: The maximum value during the period from 2020 to 2030 in the 1.5°C or 4°C scenario (showing cumulative value to regulatory risk)

Mitigation: Measures to reduce emissions of greenhouse gases that cause climate change

Adaptation: Measures to prevent or mitigate damage caused by the effects of climate change that have already occurred (or are expected to occur in the future)

Opportunities Related to Climate Change and the Effect on Finance and Business

Factor		Value chain	Risk and impact		Financial impact[1]	Management approach
Society aiming for below 1.5°C	**Opportunity from resource efficiency**	ONO	High-efficiency pharmaceutical manufacturing process	The introduction of process design that takes green and sustainable chemistry[2] into account, and high-efficiency pharmaceutical process technologies, such as continuous manufacturing, can provide opportunities to reduce energy and raw material costs.	¥2.3 billion	• Define indicators for assessing resource efficiency • Develop systems
If the temperature rises by 4°C	**Business opportunity**	Customers	Preventive/ treatment products	If disease trends change due to global warming, demand for existing drugs (for melanoma, etc.) may increase, or the development and sales of new drugs may have a favorable impact on revenue.	¥0.5 billion	• Additional indications for existing pharmaceuticals • Enhance the new compound library • Make use of open innovation, etc.
Society aiming for below 1.5°C	**Reputation opportunity**	Investors, customers, recruitment market	Corporate value improvement	It is possible that our efforts to tackle climate change will help us earn customer trust, retain employees, improve our reputation in the recruitment market, and improve ESG investors' evaluation of our performance, thus contributing to the creation of corporate value.	(Contributing to the creation of corporate value)	• Appropriately disclose the results of activities undertaken to the public

1 Financial impact: The maximum value during the period from 2020 to 2030 in the 1.5°C or 4°C scenario (opportunities from resource efficiency are cumulative values)
2 Green Sustainable Chemistry: A concept that aims to reduce environmental impacts throughout the life cycle of chemical substances in order to realize a sustainable society

issues, and below him, a corporate officer to be in charge of environmental issues. The corporate officer in charge of environment issues concurrently chairs the Environmental Management Committee and the CSR Committee, and is also a member of the Management Committee. The Environmental Management Committee discusses climate change issues at least once a quarter, and reports and discusses the results of its activities to the CSR Committee and the Executive Committee at least once every six months. Furthermore, the results are reported to the Board of Directors at least once a year and shared with all directors.
In FY2019, we established a TCFD Study Working Group with the corporate officer in charge of the environment as the person responsible, and it considers issues related to the identification and evaluates the financial impact of climate change-related risks and opportunities and responses to them, and it reviews the identified risks and opportunities every year. The TCFD Working Group, is composed of the heads of major relevant departments (Finance and Corporate Strategy & Planning) and the head of the Risk Management Office so climate-related issues can be integrated into our business strategy.
Also, we participate in the TCFD Consortium, which is a platform for companies and financial institutions that support the TCFD recommendations to discuss effective corporate disclosure and appropriate initiatives. In March, FY2021, we held an ESG briefing for institutional investors, which we have done since FY2019 and received various comments and questions.

TCFD Consortium

Strategy (Analysis and evaluation of risks and opportunities related to climate change)

Climate change-related risks and opportunities were analyzed and evaluated from the perspectives of the short term (up to 3 years), medium term (3 to 10 years) and long term (10 to 30 years) using the 1.5°C and 4°C scenarios, under the leadership of the TCFD Working Group. Continuing from FY2020, in FY2021, we reviewed the amount of financial impact of physical risks[1] based on changes in our product structure, suppliers, etc. and checked our responses to identified risks. We also confirmed that there is not a high risk for climate change for product inventory overseas or inventory for clinical trials. Also, the amount of financial impact of transition risks[2] was not revised since there were no specific changes in assumptions of calculation. Our analysis revealed no financially significant risks in either the 1.5°C or 4°C scenarios. We will continue to check trends in the international community and get an understanding of the impact of risks and opportunities that may have a relatively material financial impact.

1 Physical risks: Acute or chronic damage due to decarbonization policy that has not been clearly defined and due to disasters, etc. caused by climate change.
2 Transition risks: Risks resulting from enhancement of decarbonization policy on a global scale (e.g. climate change policy/regulation, technology development, market trends, changes in evaluation of the market)

Risk and Opportunity Management

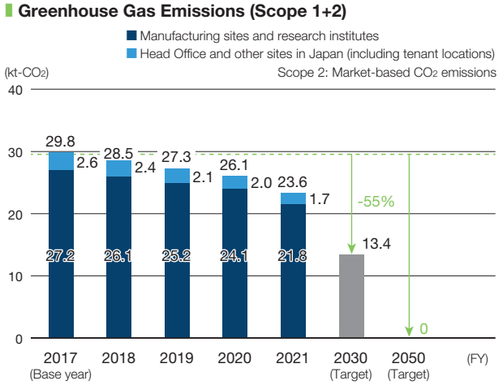
When identifying risks and opportunities, the timing, probability of occurrence and the extent of the consequences are analyzed for each risk and opportunity, details of responses to them are evaluated, and then overall priorities are determined. We prioritize and identify risks and opportunities with a large impact on our business or a high probability of occurrence, as well as with measures that are very cost effective, and the Environmental Management Committee manages progress. The Company-Wide Risk Management Committee considers measures to alleviate and respond to the identified risks, and proposes them to the Management Meeting for approval. The measures approved by the Management Meeting are implemented by the responsible people at manufacturing sites, research institutes, etc. and the risks are thus managed in a comprehensive manner. The financial impacts of risks and opportunities, and measures to respond to them, are reviewed each year, and the content of discussions is supervised by the president, representative director, and CEO through the environment management system (described in "Governance," above).

Indicators and Targets

Aiming to minimize risks and maximize opportunities associated with climate change, we are working to achieve our greenhouse gas emission reduction targets based on our medium- to long-term environmental vision. We are participating in the "Fiscal 2019 Model Project for Supporting Development of CO_2 Emission Reduction Plans to Achieve SBT" (sponsored by the Ministry of the Environment), and based on the research and advice of experts, we are formulating a highly feasible roadmap for reducing greenhouse gas emissions, incorporating new technologies, and are looking into measures and costs. To achieve our medium- and long-term targets, each year we set a single-year target and evaluate the results (progress) against the target (see pp.65). We also have been calculating greenhouse gas emissions across the entire value chain (Scope 3) for our business sites in Japan since FY2014 by dividing Scope 3 emissions into 15 categories, in accordance with the guidelines of the Ministry of the Environment. As for water risks, we analyze risk once a year. These are part of disaster/climate change risks, one of our company-wide risks, so we implement measures based on our business continuity plan (BCP), such as maintaining a proper level of inventory. In the future, we will also work to establish a collaborative relationship with our business partners, secure multiple suppliers, and consider the impact of floods/shortage of water due to climate change in our business partner selection process, etc.

Web See the CDP Climate Change response for more information on climate change risks and opportunities, greenhouse gas emissions, and more (CDP ID required).
https://www.cdp.net/en/saml/new

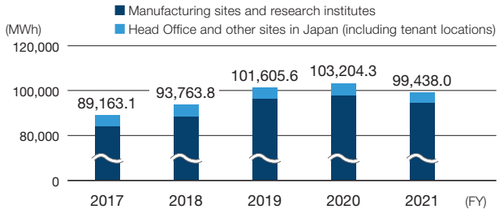
Greenhouse Gas Emissions (Scope 1+2)



Greenhouse gas emissions (Scopes 1 + 2) do not include CO_2 offset by voluntary credits (carbon neutral city gas purchased). If these voluntary credits are included, GHG emissions (Scopes 1+ 2) would be 23.0 kt-CO_2.

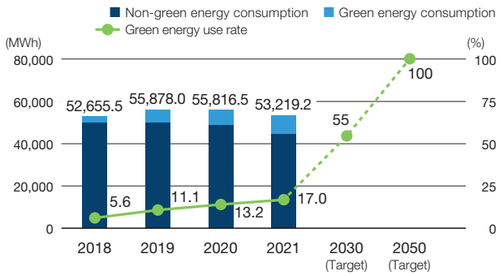
Web Greenhouse Gas Emissions across the Entire Value Chain (Scope 3)
https://sustainability.ono-pharma.com/en/themes/121

Energy Consumption



* Sites where data on greenhouse gas emissions and energy consumption were collected: Fujiyama Plant, Joto Pharmaceutical Product Development Center, Yamaguchi Plant (added from FY2018), Minase Research Institute, Fukui Research Institute, Tsukuba Research Institute, Head Office, sales offices and other offices, etc.

Electricity Consumption and Green Energy Utilization Rate*



* Green energy utilization rate: Green energy consumption / All electricity consumption

TOPICS Efforts to Introduce a Continuous Manufacturing System[1]

We are working on changing one of our manufacturing processes, wet granulation, from a batch method to a continuous method. This is expected to reduce the raw materials required for development by approximately 13%[2] by weight. In the future, we intend to further expand the scope of application of continuous manufacturing to achieve further reductions in raw materials and energy. This initiative is also positioned by TCFD analysis as one of the opportunities related to climate change.

1 "Continuous manufacturing system" is a manufacturing method in which raw materials are continuously fed into the manufacturing process and finished products are continuously taken out. Since it is automated by connecting compact equipment, it is expected to save energy and increase efficiency of manufacturing and resources compared to the batch system that is the mainstream in pharmaceutical manufacturing.
2 These figures show the raw material reduction when using a continuous system for wet granulation, one of the manufacturing, instead of a typical batch system.

Realization of a Water Recycling Society Toward Realization of a Water Recycling Society

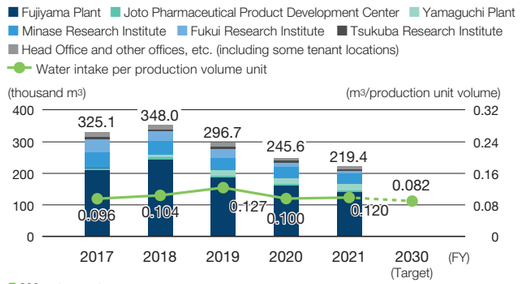
We are making efforts to create a water recycling society by establishing medium- and long-term targets (see p.65) to mitigate the load on limited water resources. Water risks and opportunities that are considered to have an impact on business are identified, analyzed, and evaluated primarily through surveys conducted by the Environmental Management Committee.
Water risk assessment at major sites that use large volumes of water (manufacturing sites and research institutes) is conducted using the WRI AQUEDUCT risk assessment tool of the World Resource Institute. As of the end of FY2021, none of our company's major sites engage in operations in areas categorized as being extremely high risk for water stress. Also, all major sites operate in areas where it is possible to use good quality fresh water as needed for business, so our business activities are not affected. ONO's rating increased from B in FY2018 to A minus in FY2019 and FY2020, and rose to the highest rating of A for FY2021 in the water security survey conducted by CDP of Britain.

Web Analysis and Evaluation of Water-related Risk and Opportunity
https://sustainability.ono-pharma.com/en/themes/123

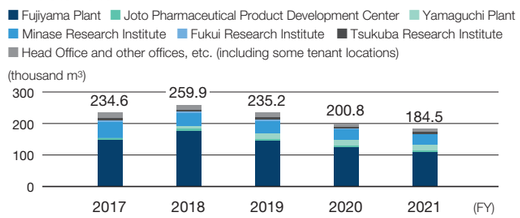
Efforts to Realize a Water Recycling Society

To reduce water consumption, we are reducing cooling water by adjusting the temperature setting of thermal drainage tanks at manufacturing sites, optimizing tank sterilization operations for pharmaceutical water, and not spraying water on air-cooled chillers or heat exchangers in laboratories. In addition, we are reducing water intake by adopting water-saving sanitary fixtures when expanding or renovating offices and renewing facilities.
The amount of water intake in FY2021 was 219.4 thousand m^3, achieving a reduction of 26.2 thousand m^3 compared to FY2020.

Water Intake (Water Resource Consumption) and Water Intake per Production Volume Unit



Wastewater



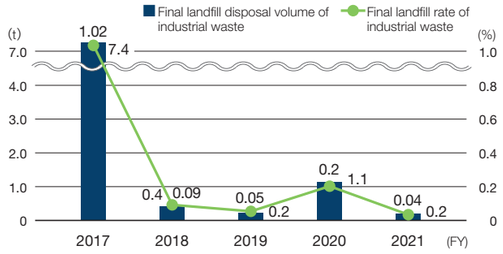
Realization of a Resource Recycling Society Toward Realization of a Resource Recycling Society

To continue our business activities while protecting the global environment, we are making company-wide efforts to realize a resource-recycling society, a key item in our medium- to long-term environmental vision.
The resource recycling subcommittee, which is under the Environmental Management Committee has promotion of the 4Rs (refuse, reduce, reuse and recycle) and selection of materials with reduced environmental impact, as its basic policies, and it promotes surveys of waste-producing and waste disposal processes, and the consideration and evaluation of measures in line with these policies.

Efforts toward the Realization of a Resource Recycling Society

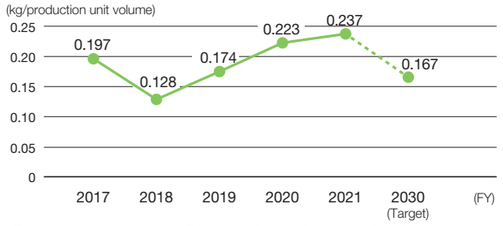
The entire company is working to reduce the generation of waste by, for example, reducing paper materials through the digitization of documents. Also, manufacturing sites and research institutes are converting waste paper and metal into valuable materials, and waste plastic into valuable materials or free materials. In addition to these efforts, our research institutes are also selling laboratory equipment that is no longer in use. We also recycle the residues from the intermediate treatment of industrial waste generated by our manufacturing sites and research institutes.
With regard to pharmaceuticals, we are promoting the reduction of environmental impact throughout the process from research to manufacturing, use, and disposal by simulating manufacturing processes, adopting a continuous manufacturing system, extending the period of use, and changing packaging materials and forms.

Final Landfill Disposal Volume and Final Landfill Disposal Rate of Industrial Waste



* Sites covered by this data: Fujiyama Plant, Joto Pharmaceutical Product Development Center, Yamaguchi Plant (Added from FY 2018), Minase Research Institute, Fukui Research Institute, Tsukuba Research Institute and Logistics centers (added from FY2021).
* Final industrial landfill disposal volume of industrial waste in FY2017 includes the amount of waste (5.8 tons) from renovation of the Joto Pharmaceutical Product Development Center.

Industrial Waste Volume per Production Volume Unit



* The industrial waste volume in FY2017 (25.64 tons) from renovation of the Joto Pharmaceutical Product Development Center was excluded from the calculation.

Biodiversity
Stance on Conserving Biodiversity

As a pharmaceutical company that handles various chemical substances and samples of human and animal origin (blood, tissue, cells, genes, etc.), we believe it is our responsibility to properly manage these substances and prevent air, water, and soil contamination. We also recognize that our business activities benefit from the global environment, and we place great importance on conserving biodiversity.
Based on this belief, we have established an action policy for conserving biodiversity.

Action policy on conserving biodiversity

- Recognizing the impact of our business activities on biodiversity, we take the conservation of biodiversity into consideration in our business activities.
- We comply with treaties, laws and regulations concerning biodiversity in each country and region.
- We appropriately use and manage living modified organisms and pathogens in accordance with relevant laws and regulations.
- We proactively communicate with internal and external stakeholders and promote biodiversity conservation.
- We enhance the awareness of our employees and promote activities to conserve biodiversity with the participation of all employees.

Key Initiatives for Biodiversity Conservation

Chemical substances are properly managed in accordance with the PRTR system of the Act on the Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof, and wastewater is managed in accordance with our own standards, which are stricter than related laws.
Also, we comply with internal rules and regulations established in accordance with the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act) and the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Infectious Diseases Act), etc., regarding genetically modified organisms and pathogens used in drug discovery research and manufacturing activities, preventing their spread or leakage into the environment. In particular, the Fujiyama Plant, our main manufacturing site, employs Whole Effluent Toxicity (WTE) testing using biological responses to confirm that wastewater from the plant has no impact on aquatic organisms in rivers and the sea. In addition, the environmental impact of the active ingredients and metabolites of new drugs for which we are seeking regulatory approval is appropriately evaluated in accordance with the guidelines of each country.
Furthermore, employees at our manufacturing sites and research institutes regularly clean up the areas around their premises to contribute to the preservation of the surrounding environment and biodiversity, and to raise employee awareness. Also, in the past we participated in cleaning up around the 5th station at Mt. Fuji and cleaning up around the spring at Minase Shrine, “Rikyu-no-mizu,” which has been selected as one of the 100 best waters in Japan, but these have not been conducted since FY2020 due to the outbreak of COVID-19.

Web The details of our environmental initiatives and environmental data are on our sustainability web page.
https://sustainability.ono-pharma.com/en/themes/118

Material Issue 15

Respect for Human Rights

Management of Priority Issues

Reason for being a priority issue	We believe that we have a responsibility to work toward the realization of a society in which people’s human rights are respected through our business activities, and we are working to strengthen our human rights risk management. We also recognize that the right to access necessary medical care and to live a healthy life is a human rights issue. As a pharmaceutical company with problem-solving capabilities, we believe that we have a responsibility to contribute to this issue to the maximum extent possible.
Vision over the medium to long term	**Human rights risk management** A human rights risk management system has been established within the Ono Pharmaceutical Group to minimize the negative impact of human rights on business activities. **Improving access to healthcare** • We are delivering innovative medicines for rare and pediatric diseases. • We are contributing to local capacity-building* in areas with immature medical infrastructures (in collaboration with NPOs and NGOs). * Providing support for the development of medical human resources and the establishment of medical systems so that communities facing challenges can overcome them on their own.
Indicators	**Human rights risk management (up to 2026)** • Conduct human rights due diligence within the Group • Conduct human rights risk assessments for high priority suppliers **Improving access to healthcare** • Number of approved rare disease/pediatric indications • Project outcome goals (new project to begin in FY2022)
Major initiatives	**Human rights risk management** • Conduct human rights due diligence **Improving access to healthcare** • Develop new drugs and get additional approvals for rare diseases and pediatric indications with high unmet medical needs • Collaborate with NPOs and NGOs and support local capacity-building in areas with immature healthcare infrastructure

Basic Stance on Human Rights

In all of our business activities in and outside Japan, ONO understands and respects the human rights of each individual and the diversity of their values, personalities, and characteristics and will act accordingly. Upholding these principles, we established and administer our personnel system so that internally and externally discrimination and bullying of any type on the basis of race, nationality, ethnicity, gender, age, color, religion, or belief/philosophy, is prohibited. We also prohibit any form of harassment and conduct compliance training.
Furthermore, as a signatory of the United Nations Global Compact (UNGC), we support its ten principles. In addition, we also fully respect human rights initiatives in compliance with the following international standards, the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Convention on Economic, Social and Cultural Rights, the International Labour Organization (ILO)’s Declaration on Fundamental Principles and Rights at Work, and the UN Guiding Principles on Business and Human Rights.

Web ONO PHARMACEUTICAL Human Rights Global Policy
https://www.ono-pharma.com/company/policies/human_rights.html

Initiatives for Human Rights Due Diligence

In accordance with the United Nations Guiding Principles on Business and Human Rights, we have established and continuously implement a human rights due diligence mechanism to prevent or mitigate the negative impacts of our company on human rights in society.
We use EcoVadis’ CSR evaluation system to objectively and continually monitor the CSR status of important suppliers in our supply chain. With this system we can obtain reliable information on the CSR management of our business partners at least once a year, and propose appropriate corrective measures to them. In the fiscal 2021 assessment, no companies were classified as high CSR risk. In addition, we will conduct comprehensive human rights due diligence from FY2022.

Improving access to healthcare

Even today as we see remarkable developments in the medical field, there are many diseases against which no effective treatment exists.
Also, in low- and lower middle-income countries, there are many people who have difficulty receiving necessary medical care due to various reasons such as inadequate medical infrastructure and poverty.
Under the corporate philosophy Dedicated to the Fight against Disease and Pain, we aim to improve access to healthcare by pursuing the following goals: the development of innovative pharmaceutical products, improvement of medical infrastructure, and establishment of partnerships with outside parties. We currently sell our pharmaceutical products by ourselves in Japan, South Korea, and Taiwan; in Japan and Asia, we will make efforts for improving access to healthcare including the treatment of rare diseases. In other regions, we are providing pharmaceuticals with the help of our partner companies. We are also working on supporting medium- and long-term activities to strengthen medical systems by means such as medical education and the development of medical infrastructure through partnerships with NPOs and the Global Health Innovative Technology Fund.

The Direction of our Efforts

- Promotion of research and development for measures against diseases for which patients' medical needs are not yet met, rare diseases, and intractable diseases
- Local medical education, training of medical personnel, improvement of medical equipment in countries and regions where medical infrastructure is not fully developed
- Strengthening the medical system through partnerships with external parties

Web Our Policies on Intellectual Property Rights and on Patents in Countries with Limited Access to Healthcare
https://sustainability.ono-pharma.com/en/themes/102#927

Development of Pharmaceutical Products to Improve Access to Healthcare

We are working to develop and provide drugs for rare diseases, for which the number of patients is small and it is difficult to develop treatments, through in-house drug discovery and licensing activities. We are also aiming at improving access to medical care for pediatric patients, by working to obtain indications with the belief that drugs should be appropriately evaluated for pediatric patients.
For drug discovery research targeting intractable diseases, we are working to provide new treatment options through industry-academia collaboration. Together with Keio University, Kochi University, Iwate Medical University, the National Institutes of Biomedical Innovation, Health and Nutrition, Mitsubishi Tanabe Pharma Corporation, and Daiichi Sankyo Company, Limited, we launched the Immune-mediated Inflammatory Diseases Consortium for Drug Development in 2018 with the aim of conducting drug discovery research targeting immunoinflammatory intractable diseases. We believe that the results from this consortium will lead to the discovery of next-generation drugs with high utility for immunoinflammatory intractable diseases and provide new treatment options for patients and healthcare professionals.

Efforts Made against Rare Diseases (as of July 29, 2022)

Product name	Therapeutic indication*	Date designated as an orphan drug	Development Status
OPDIVO intravenous infusion	Malignant melanoma	June 17, 2013	Approved
	Hodgkin's lymphoma	March 16, 2016	Approved
	Malignant pleural mesothelioma	December 1, 2017	Approved
	Cancer of unknown primary	March 11, 2021	Approved
DEMSER Capsules	Improvement of catecholamine excess and various symptoms in pheochromocytoma	May 25, 2015	Approved
KYPROLIS for intravenous infusion	Relapsed or refractory multiple myeloma	August 20, 2015	Approved
ONOACT for intravenous infusion	Life-threatening refractory and emergent cardiac arrhythmias: ventricular fibrillation and hemodynamically unstable ventricular tachycardia	August 24, 2016	Approved
MEKTOVI Tablets	NRAS or $BRAF^{V600}$ mutation-positive malignant melanoma	December 4, 2013	Approved
BRAFTOVI Capsules	$BRAF^{V600}$ mutation-positive malignant melanoma	December 4, 2013	Approved
VELEXBRU Tablets	Primary central nervous system lymphoma	August 20, 2019	Approved
	Waldenström's macroglobulinemia, lymphoplasmacytic lymphoma	November 19, 2019	Approved

* Anticipated indications or diseases on the designation

Efforts to Obtain Approval for Pediatric Use (as of July 29, 2022)

Product name	Therapeutic indication	Status
ONON Dry Syrup	Bronchial asthma, allergic rhinitis	Approved
EMEND Capsules	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc.) (including the delayed phase)	Approved
PROEMEND for intravenous infusion	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc.) (including the delayed phase)	Approved
ORENCIA for intravenous infusion	Active polyarticular juvenile idiopathic arthritis	Approved
DEMSER Capsules	Improvement of status of catecholamine excess secretion in patients with pheochromocytoma	Approved
OPDIVO intravenous infusion	Relapsed or refractory classical Hodgkin lymphoma	Approved
ONOACT for intravenous infusion	Tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter) in patients with low cardiac function	Filed

ONO SWITCH Project

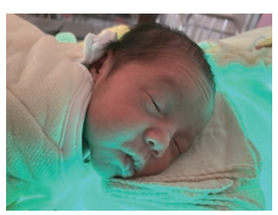
As an effort made to promote both medical system support and work style reform, we have been working on the ONO SWITCH Project since August 2018. This is an effort to make donations to NPOs and NGOs related to medical care using the money saved through the reduction of overtime work through the promotion of work style reform, aiming to further promote the embodiment of the corporate philosophy Dedicated to the Fight against Disease and Pain by contributing to the promotion of working style reform, healthcare, and people's health around the world.
The project was named SWITCH by abbreviating **S**ave the **W**orld with our work style **I**mprovemen**T** and **CH**ange (meaning saving the world through improvement and reform of our ways of working). The project name also expresses switching work methods to new ones, switching the funds obtained through working style reform to donation, and switching to the process of reexamining how to work.
In this project, we will work on improving access to healthcare products and improving medical infrastructure through partnerships with outside parties.

Web ONO SWITCH Project
https://sustainability.ono-pharma.com/en/themes/102#929

Participation in the Global Health Innovative Technology Fund

We became a member company of the Global Health Innovative Technology Fund (GHIT Fund) in 2018. The GHIT Fund is an international, non-profit organization that invests in the development of new drugs, vaccines, and diagnostic agents against less marketable diseases such as malaria, tuberculosis and neglected tropical diseases, and is funded by the Japanese government, the Bill & Melinda Gates Foundation, the Welcome Trust, and private enterprises in Japan and overseas. In order to reduce the health disparities between developed countries and low-and middle-income countries, the therapeutic agents, vaccines, and diagnostic agents developed through the GHIT Fund's investments are priced according to the "No Gain, No Loss" principle. We understand the efforts and policy, and we contribute to the funding of the GHIT Fund. Through participation in the GHIT Fund, we will strengthen the establishment of partnerships aiming to improve access to healthcare in low- and middle-income countries.

Recipients of Support from the ONO SWITCH Project (FY2021)

Partner (Regions with ONO-sponsored initiatives)	Description of efforts made	
	FY2021 Plan	FY2021 Results
Japan Committee, Vaccines for the World's Children (Bhutan)	**Provide DPT (diphtheria/pertussis/tetanus) vaccines for 53,500 children**	The DPT vaccine was given to 96% of 2 year olds. (The target vaccination rate was over 95%). We were also able to systematically conduct on-site vaccination of the children of nomads.
	Hepatitis B vaccines for 9,000 people	The hepatitis B vaccine was given to 96% of newborns. (The target immunization coverage was 95% or higher.)
	TD (tetanus/diphtheria) vaccines for 69,482 people	The TD vaccine was given to 96% of children and 92.8% of pregnant women. (The target immunization coverage was 95% or more) In addition, systematic mass vaccinations at schools and other locations were also done.
	Provide 5 refrigerators for vaccines	With our support pharmacy refrigerators for vaccines were installed in 5 facilities and are in continual use.
		 
Japan Heart (Cambodia)	**Donations of equipment for the early detection of neonatal jaundice and phototherapeutic devices for jaundice** We donated new testing equipment because the bilirubin* analyzer currently in use, which is necessary for the diagnosis of jaundice, breaks down repeatedly. In addition, we donated the latest phototherapy equipment, with high levels of safety, necessary for jaundice treatment. We also donated medical equipment necessary for managing the body temperature of newborns. * Bilirubin: The yellow pigment that forms when the hemoglobin in old red blood cells breaks down.	The donated testing equipment was used to examine all babies admitted after delivery, and the phototherapy equipment was used for babies whose bilirubin was a concern at the public hospital we collaborate with, while admissions were suspended at the hospital due to the spread of COVID-19. Japan Heart commented, "We used the donated analyzer and confirmed the safety of the babies. We have been able to avoid unnecessary blood sampling based on the readings from the analyzer. It has also made it easier to evaluate after phototherapy has been started. We have been able to prevent elevated bilirubin. Compared to the previous analyzer, the median value and history can now be checked, making it easier to use. In addition to 53 inpatients, we were able to measure several outpatients." The newly donated infant warmers (open incubators) take less time to warm up than those previously used and are spacious making them very easy to use and perform procedures. It is also used for neonatal care after C-sections when an obstetrician is in the hospital.
	Training is provided so that local medical personnel can provide treatment by themselves for newborns who require breathing support and temperature control shortly after birth.	Training was conducted so that local medical personnel could provide treatment by themselves for newborns requiring breathing support and temperature control shortly after birth. Three local medical personnel are now able to do this.
		 

Recipients of ONO SWITCH Project (FY2021)

Partner (Regions with ONO-sponsored initiatives)	Description of efforts made	
	FY2021 Plan	FY2021 Results
Japan Heart (Cambodia)	**Support for a student who is aiming to become a healthcare professional** For a student who is good enough to enter medical or nursing school but has difficulty attending school due to family financial reasons, the program provides study support for study and, after graduation, a two-year training period at the Japan Heart Children's Medical Center. We are continuing support for the Cambodian nursing student we have been supporting since FY2018.	The Cambodian nursing student we have been supporting since FY2018 advanced to the fourth year on November 15, 2021. Currently, due to the impact of COVID-19, she is continuing to take classes online. Not only are her grades excellent, but she also actively participates in volunteer work in medical activities on days when she does not have classes. Although she is not yet a medical professional, she is growing into a very reliable person, seeking out what she can do while still a student to "bring medical care to places where it is not available." 
	Environmental upgrades at Japan Heart Children's Medical Center (making the environment more sanitary during the rainy season) The grounds around the Japan Heart Children's Medical Center were not well maintained, and every year puddles of water formed during the rainy season. Puddles that lasted a long time led to mosquito outbreaks. In addition, because the paths were muddy, patients' and accompanying family members' feet got dirty, and the floors of the hospital became dirty as well. To solve this problem, we created a channel to draw water from the areas where water tended to accumulate to the sewer system, and paved the gravel road in front of the hospital, improving the sanitation of the environment around the hospital.	With the improvement of the environment around the Japan Heart Children's Medical Center it has become easier to use a wheelchair due to reduced vibration. Previously, on sunny days, dust would fly up and enter the hospital, and when it rained, and it was dirty with mud even in the entrance, but since the area was paved, it has been kept clean. Even after it rains, the feet of patients and staff are less likely to get dirty, and the hospital is kept clean and comfortable. In addition, since a waterway has been secured, drainage has been improved, preventing water from pooling for long periods of time. The sanitation of the environment has been greatly improved. 
People's Hope Japan (Myanmar)	**Skills monitoring for midwives and auxiliary midwives (2nd time)** We will do a second round of skills monitoring, following up on FY2020, to see if they are applying the knowledge and skills they've learned in clinical settings, and we will measure retention and improvement. In addition, we plan to train people for a mother and child health promotion committee, according to local needs. Post-graduate training for midwives and refresher training for auxiliary midwives **Post-graduate training for midwives and refresher training for auxiliary midwives** The training scheduled for FY2020 will be implemented as soon as the local environment is ready. Note: Due to the changes in the situation in Myanmar after February 2021, the assistance may be changed to more urgent assistance.	Due to the difficult domestic situation in Myanmar since February 2021, the planned skills monitoring for midwives and auxiliary midwives and post-graduate training for midwives and refresher training for auxiliary midwives could not be implemented, and were postponed to the next fiscal year. In place of the original plan, we trained volunteer maternal and child healthcare promoters to serve as a bridge between local residents and health services. In March 2022, we conducted two sessions of training for volunteers on maternal health checkups, care for newborns, and danger signs during pregnancy, and trained 60 mother and child healthcare promoters in 13 villages. The third training was held in May 2022 (25 mother and child healthcare promoters from 6 villages). Furthermore, training will continue to be conducted in villages that have been to be safe and that have the needs. The trained mother and child healthcare promoters provide health education and home visits to expectant and nursing mothers, while ensuring their safety.  Mother and child health promoter's activities in a village. (Photo taken in August 2019)

The activities of Future Code (supported area: Bangladesh), which we supported in FY2020, were delayed due to strict national regulations caused by COVID-19. A new hospital that had been planned opened in December 2021, and we donated PCR machines to it. As of May 10, 2022, a total of 31 PCR tests had been conducted to diagnose COVID-19, of which 12 were positive, and the number of deaths among those who tested positive was zero. Of those tested with the PCR, 61% were poor and were treated free of charge.

Material Issue 16

Thorough Compliance

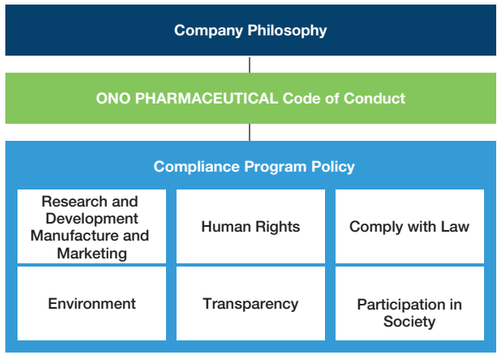
Management of Priority Issues

Reason for being a priority issue	As a pharmaceutical company involved in pharmaceuticals upon which human lives depend, we must not only comply with laws and regulations but also act in accordance with high ethical standards. In addition, compliance problems are a serious risk that could damage our brand and trust, which are our important non-financial assets, as well as affect the continuation of our business.
Vision over the medium to long term	Establish a compliance risk management system to support global business expansion and prevent compliance violations.
Indicators	Number of significant compliance violations*: 0 * Violations that have a great impact on sales and profits and have a great social impact
Major initiatives	• Establish overall risk management (ERM) for global response, including compliance • Comply with relevant laws and regulations of the pharmaceutical business, promote proper use of pharmaceuticals, prevent corruption and corrupt practices, protect information, etc. • Foster a culture of proactive involvement in preventing compliance violations • Strengthen governance of compliance risks by the Board of Directors

ONO PHARMACEUTICAL Compliance System

Being aware of our responsibilities as a pharmaceutical company dealing in pharmaceuticals upon which human lives depend, ONO has a Code of Conduct, the ONO PHARMACEUTICAL Code of Conduct, to ensure that it acts in compliance with laws and regulations and that it meets high ethical standards. Under our Corporate Philosophy, we established our Code of Conduct as a basic guideline for corporate activities and the Compliance Program Policy as the behavioral standard for those activities. We also formulated and comply with our Code of Practice, which is based on the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice for promotional activities.
In practicing our compliance system, we make sure our employees know about ensuring transparency, preventing fraud and corruption, and are constantly aware of domestic and international social conditions.

Compliance System



Web Corporate Philosophy / ONO PHARMACEUTICAL Code of Conduct
https://www.ono-pharma.com/company/mission.html

Web ONO PHARMACEUTICAL Compliance Program Policy
https://www.ono-pharma.com/company/policies/compliance.html

Web ONO PHARMACEUTICAL Code of Practice
https://www.ono-pharma.com/company/policies/cop.html

Compliance Promotion System

To promote compliance, we have appointed the Executive Director of Corporate Strategy & Planning, who is a Senior Executive Officer and a Member of the Board of Directors, as the Corporate Compliance Officer and set up a Compliance Committee. This Committee examines and deliberates on compliance-related issues, plans and promotes relevant training programs. It also cooperates with the internal auditing department checks the status of initiatives at each business location. In addition, the Compliance Committee manages risk in cooperation with the Risk Management Committee.
In FY2021, because of the serious compliance violation that occurred in the previous fiscal year, we took measures to prevent recurrence, including the implementation of company-wide training. We also worked to strengthen the Board of Directors' supervisory system by regularly reporting the progress of such measures (e.g., the status training implementation) to the Board of Directors and receiving advice from outside directors.
In addition, a Compliance Officer has been appointed in each division to be in charge of strengthening compliance. In addition, a risk manager, who is responsible for overall risk management of the organization, works with compliance managers, who have been newly assigned to all departments to serve as consultation counters for compliance issues in the workplace, to establish an operational system that promptly takes measures to respond to consultation issues raised within the organization. Information on consultation cases is also shared with the Assessment Office, newly established within the Compliance Division, which provides advice to the compliance managers.
In the Sales and Marketing Division, a specially assigned compliance officer is in charge of overall compliance. The officer regularly participates in compliance promotion meetings within the division and provides advice and suggestions to ensure proper operations and to establish an awareness of preventive measures.
We provide guidance to group companies in creating systems and rules to prevent the occurrence of noncompliance, and we urge our suppliers to do the same.

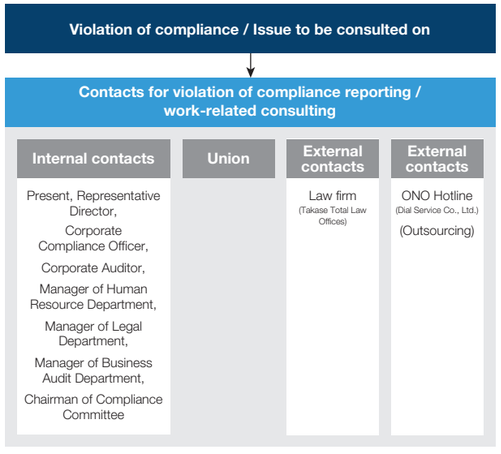
Reporting and Consultation System

We have internal and external contact windows, such as the 24-hour external contact service called the ONO Hotline, which was set up to prevent compliance violations, including harassment, to ensure appropriate work environments, and to take measures promptly to minimize any loss of social credibility in the event of a compliance violation. We also have a system to ensure that informants can directly report to or consult with top management–that is, the Representative Director, the Corporate Compliance Officer, or the Corporate Auditors. We ensure that matters concerning privacy, such as the informant's name and reported content, are kept strictly confidential, and are not disclosed except to those necessary for the survey, and we also support anonymous reporting. In addition, we do not bring detriment to such an informant solely because of the use of the system and they are legally protected. These are clearly stated in the Whistleblower Regulations, which were newly established in light of the revised Whistleblower Protection Act that came into force in FY2022, and are thoroughly communicated to all employees. Furthermore, we are working to make the system available in the entire group so that employees and others can report or consult without hesitation.

Compliance Education

To promote compliance, we recognize that it is important to continually conduct employee training and awareness-raising activities. We therefore provide compliance training to our officers and all employees every year.
In FY2021, taking a lesson from the serious case of noncompliance that occurred in the previous fiscal year, we conducted training sessions with discussions to thoroughly prevent recurrence, as well as education and training on preventing bribery.
We also conduct training on harassment annually, and are strengthening our efforts to create a comfortable work environment.
As for the training related to the Guidelines on Activities to Provide Sales Information, the contents of the training are based on actual compliance issues. We provide not only regular training, but if a problem arises, we also conduct training as soon as possible to prevent recurrence. We also promote risk-based training programs for other compliance themes.

Reporting and Consultation System

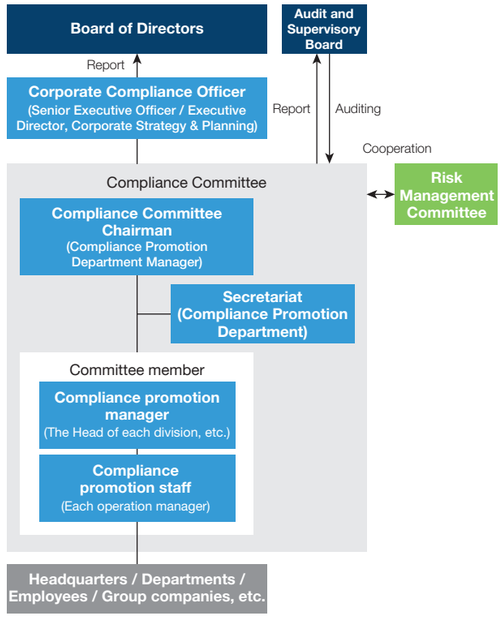


Web Reporting and Consultation System
https://sustainability.ono-pharma.com/en/themes/81#911

Ethical Considerations

We always give consideration to ethical treatment in various stages of research and development.
For research using human-derived samples (blood, tissue, cells, genes, etc.), we have established internal ethical rules based on the basic guidelines issued by the Japanese government. We have also established an advisory body, the Ethics Committee for Medical and Health Research Involving Human Subjects, comprising members from inside and outside the company, to ensure that such research is conducted only after the Committee conducts strict assessment of its ethical and scientific validity.
For research using laboratory animals, we have established an Institutional Animal Care and Use Committee. The Committee reviews submitted animal experimentation plans in advance to determine whether they have been prepared based on the principles of the 3Rs* to ensure that animal experiments are

Compliance Promotion System



carried out appropriately, with respect for the lives of animals and taking into consideration animal welfare. In addition, we conduct self-inspections and assessments of the implementation status of animal experiments. In recognition of these initiatives, we have acquired third-party certification from the Japan Pharmaceutical Information Center.
We ensure that clinical trials, which are essential for verifying the safety and efficacy of pharmaceuticals under development, are carried out in a highly ethical manner, with respect for the human rights and with particular attention to the safety of study subjects. We ascertain the true value of drugs step-by-step by taking all necessary and appropriate procedures that comply with Japan's "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceutical and Medical Device Act)" and other related legislation, as well as the global standards specified based on the spirit of the Declaration of Helsinki. In the past, many drug-induced injury cases occurred due to inadequate monitoring of the safety of pharmaceutical products. We regularly provide education on drug-induced injuries to all employees so that they will never forget patients' pain, the tragedy of the drug-induced suffering, and the grave responsibility of a pharmaceutical company.

* Internationally accepted and established principles for the proper care and keeping of laboratory animals and animal experimentation. The 3 principles are Replacement (use of alternative methods), Reduction (reducing the number of test animals) and Refinement (alleviation of pain).

Web Human Rights
https://www.ono-pharma.com/company/policies/respect_human_rights.html

Web Animal Ethics
https://www.ono-pharma.com/company/policies/ethical_considerations_in_animal_experiments.html

Fair and Transparent Business Activities

In order to conduct fair and transparent business activities, we have e-learning and also a reinforcement month for training in each division. We provide thorough education to all employees about the prevention of fraud and corruption every year.
To contribute to healthcare and people's health around the world through continuous new drug creation and a stable supply of our products, collaborative activities support for patient organizations to help patients overcome disease and pain, and cooperation with research and medical institutions is indispensable. To enhance the fairness and transparency of these cooperative and collaborative activities, it is important to ensure transparent relationships with our partners. We therefore disclose information on the costs of our assistance to medical institutions and patient organizations in accordance with our transparency guidelines, which were developed in line with the relevant guidelines of JPMA.
Regarding tax compliance, we have established a global tax policy, the ONO PHARMACEUTICAL Global Tax Policy. All tax-related work is undertaken in strict accordance with this policy and under the responsibility of the director in charge of compliance, namely the Executive Director of the Corporate Strategy & Planning Division, who is a Senior Executive Officer and Member of the Board of Directors.
Amid globally mounting interest in compliance with laws governing unfair and corrupt practices, we established the ONO PHARMACEUTICAL Global Anti-Bribery and Corruption Policy and the Regulations on Bribery Prevention in 2017 to clearly define and state our company's stance and system in preventing bribery and corruption. We endeavor to ensure strict implementation of the policy and regulations. Furthermore, we support Transparency International's Business Principles for Countering Bribery, an international anti-bribery standard.
As for research receiving public funds as research funding, we have formulated the Action Guidelines for Publicly Funded Research and the Regulations on Publicly Funded Research, in compliance with the relevant guidelines established by the Japanese government, to ensure further appropriate implementation and management of research projects.

Web Engagement to Achieve Transparency in Relationships with Medical Institutions, etc. (only in Japanese)
https://sustainability.ono.co.jp/ja/themes/120#1021

Web Engagement to Achieve Transparency in Relationships with Patient Groups (only in Japanese)
https://sustainability.ono.co.jp/ja/themes/120#1022

Web Operation and Management System of Public Research Funds
https://www.ono-pharma.com/company/policies/public_research.html

Web ONO PHARMACEUTICAL Global Tax Policy
https://www.ono-pharma.com/company/policies/tax_policy_jp.html

Web Tax Reporting by Country
https://s3-ap-northeast-1.amazonaws.com/sustainability-cms-ono2020en-csr-s3/data/pdf/tax/Tax%20Reporting%20by%20Country%20for%20the%20Fiscal%20Year%20Ended%20March%2031,%202021.pdf

Web ONO PHARMACEUTICAL Global Anti-Bribery and Corruption Policy
https://www.ono-pharma.com/company/policies/bribery_prevention_globalpolicy.html

Pursuit of Fair Promotion Activities

We define "promotions" as "Providing and transmitting drug information to healthcare professionals and promoting the proper use and spread of ethical drugs based on such information." All employees involved in promotions carry out fair promotion activities, while always examining whether they are acting in accordance with the spirit of the ONO PHARMACEUTICAL Code of Practice, which conforms with the JPMA Code of Practice, regardless of whether there are specific provisions or descriptions in the Code. Furthermore, based on the Company's Code, we not only comply with the Guidelines on Activities to Provide Sales Information on Prescription Drugs issued by the Ministry of Health, Labour and Welfare of Japan, and the Promotion Code for Prescription Drugs established by JPMA, but also respect the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Practice.

Web Responsible Promotion Activities
https://sustainability.ono-pharma.com/en/themes/83

Material Issue 17

Supply Chain Management

Management of Priority Issues

Reason for being a priority issue	In order to provide a stable supply of our products to patients and realize a sustainable society, we believe it is important to build a sound network with all of our business partners in our supply chain and work together with them to improve human rights and labor conditions and protect the natural environment.
Vision over the medium to long term	Strengthen collaborative relationships with business partners and manage sustainability-related risks such as the natural environment and human rights
Indicators	(up to 2026) • Establish a stronger risk management system (formulate policies and a code of conduct, make the system well established) • Comprehensive evaluations of companies in high-risk areas
Major initiatives	• Share our code of conduct, get consent forms • Assess risk • Carry out on-site audits • Confirm corrective action efforts

Our Stance on Supply Chain Management

As the social structure changes with technological innovation and globalization, it is difficult to sustain business activities without collaborating with suppliers, and supply chain management is becoming increasingly important.
Also, to contribute to the realization of a sustainable society, rather than roll out activities on our own, it is important to work with all of our suppliers in the supply chain to establish a management system for human rights, the labor environment, the natural environment, and other issues and strengthen our efforts together. We have built a sound network with our suppliers to ensure the quality and stable supply of pharmaceutical products. While maintaining and strengthening this network, we will develop a management system and initiatives for human rights, the labor environment, the natural environment, and other issues aiming to enhance the corporate value of both our company and our suppliers.
All employees involved in procurement activities comply with the Basic Policy for Procurement Activities, and we have formulated CSR Procurement Guidelines, which outlines items for which we request cooperation from our suppliers.

Web Basic Policy for Procurement Activities and CSR Procurement Guidelines
https://www.ono-pharma.com/company/policies/procurement.html

Sustainability Initiatives of Suppliers

To identify the sustainability status of the suppliers in the supply chain objectively and continuously, we use the EcoVadis sustainability evaluation system (hereinafter, "EcoVadis"). By using EcoVadis, highly-reliable information concerning the sustainability management of suppliers can be obtained and appropriate corrective actions can be proposed. We hold explanatory meetings for the suppliers who request evaluation by EcoVadis so they can understand our sustainability policy and activities in procurement. According to the evaluation in FY2021, as in previous year, there were no suppliers that fell under high sustainability risk.
In addition, we have provided several of our suppliers who were evaluated by EcoVadis in FY2020 with opportunities to confirm their sustainability-related management systems and corrective action plans, and we have confirmed that these companies have strengthened their efforts due to the FY2021 evaluations.
Furthermore, in FY2021, we conducted an analysis of sustainability-related risks in our supply chain, based on information such as industry type and availability of alternative suppliers, to further strengthen the foundation of our internal supply chain management in the future. We plan to roll out initiatives in FY2022 based on the results of this analysis.

Social Contribution Activities

Basic Approach

To contribute to the realization of a sustainable society, we engage in various activities under ONO's Global Policy for Social Contribution Activities. In addition, in consideration of the relationship between current and future business activities and our business resources, we determine priority fields to focus on and then promote activities.

Web ONO's Global Policy for Social Contribution Activities
https://sustainability.ono-pharma.com/en/themes/109#963

Efforts for the Advancement of Medicine and Pharmacy

We are making efforts to meet unmet medical needs and contribute to the advancement of medicine and pharmacy. At the ONO Medical Research Foundation, which was established with donations from ONO in 1988 grants for research activities in the field of lipid metabolism disorders are provided and research and treatment in that field are promoted through various projects, contributing to the health and welfare of the public. The Foundation has provided research grants and research promotion grants every year since its establishment and gave the Osamu Hayaishi Memorial Award to one researcher, research grants to 12 researchers, and research promotion grants (for researchers under 40 years of age) to 16 researchers, respectively, in FY2021. In addition, since 2017, we have supported the Japanese Biochemical Society's new Osamu Hayaishi Memorial Scholarship for Study Abroad, which assists researchers who are highly motivated to research biochemistry-related life sciences in general. In FY2021 the scholarship supported 8 researchers. Furthermore, through the Ono Pharma Foundation's research grants to overseas researchers, we contribute to promoting research and the foundation of innovation.

Efforts for Supporting Patients and Their Families

We conduct the following activities to support the health of a wide range of people, such as patients and the families of patients.

Transmitting Information through the Website

We continually provide the latest information that is useful for medical care through content and applications.

- **Cooperation in Holding Seminars for Citizens on Diseases**
  We cooperate with, and host, disease-related public seminars to spread disease awareness and disseminate correct information. Five webinars were held in FY2021, mainly in the areas of rheumatism, cancer, and diabetes, with approximately 700 people participating.
- **For Patients and Their Families**
  We operate a website explaining specific symptoms and treatment of familiar diseases, and things that should be done everyday.
- **ONO ONCOLOGY (Information for the general public and patients)**
  We operate a website in cooperation with supervising physicians where visitors can learn about diseases and treatments in oncology as well as the concept of cancer immunity. In FY2020, we added a page titled "Cancer and Novel Coronavirus: Precautions against the spread of infection" and provided appropriate scientifically-based information to support the treatment and lives of patients with cancer during the COVID-19 pandemic.
- **Dementia Treatment Connected by Smiles and Heart** (Site closed at the end of March, 2022)
  We operated a website for people involved in dementia treatment and nursing care that discussed dementia.
- **Grandma's World**
  We are showing a short movie to increase dementia awareness.
- **Application for Patients with Lifestyle Diseases**
  (Application closed down at the end of June 2021)
  We provided free smartphone applications aimed at supporting patients with lifestyle diseases
- **"FukuSapo®" (A digital tool to support management of side-effects)**
  We provide a support tool free of charge to help patients receiving treatment with immune checkpoint inhibitors. The tool manages their physical condition to assist in the early detection and early treatment of side effects, especially with regard to immune-related adverse events.

Support for Solaputi Kids' Camp

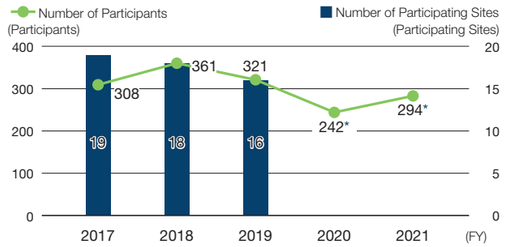
We have been a supporting member of Solaputi Kids' Camp (Takikawa, Hokkaido) since FY2014. Solaputi Kids' Camp is a dream camp with medical care for children with intractable diseases. We also provided support for a new project, "Snow Gift," in the midst of having to scale back camp operations due to the spread of COVID-19.
Snow Gift is a project in which snow from the camp is packed in boxes and delivered to hospitals and other facilities in areas where there is no snowfall so that children can play in the snow. In some cases, however, smooth delivery of packages to hospitals was not possible. Because of this, our medical representatives, who visit hospitals on a daily basis, supported this project by becoming snow-carrying volunteers. In FY2021, from January to March 2022, our medical representatives delivered snow gifts by hand to the person in charge at six medical institutions, giving children in the hospital who had no opportunity to experience snow the joy of playing in the snow. The children, their guardians, and medical staff who played in the snow later expressed their delight, and employees who participated in the program commented that they were glad to have been able to help "bring the fun (snow)" to the children.

Children playing with snow

Participation in Relay For Life (since FY2014)

We participate in activities that support patients with cancer and their families, deal with cancer throughout an entire community, and aim to overcome cancer We participated in the Self Walk Relay in FY2020 and FY2021.

Participation in the Relay For Life*



* FY2020 and FY2021 data show the number of self-walk relay participants.

Efforts toward Education for Children's Health

We are proactively engaging in activities to support the development of children, who will be responsible for the future.

Efforts for Cancer Education in High School

With the full-fledged start of cancer education in high schools scheduled for April 2022, there are concerns in the schools about the content of classes and teaching materials, which are left to the discretion of each school. In response, cancer specialists, government officials, and educators gathered at the Osaka Summit on Cancer Education to identify issues for promoting cancer education.
To promote cancer education, in which children acquire correct knowledge about cancer and learn the importance of health and life, we will coordinate with related parties to identify which of the issues brought up that we should address from FY2022 onward.

Implementation of the "Healthy Body Campaign" (since FY2014)

To contribute to reducing childhood obesity, a social issue in areas affected by the Great East Japan Earthquake, we are cooperating with top athletes and medical specialists on lifestyle-related illnesses and carrying out reconstruction assistance. Activities have been cancelled since FY2019 due to the impact of COVID-19.

Activities in March 2019

Travelling Science Classes "Kusuri no Himitsu Manabu" (Minase Research Institute: Since FY2015; Joto Pharmaceutical Product Development Center: Since FY2019)

Classes for 6th grade elementary school students near these facilities with the aim of increasing interest in science with our researchers as lecturers who travel to their schools.

Travelling Classes at Hoei Elementary School (top) and Shimamoto Town Third Elementary School (bottom)

Donation of toothbrushes (Minase Research Institute: Since FY2014; Joto Pharmaceutical Product Development Center: Since FY2018)

We donates toothbrush sets and toothbrushes to children in elementary schools, kindergartens, and nursery schools near these facilities for Tooth and Mouth Health Week, from June 4 to 10.

Sponsoring the Kokoro no Gekijo (Theatre of the Heart), hosted by the Shiki Theatre Company and Butai Geijutsu (Performing Arts) Center (since FY2017)

Children are invited to the theater and provided with opportunities to view stage performances in order to encourage them to think about the importance of life and consideration for others. In FY2021 videos were broadcast.

Hajimarinoki no shinwa – Kosoado no mori no monogatari – (The Myth of the Starting Tree – The story of the forest called Kosoado –)
Photo by Takahiro Higuchi

Sponsoring the Nakanoshima Children's Book Forest (since FY2017)

We support the operation of this facility because we share the facility's desire to provide children with access to a wide variety of books to nurture their unlimited imagination and curiosity.

Web Social contribution activities
https://sustainability.ono-pharma.com/en/themes/131

Strengthening of Corporate Governance

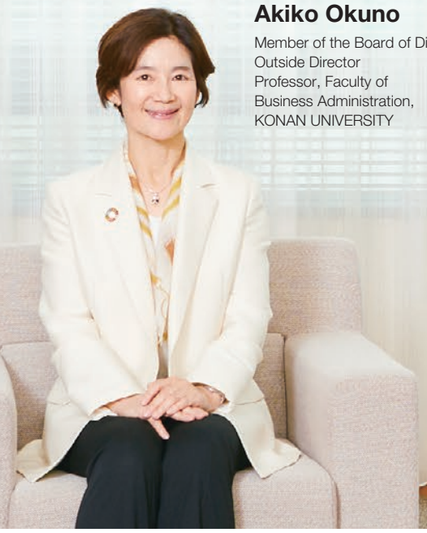
**We have been working to strengthen our governance since the introduction of the Corporate Officer System in 2011.
In 2013, we appointed two outside directors, and in 2015, we appointed a female director as an outside audit & supervisory board member.
In 2016, we began evaluating the effectiveness of our Board of Directors, and in 2020 we welcomed a female outside director, and starting in 2022, we appointed an outside director to chair a meeting that considers executive appointments and compensation proposals.
In this section, we introduce our efforts to Improve Corporate Governance.**

Strengthening of Corporate Governance

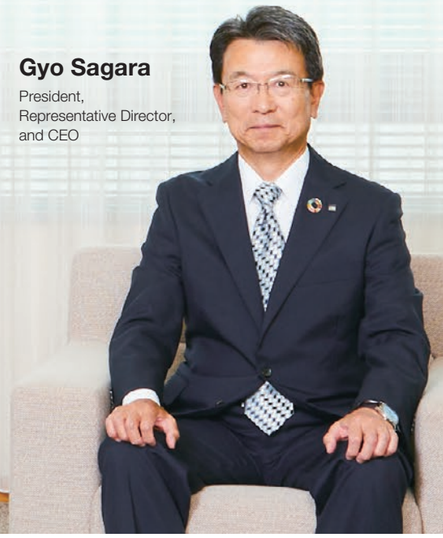
Round-table Discussion

with the Outside Directors

Shusaku Nagae
Member of the Board of Directors, Outside Director
Special Corporate Advisor, Panasonic Holdings Corporation



Akiko Okuno
Member of the Board of Directors, Outside Director
Professor, Faculty of Business Administration, KONAN UNIVERSITY



Gyo Sagara
President, Representative Director, and CEO

Masao Nomura
Member of the Board of Directors, Outside Director
Senior Adviser to the Board, Iwatani Corporation
Outside Director, Keihanshin Building Co., Ltd.

Enhance the Objectivity and Transparency of Management and Realize Our Corporate Philosophy

We are promoting efforts to strengthen corporate governance. President Sagara and the three outside directors, who have diverse backgrounds, discussed the company's vision for sustainable growth and the significance of reorganizing material issues.

Accelerating Actions to Realize Our Corporate Philosophy

Sagara The word "purpose" has been used a lot lately, and for us, our corporate philosophy, "Dedicated to the Fight against Disease and Pain," is exactly that. In 2014, we formulated our mission statement, Our Vision, and Action Guidelines to guide us in realizing our corporate philosophy. We will continue to be "passionate challengers" to deliver innovative medicines to patients with what are called unmet medical needs for which treatments have not yet been established.

Nomura I've served as an outside director for four years now, but when I was first asked to become an outside director, before anything else, I was impressed by the corporate philosophy. When managing a company, the tendency is to lean toward product development with a focus on profit, but I was moved by the corporate philosophy of what we can do for those who are suffering and struggling now. Furthermore, in the sustainable management policy newly formulated this year, contribution to people's health is newly mentioned. People have been talking about our being in a time of 100-year lifespans for a good while now, but I expect that the company will take on the challenge of the future being "a time of healthy lifespans of 100 years." I would like to thoroughly fulfill my function as an outside director so that we can make further contributions to society, with disease and pain, and health, as keywords.

Okuno As you all say, we have a great corporate philosophy. The next step is how to instill it in our employees. One of our tools is a mission statement movie, which is shown at various occasions, such as company gatherings and training sessions. I have seen it several times and it is very good. The history of innovation shown, of course, but also the significance of what it is that we are working for, is front and center, and it is an excellent way to promote the instillation of the mission statement. Further, as a next step, management needs to take a step to watch and measure the degree to which it is instilled in employees and how it is expressed in their behavior.

Nagae It has only been a year since I became an outside director, but I remember feeling a great deal of empathy when I first heard the corporate philosophy. However, while every company has a great corporate philosophy, the question is how all employees can work together to realize it. That's why I think it's important to constantly make efforts to instill it. If all employees work together to fulfill their company's mission, sales and profits will follow as a result, and I believe that we must make it that way. I have high expectations that the company will not only help people suffering from intractable diseases, but also address the need to extend healthy life expectancy.

Promoting the Medium-Term Management Plan

Sagara As a roadmap to realize our corporate philosophy, in addition to our mission statement, in 2017 we formulated three 5-year medium-term management plans targeting 2031, fifteen years later. We are now in our second period, which started in fiscal 2022, and we would like to establish a firm future vision based on the results and challenges of the first period, and draw a roadmap to achieve it. At the core of this vision are four growth strategies: Maximizing Product Value, Reinforcement of Pipelines and Acceleration of Global Development, Realization of Direct Sales in the US and Europe, and Expansion of Business Domains. We are also focusing on intangibles, such as human and intellectual assets, as well as digital and IT infrastructure. More to the point, we consider our expertise in open innovation to be a great asset, and we intend to pursue it so that we can further demonstrate this strength.

Nomura Recently, an all-division meeting was held with the participation of all employees to disseminate the medium-term management plan to employees, and what I felt there was the closeness between management and general employees. I believe that employees had an opportunity to speak up, and each one of them could recognize "what I do" and "what I can do." A training plan was also discussed at the board meeting, and I could see that the company is trying to develop human resources with a very broad range of skills and characteristics through various training programs. I have also experienced talents and corporate planning in the course of managing a company, so I hope to make positive comments and proposals as an outside director, based on my own experience and while learning something new.

Okuno My specialty is people. In terms of growth strategies, I believe that I can contribute to the strengthening of the management foundation that forms the base of such strategies. In particular, Ono is currently strengthening its efforts to develop human resources in digital and innovation, and the planning and operation of a wide variety of training programs, including e-learning, is being visualized by the Board of Directors, and I myself am watching the progress with great anticipation. If I were to make a

Round-table Discussion with the Outside Directors

request, it would be to see a greater focus on diversity. I have pointed out to the Board of Directors that I would like to see a firm count of the number of women and foreigners who have participated in the training programs.

Nagae In pursuing our growth strategy, I'm focusing on strengthening corporate infrastructure, particularly in the area of expanding human capital. While strict compliance is a major mission for any company, I believe that compliance is a matter of corporate culture, or in other words, a matter of people. I have been practicing kendo for a long time, and there is the idea that kendo is a path of human development. Winning is not the ultimate goal. The main objective is to develop people, and by doing so, the results will naturally follow. I believe that in a company as well, the development of people is the basis of everything. Creating a corporate culture in which people can say anything to each other. That is the key to preventing misconduct, encouraging employees to take on new challenges, and leading to innovation, so I would like to support and encourage this point in particular.

Management Issues and Redefining Material Issues

Sagara The material issues we identified in 2018 had a strong orientation to CSR issues, but this year we reorganized them from the perspective of important issues for overall management. In line with the medium-term management plan, we have clarified more clearly what kind of value creation we are aiming for and what kind of foundation we need to build in order to achieve that.

Nomura I believe that this reorganization has enabled each and every employee to more clearly recognize what they should do. Defining material issues is not the end of the process once, it is important for the field to take action and achieve results, so in that sense, it has become very easy to understand, and I am now looking forward to seeing what reports will be presented at next year's all-division meeting. As an outside director, I would like to collect and provide as much outside information as possible to further evolve material issues.

Okuno It's very significant that material issues were newly redefined as management issues this time. I think the reason for this is probably that CSR issues are considered to be things that are separate from the company's core business and not things that employees considered to be their own issues. However, now that they have become management issues, they are widely recognized as issues in our core business. That was a breakthrough.

Nagae Five or six years ago, the SDGs were already commonplace in Europe and the United States, but awareness was still low among Japanese managers. Now, however, awareness has spread considerably. Definition of material issues has also become commonplace, but it is important for each employee to think "what number of the SDGs is the work I'm doing now connected to, and which material issue will be solved?" and really feel the link of their work to the SDGs.

Increase Transparency and Objectivity in Executive Appointments and Executive Compensation

Sagara We now have three outside directors with diverse backgrounds: Mr. Nomura and Mr. Nagae, who have experience in corporate management, and Ms. Okuno, a university professor specializing in business administration, and I believe that we have reached a very ideal form. By incorporating objective opinions not only at Board of Directors meetings but also at meetings related to executive personnel and executive compensation, we believe that we have secured a level of transparency that allows us to provide thorough explanations to our stakeholders.

Nomura I have just assumed the chairmanship of the Executive Compensation Meeting. I will fulfill my position with objectivity and practicality, as well as keeping the word common sense in mind, which I have valued as a manager.

Nagae I think that although thinking about compensation systems differs depending on the company, I believe it is important to make sure that it is not too different from what is generally acceptable. Regarding executive appointments, the Board of Directors then makes decisions after review by the Executive Appointment Meeting. I think it is good that we can deepen information and discussion in this process. On the other hand, I also feel that it is necessary to create a system that allows us to understand more in-depth personal information about director candidates, such as their personalities and backgrounds.

Okuno Compensation, evaluation and appointments, I believe these are all interlinked. While we cannot compete with those within the company in terms of the amount of information we have, I feel that our role is to look at it from the perspective of whether we can explain it to the outside world. If it is not at least satisfactory to us, it cannot be satisfactorily explained to those outside the company.

For Further Growth in the Future

Sagara Please tell me what you feel are the challenges at Ono Pharmaceutical today.

Nomura I believe that there is a need for a thicker layer of senior management. Ono's business performance has been expanding very rapidly over the past few years, and the number of employees has been increasing. Since we have gathered human resources from various fields, I believe that one of our major challenges is to increase the number of leaders.

Nagae When a company grows, there comes a desire for expansion, but this also entails the risk of failure. However, to grow further, one must be prepared to take on challenges, even if it involves some risk. It is important to be resourceful and change one's thinking and actions immediately when something happens. Also, as the company grows, various rules will become necessary, so I think it is important to start considering ahead of time what rules will be necessary in terms of governance and compliance.

Okuno In terms of my role, as I said before, it is still to strengthen diversity. I have had limited contact with employees due to the COVID-19 pandemic, but there seems to be many

excellent people. I would very much like to ask you to create a system to pick up these people and make them role models.

To Know More about Ono Pharmaceuticals

Nomura Ono's support system for outside directors is excellent, and we are making good use of the information in the trade press that you provide to us to gain expertise. I think that if you could go one step further and include information about the weaknesses of us outside directors, and other information that the company would definitely like us know, it would help us understand the company better.

Okuno I was limited by the COVID-19 pandemic, so my contact with the company and its employees itself was limited. I wish we had more opportunities to get to know the company in the flesh, as it were, during our monthly board meetings. With the return of the face-to-face format, I honestly feel that I would like to visit more places, if requested. I believe that new contacts would emerge from such visits, and we would probably be able to share with each other more information that we want and need. I hear that there are plans for outside directors to have research institute and factory tours in the future, and I would like for us to have more contact with employees in a variety of ways.

Nagae I am impressed that Ono is responding well to the requests of outside directors. Now it is important for me to study the information provided to me on my own, and I would like to ask for continued support in this regard.

Sagara We recognize that providing more opportunities and increasing the quantity and quality of information in order to receive better proposals and recommendations from all of you will strengthen Ono, and we will continue to be proactive in this regard.

Thank you very much for your time today.

Management (as of July 1, 2022)

Gyo Sagara

President, Representative Director, and Chief Executive Officer

Number of the Company's shares held : 56,500

April 1983	Joined the Company
April 2006	Executive Director, General Administration and Senior Director, Corporate Management
June 2006	Member of the Board of Directors
April 2007	Executive Director, Corporate Management
November 2007	Executive Director, Sales and Marketing
December 2007	Managing Member of the Board of Directors
February 2008	Member of the Board of Directors, Vice President
April 2008	Executive Director, Corporate Management
June 2008	Vice President and Representative Director
September 2008	President, Representative Director & CEO (to date)

Toshihiro Tsujinaka

Member of the Board of Directors, Senior Executive Officer
Executive Director, Corporate Strategy & Planning

Number of the Company's shares held : 11,800

April 1988	Joined the Company
June 2004	Senior Director, Koshinetsu Branch Sales Division
November 2007	Senior Director, Sales Operations
October 2012	Senior Director, Sendai Branch Sales Division
October 2015	Senior Director, Oncology Planning & Promotion Division Director, Oncology Business Division
April 2016	Corporate Officer
June 2016	Executive Director, Corporate Strategy & Planning (to date)
October 2018	Corporate Executive Officer
June 2019	Member of the Board of Directors, Executive Officer
June 2020	Member of the Board of Directors, Senior Executive Officer (to date)
June 2021	

Toichi Takino

Member of the Board of Directors, Senior Executive Officer
Executive Director, Discovery & Research

Number of the Company's shares held : 12,300

April 1995	Joined the Company
April 2006	Senior Director, International Business
April 2008	Senior Director, Business Development
May 2008	Senior Director, Global Business Development & Licensing
July 2009	Vice President, ONO PHARMA USA INC.
June 2011	Corporate Officer
April 2012	Executive Director, Corporate Development & Strategy
October 2018	Executive Director, Discovery and Research Division
April 2019	Executive Director, Discovery & Research (to date)
June 2019	Corporate Executive Officer
June 2020	Member of the Board of Directors, Executive Officer
June 2021	Member of the Board of Directors, Senior Executive Officer (to date)

Akiko Okuno

Member of the Board of Directors, Outside Director

Number of the Company's shares held : 0

April 2002	Associate Professor, Faculty of Economics, Osaka University of Economics and Law
April 2004	Associate Professor, Faculty of Business Administration, Tezukayama University
April 2010	Professor, Faculty of Business Administration, Tezukayama University
April 2012	Professor, Faculty of Business Administration, KONAN UNIVERSITY (to date)
June 2020	Member of the Board of Directors, Outside Director (to date)

[Status or important concurrent holding of positions]
Professor, Faculty of Business Administration, KONAN UNIVERSITY

Shusaku Nagae

Member of the Board of Directors, Outside Director

Number of the Company's shares held : 0

April 1972	Joined Matsushita Electric Works, Ltd.
December 2004	Managing Executive Officer, Matsushita Electric Works, Ltd.
June 2007	Managing Director, Matsushita Electric Works, Ltd.
June 2010	Representative Director, President, Panasonic Electric Works Co., Ltd.
April 2011	Senior Managing Executive Officer, Panasonic Corporation (currently Panasonic Holdings Corporation)
June 2012	Representative Director, Executive Vice Panasonic Corporation
June 2013	Representative Director, Chairman of the Board, Panasonic Corporation
June 2017	Director, Chairman of the Board, Panasonic Corporation
June 2021	Member of the Board of Directors, Outside Director (to date)
June 2021	Special Corporate Advisor, Panasonic Corporation (currently Panasonic Holdings Corporation)(to date)

[Status or important concurrent holding of positions]
Special Corporate Advisor, Panasonic Holdings Corporation

Katsuyoshi Nishimura

Audit & Supervisory Board Member

Number of the Company's shares held : 11,700

April 1977	Joined the Company
April 2003	Senior Director, Research Management and General Affairs
October 2005	Deputy Executive Director,Discovery & and Senior Director, Research Management and General Affairs
April 2006	Deputy Executive Director, Sales and Marketing and Senior Director, Sales Operations
June 2007	Senior Director, Sales Operations
November 2007	Director, Business Audit Department
June 2010	Senior Director, Research Management and General Affairs
June 2011	Full-time Audit & Supervisory Board Member (to date)

Isao Ono

Member of the Board of Directors, Executive Officer
Director, Corporate Research

Number of the Company's shares held : 1,511,175

April 1981	Joined the Company
February 1986	Member of the Board of Directors
May 1990	Deputy Executive Director, Production
June 1992	Senior Director, Human Resources Development and Assistant Director of Tokyo Branch Office
August 1995	Director, CI
September 2005	Director, Environmental Management
June 2011	Member of the Board of Directors, Corporate Officer
April 2014	Director, Corporate Research (to date)
June 2015	Member of the Board of Directors, Executive Officer (to date)

Kiyoaki Idemitsu

Member of the Board of Directors, Executive Officer
Executive Director, Clinical Development

Number of the Company's shares held : 4,800

April 1987	Joined the Company
December 2000	President, ONO PHARMA UK LTD.
January 2008	Senior Director, Discovery Research Alliance
January 2010	Senior Director, Global Business Department & Licensing
April 2012	Division Director, Discovery Research Alliance Division
October 2013	Senior Director, Nivolumab Strategic Planning
April 2017	Division Director, Medical Affairs
October 2018	Corporate Officer
October 2018	Executive Director, Clinical Development (to date)
June 2020	Corporate Executive Officer
June 2021	Member of the Board of Directors, Executive Officer (to date)

Masao Nomura

Member of the Board of Directors, Outside Director

Number of the Company's shares held : 5,000

March 1972	Joined Iwatani Corporation
June 2007	Director, Executive Officer, Iwatani Corporation
April 2009	Executive Director, Executive Officer, Iwatani Corporation
April 2010	Senior Executive Director, Executive Officer, Iwatani Corporation
June 2012	President, Representative Director, Executive Officer, Iwatani Corporation
April 2017	Director, Senior Adviser to the Board, Executive Officer, Iwatani Corporation
June 2017	Senior Adviser to the Board, Iwatani Corporation
June 2018	Member of the Board of Directors, Outside Director (to date)
June 2019	Outside Director, Keihanshin Building Co., Ltd. (to date)
June 2020	Outside Director, NEW COSMOS ELECTRIC CO., LTD.
July 2022	Corporate Advisor, Iwatani Corporation (to date)

[Status or important concurrent holding of positions]
Corporate Advisor, Iwatani Corporation
Outside Director, Keihanshin Building Co., Ltd.

Hironobu Tanisaka

Audit & Supervisory Board Member

Number of the Company's shares held : 1,400

April 1984	Joined the Company
August 2007	Senior Director, Legal Department
January 2018	Senior Director, Business Audit Department
June 2021	Full-time Audit & Supervisory Board Member (to date)

Yasuo Hishiyama

Outside Audit & Supervisory Board Member

Number of the Company's shares held : 0

April 1999	Appointed as a judge (served at Sendai District Court,Saitama District Court and Osaka Family Court)
April 2006	Registered as an attorney at law (Dai-Ichi Tokyo Bar Association)
April 2006	Joined TANABE & PARTNERS (to date)
January 2010	Member or appraisal committee (Land Lease Non-Contentious Cases) at Tokyo District Court (to date)
June 2016	Outside Audit & Supervisory Board Member (to date)

[Status or important concurrent holding of positions]
Partner Attorney at Law, TANABE & PARTNERS
Member or appraisal committee (Land Lease Non-Contentious Cases) at Tokyo District Court

Akiko Tanabe

Outside Audit & Supervisory Board Member

Number of the Company's shares held : 0

October 1993	Joined Century Audit Corporation (Present: Ernst & Young ShinNihon LLC)
May 1997	Registered as Certified Public Accountant
January 2012	Established Akiko Tanabe CPA office (to date)
June 2015	Outside Director, OIE SANGYO CO.,LTD. (to date)
July 2019	Partner of Midosuji Audit Corporation (to date)
April 2020	Provisional Outside Audit & Supervisory Board Member
June 2020	Outside Audit & Supervisory Board Member (to date)

[Status or important concurrent holding of positions]
Representative, Akiko Tanabe CPA office
Outside Director, OIE SANGYO CO., LTD.
Partner of Midosuji Audit Corporation

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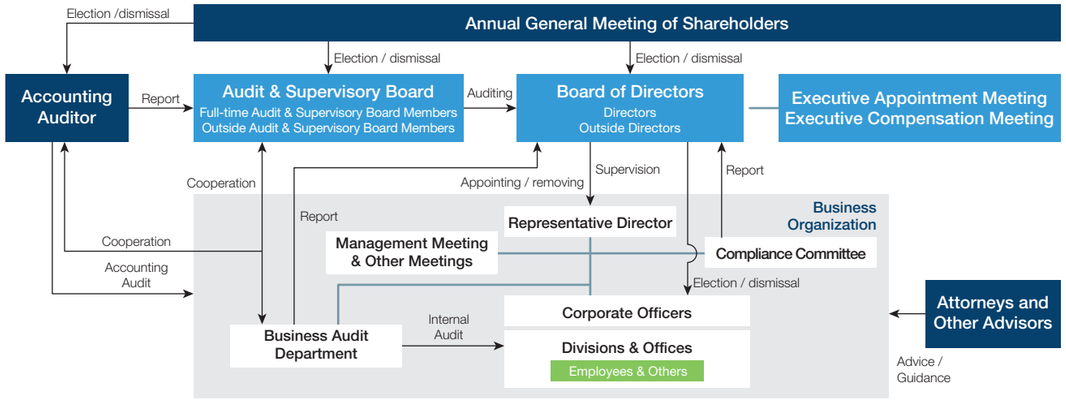
Corporate Governance

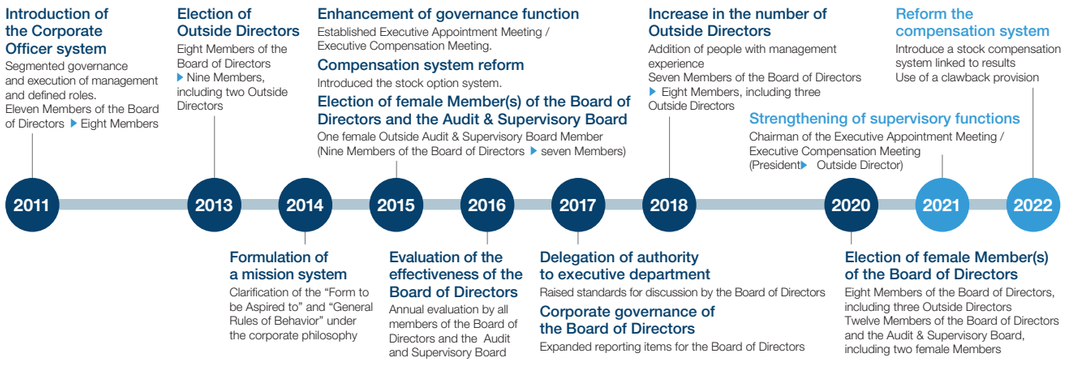
Corporate Governance Structure

As part of our endeavors to strengthen corporate governance, ONO has adopted an organizational framework with an Audit & Supervisory Board, whose task is to focus on enhancing the functions of the Board of Directors and the Audit & Supervisory Board. ONO has established an Executive Appointment Meeting and an Executive Compensation Meeting, both of which are composed of a majority of Outside Directors and have an Outside Director as chairman to ensure independence and objectivity with regard to the appointment and compensation of executives. Regarding business execution, we have adopted a corporate officer system to improve management efficiency and speed up decision-making. On the other hand, important matters related to business execution are deliberated and determined by the Management Meeting and other meetings chaired by the responsible members of the Board of Directors or Corporate Officers. Thus, we strive to achieve optimal business operations by ensuring effective working of mutual supervisory functions.

Corporate Governance Structure



Initiatives to Strengthen Corporate Governance



Corporate Governance Code

ONO follows all the principles in the Corporate Governance Code stipulated by the Tokyo Stock Exchange. In consideration of the intent of the Corporate Governance Code, we are committed to improving the efficiency, soundness, transparency, etc. of management, and improving our systems to be more suitable for our business operations going forward, too, through the evaluation of effectiveness through the annual evaluation the Board's effectiveness.

Web For more details about our company's corporate governance, please refer to the following Corporate Governance Report.
https://www.ono-pharma.com/sites/default/files/en/ir/corporate_governance_report_en.pdf

Board of Directors

We work to ensure an appropriate number and composition of directors on the Board of Directors, with focus on an expedited and accurate decision-making process while enhancing management transparency and supervisory functions.
We nominate candidates for the Board of Directors by taking into consideration the balance of their knowledge, experience, and capability, as well as diversity, so that the Board of Directors as a whole can make technical and comprehensive management decisions. In addition, we nominate candidates for Outside Directors from those who have high levels of expertise in corporate management on the premise that they satisfy the standards for Independent Directors set out by the Tokyo Stock Exchange, with a basic policy of at least one-third of the Board of Directors being Outside Directors (currently, three of eight members of the Board Directors are Outside Directors). The term of office for members of the Board of Directors is set at one year to maintain clarity of the responsibilities of management and to ensure we can respond quickly to changes in the business environment.
A meeting of the Board of Directors is held once every month in principle, with the attendance of the members of the Board of Directors and the Audit & Supervisory Board, to decide on important management issues and to supervise the status of the execution of duties by members of the Board of Directors. In order for members of the Board of Directors and Audit & Supervisory Board to appropriately fulfill their roles and responsibilities, the attendance rate at the meetings of the Board of Directors is, in principle, set at 75% or more. Taking into account the time required to be devoted to duties as a member of the Board of Directors or Audit & Supervisory Board, we set a limit on the number of companies the members of the Board of Directors and Audit & Supervisory Board are allowed to concurrently serve as officers or in other capacities (appointment as officers of listed companies, etc.) at up to, in principle, four companies not including us.

Audit & Supervisory Board

From the perspective of strengthening audit functions, the Audit & Supervisory Board is composed of two independent members along with two full-time members who have expert knowledge of our business operations and who are highly skilled in collecting auditing information. These Outside and full-time members work together to achieve high auditing efficiency.
A meeting of the Audit & Supervisory Board is held regularly. The Audit &Supervisory Board strives to enhance management's supervision by enhancing efficiency through cooperation with the Business Audit Department and audit effectiveness through cooperation with the Accounting Auditor.

Executive Appointment Meeting

The Executive Appointment Meeting is composed of three Outside Directors, one of whom is the Chairperson, the President, Representative Director, and Chief Executive Officer, and the Director in charge of Personnel. With all members attending, they ensure the transparency and objectivity of the appointment of candidates for the Board of Directors, Audit & Supervisory Board, and senior management, and discuss the policies for planning the succession of the chief executive officer (President, CEO) and senior management, and the state of our corporate governance. Executive appointments to be submitted to the Board of Directors are discussed at the Executive Appointment Meeting, and submitted to and approved by the Board of Directors.

Executive Compensation Meeting

The Executive Compensation Meeting is composed of three Outside Directors, one of whom is the Chairman, and the President, Representative Director, and Chief Executive Officer. With all members attending they ensure the transparency and objectivity of, and deliberate on the amounts of compensation for each member of the Board of Directors and the calculation methods thereof, and the appropriateness and future form of the executive remuneration compensation system, etc. Also, when considering the compensation (including bonus) for the President, the President withdraws, and it is handled without his direct participation. Compensation, etc. of members of the Board of Directors is discussed at the Executive Compensation Meeting, and submitted to and approved by the Board of Directors.

Attendance at the Meetings of the Board of Directors and the Audit & Supervisory Board
One year from June 17, 2021 (the end of the 73rd Annual General Meeting of Shareholders)

	Name	Board of Directors	Audit & Supervisory Board	Executive Appointment Meeting	Executive Compensation Meeting
Member of the Board of Director	Gyo Sagara	◎100%	–	100%	100%
	Toshihiro Tsujinaka	100%	–	100%	–
	Toichi Takino	100%	–	–	–
	Isao Ono	100%	–	–	–
	Kiyoaki Idemitsu	100%	–	–	–
Outside Director	Masao Nomura	100%	–	◎*100%	◎*100%
	Akiko Okuno	100%	–	100%	100%
	Shusaku Nagae	100%	–	100%	100%
Audit & Supervisory Board Member	Katsuyoshi Nishimura	100%	◎100%	–	–
	Hironobu Tanisaka	100%	100%	–	–
Outside Audit & Supervisory Board Member	Yasuo Hishiyama	100%	100%	–	–
	Akiko Tanabe	100%	100%	–	–

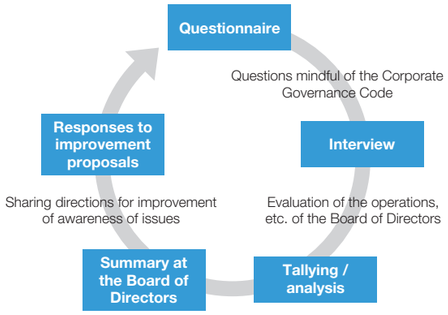
◎: Chairperson (*assumed the position in January 2022)
Number of meetings held since appointment
Board of Directors meetings: 15, Audit & Supervisory Board meetings: 16, Executive Appointment Meetings: 4, and Executive Compensation Meetings: 5

Evaluation of the Effectiveness of the Board of Directors

ONO conducts self-evaluations on the composition, operation and other matters of the Board of Directors once a year with the aim of improving the effectiveness of the Board of Directors as a whole. The results of the FY2021 analysis and evaluation of the effectiveness of the Board as a whole are summarized as follows:

1 Method of Evaluation

ONO conducted a questionnaire of all the members of the Board of Directors and Audit & Supervisory Board requiring them to write their names on the answer sheets, and also held one-on-one interviews with them, after explaining the purpose of the questionnaire and interviews at a meeting of the Board of Directors.
Based on the answers and opinions gained from the questionnaire and interviews, the Board of Directors conducted analysis and self-assessments of its effectiveness and discussed difficulties to tackling issues as well.



Major contents of the questionnaire and interviews

- Size and composition of the Board of Directors
- Operation of the Board of Directors
- Roles and responsibilities of the Board of Directors

2 Summary of Results of Analysis and Evaluation

- The Board of Directors makes important management decisions in an expeditious and appropriate manner, and a system that allows appropriate supervision of business execution is ensured.
- Measures have been taken on an ongoing basis to improve the operation of the Board of Directors, including a review of matters for deliberation at the Board of Directors in light of the management environment and the situation of the Company.
- Members of the Board of Directors and Audit & Supervisory Board, including Outside Directors and Outside Audit & Supervisory Board members, are freely expressing their opinions from their own perspectives, based on the common understanding of the corporate philosophy and the management issues of the Company.
- Based on the results above, ONO concluded that the effectiveness of the Board of Directors is ensured.

3 Initiatives to Improve Effectiveness

Amid the drastically changing environment surrounding the Company, the Board of Directors will further improve its effectiveness by enhancing discussions on the direction of management from a medium- to long-term perspective.

Improvement Status Based on Evaluation of the Effectiveness of the Board of Directors

Major improvements in FY2021	
Composition of the Board of Directors	Increased the number of Outside Board members with management experience
Corporate governance of the Board of Directors	Increased information provided to Outside Directors and broadened discussions regarding medium- to long-term management
Role and functions of Outside Directors	Chairman of the Executive Appointment Meeting and the Executive Compensation Meeting

Outside Directors and Outside Audit & Supervisory Board Members

Outside officers provide useful advice and suggestions for our business management based on their abundant experience and profound knowledge.
The Outside Directors oversee our business operations and take part in our decision-making process from an independent and objective standpoint. They are involved in the process of making important decisions, such as the nomination of officers and executive compensation, help to ensure transparency and objectivity, and enhance the function of the Board of Directors by serving as members of the Executive Appointment Meeting and the Executive Compensation Meeting.
As experts in law and corporate accounting, the Outside Audit & Supervisory Board members carry out audits from an independent and objective standpoint to ensure that our management remains sound.
There are no special interest relationships between outside officers and ONO, such as personal relationships, capital relationships, or business relationships. Because of this we believe there is no risk of conflict of interest with general shareholders.

Cooperation between Outside Directors and the Audit & Supervisory Board

Since FY2015, we have held annual cooperation meetings between Outside Directors and the Audit & Supervisory Board hosted by the Audit & Supervisory Board. One of the purposes of these meetings is to facilitate cooperation between Outside Directors and the Audit & Supervisory Board, who monitor business management as non-executive officers.
In this meeting, full-time Audit & Supervisory Board members, who are familiar with the operations of ONO, Outside Audit & Supervisory Board members, who are experts in law and corporate accounting, and Outside Directors, who have abundant experience and knowledge, come to an understanding of each other's viewpoints and differences in authority and then exchange opinions related to the issues and themes surrounding business management.

Support System for Outside Directors and Outside Audit & Supervisory Board Members

The Company supports Outside Directors by providing information to and receiving information from them through the Corporate Governance Office, which serves as the secretariat of the Board of Directors.
Full-time Audit & Supervisory Board members mainly provide Outside Audit & Supervisory Board members with information at meetings of the Audit & Supervisory Board and other occasions in an appropriate manner.
In addition, support for the Audit & Supervisory Board members, including Outside Audit & Supervisory Board members, is provided by the person in charge of supporting the duties of the Audit & Supervisory Board.

Major Fields of Expertise and Experience of Members of the Board of Directors and Audit & Supervisory Board Members

- **Subject persons** Members of the Board of Directors and Audit & Supervisory Board Members who are required to attend the Board of Directors' meetings
- **Skill recognition criteria In-house** Members of the Board of Directors: Experiences in operations and management positions; Outside Members of the Board of Directors/Audit & Supervisory Board Members: Fields where supervision, auditing, and advice are expected.

	Name	Major fields of expertise and experience							
		Corporate management	Finance/ Accounting	Legal/Risk management	Research and development	Corporate Development & Strategy/Marketing	Human resources/Human capital development	ESG/ Sustainability	Global experience
Members of the Board of Directors	Gyo Sagara	●	●			●		●	
	Toshihiro Tsujinaka		●			●	●		
	Toichi Takino				●	●			●
	Isao Ono					●	●	●	
	Kiyoaki Idemitsu				●	●			●
	Masao Nomura	●	●	●		●	●	●	
	Akiko Okuno						●	●	●
	Shusaku Nagae	●			●	●		●	●
Audit & Supervisory Board Members	Katsuyoshi Nishimura			●		●		●	
	Hironobu Tanisaka			●				●	
	Yasuo Hishiyama			●				●	
	Akiko Tanabe		●					●	

Expected Roles of Outside Directors and Outside Audit & Supervisory Board Members

	Name	Expected roles
Outside Directors	Masao Nomura	Mr. Nomura has abundant experience and high-level knowledge because he has served as a corporate executive for many years, and he has fulfilled important roles as an Outside Director by providing appropriate supervision of the Company's management from an independent perspective as well as useful advice and suggestions on overall management. We expect that Mr. Nomura will continue to be involved in the Company's management as an Outside Director and thereby contribute to increasing the Company's value due to his experience and knowledge from being a corporate executive.
	Akiko Okuno	Ms. Okuno has extensive academic knowledge as a university professor specializing in business administration. She has fulfilled important roles as an Outside Director by providing appropriate supervision of the Company's management from an independent standpoint as well as useful advice and suggestions based on her knowledge in her fields of expertise, such as women's labor and personnel appraisal systems. We expect that Ms. Okuno will contribute to increasing the Company's value due to her expertise cultivated through business science research and the results of her work by being involved in ONO's management as an Outside Director.
	Shusaku Nagae	Mr. Nagae has abundant experience and high-level knowledge because he has served as a corporate executive for many years. He appropriately supervises our management from an independent perspective, and provides useful advice and suggestions related to overall management, fulfilling an important role as an Outside Director. We expect that based on his results as a corporate manager, knowledge, and work to date, Mr. Nagae will continue to be involved in the Company's management as an Outside Director and thereby contribute to increasing the Company's value.
Outside Audit & Supervisory Board Members	Yasuo Hishiyama	With abundant experience and high-level knowledge of corporate legal affairs as an attorney-at-law, Mr. Hishiyama has fulfilled important roles as an Outside Audit & Supervisory Board member. He has provided appropriate supervision of the operations of the Board of Directors from an expert and independent standpoint, as well as making comments and suggestions as needed. We expect that Mr. Hishiyama will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of the Company as an Outside Audit & Supervisory Board member.
	Akiko Tanabe	With abundant experience and considerable knowledge of accounting as a certified public accountant, Ms. Tanabe has fulfilled important roles as an Outside Audit & Supervisory Board member. She has provided appropriate supervision of the operations of the Board of Directors from an expert and independent standpoint as well as making comments and suggestions as required. We expect that Ms. Tanabe will contribute to maintaining and improving sound management and appropriate operation by being involved in the management of the Company as an Outside Audit & Supervisory Board member.

Executive Compensation

1 Basic Stance on Executive Compensation

- The compensation of members of the Board of Directors encourages them to continue pursuing a medium- to long-term vision so that they can address achieving sustainable growth as a research and development-type pharmaceutical company, share awareness of interests with shareholders, and improve company value. The compensation makes it possible to increase the awareness of the Board of Directors (excluding Outside Directors) of performance goals and facilitate their contribution to improving company value.
- Compensation for Directors and Audit & Supervisory Board members shall be set to an appropriate level, taking into consideration the scale of the Company's business, responsibilities, management strategy, etc., and referring to the management compensation database of an external professional organization, with the prerequisite that the level of compensation is appropriate to secure excellent human resources.
- Compensation of members of the Board of Directors (excluding Outside Directors) consists of Basic Compensation that is fixed compensation, Performance-based Compensation that is a short-term incentive, and Stock-based Compensation that is a medium- to long-term incentive. As for Outside Directors and Audit & Supervisory Board members, in consideration of their duties they receive only Basic Compensation that is fixed compensation.

2 The Process to Determine Director Compensation

- The amount of individual compensation of members of the Board of Directors is proposed to and determined by the Board of Directors to the extent that approval is obtained at the annual general meeting of shareholders after examination at the Executive Compensation Meeting.
- The amount of compensation of Audit & Supervisory Board members is determined in discussions among Audit & Supervisory Board members to the extent that approval is obtained at the annual general meeting of shareholders.

3 Revision of the Directors' Compensation System

In FY2022, we revised the compensation system for directors in order to strengthen the incentive to improve corporate value over the medium- to long-term and to promote further value sharing with shareholders, with the aim of becoming a global specialty pharmaceutical company.

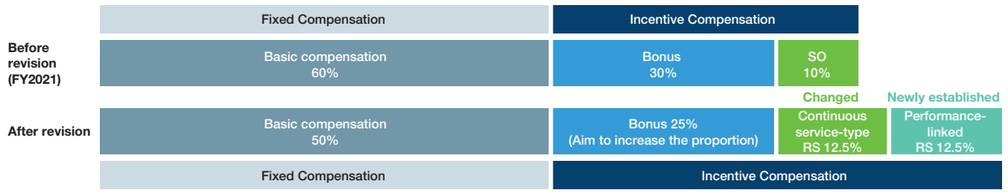
Purpose of the Revision

- Strengthen the incentive to improve corporate value over the medium- to long-term with the aim of becoming a Global Specialty Pharma.
- Increase the proportion of incentive compensation and stock compensation to promote further value sharing with shareholders.
- Strengthen compensation governance.

Main Points of the Revision

- Make it possible to increase the proportion of variable compensation.
- Replace the old stock compensation-type stock option system with a continuous service restricted transfer stock compensation plan.
- Newly establish a performance-linked restricted transfer stock compensation plan.
- Establish a clawback provision for the performance-linked restricted transfer stock compensation plan.

Changes to the Composition of Director's Compensation (excluding Outside Directors) due to Revision of the System (when standard targets have been achieved)



Note: The proportions of the compensation structure for directors (excluding Outside Directors) will be determined based on the characteristics of ONO's business, management issues at the time, and the business environment. The proportion of each type of remuneration after revision is an estimate calculated based on a certain company size and the unit price of the Company's shares, and is only a guideline figure and will change according to changes in business performance and stock price, etc. SO stands for stock option for stock-linked compensation and RS for restricted transfer stock.

About the New Stock Compensation Plan

Continuous service-type Restricted transfer stock compensation	Overview of the Plan • In principle, stock restrictions shall be released and the stock delivered in a lump sum after the retirement of a director. • The number of shares to be delivered will be calculated according to the level of responsibility in making decisions. • The shares will be delivered after the end of the annual general meeting of shareholders.
Performance-linked Restricted transfer stock compensation[1]	Overview of the Plan • In principle, stock restrictions shall be released and the stock delivered in a lump sum after the retirement of a director. • The number of shares to be delivered will be calculated based on the degree of achievement of performance targets (including ESG targets) set on a fiscal year-by-fiscal year basis, which are tied to medium- to long-term management targets and management issues, and the degree of achievement of target figures for performance indicators for each fiscal year. • Based on the results of the performance evaluation after the end of the performance evaluation period (one fiscal year), the shares will be delivered after the end of the annual general meeting of shareholders (post-delivery type). The Actual Method of Calculation for Each Director • Number of shares to be delivered to each Director = the base number of shares[2] x percentage to be delivered[3]

1 The same number of performance-linked restricted transfer shares will be issued to executive officers who do not concurrently serve as Directors.
2 The Board of Directors shall determine the amount of the compensation based on the position, responsibility, etc. of the Director.
3 The Board of Directors will determine the percentage of achievement of each performance target, etc. for each performance evaluation period in the range of 0 to 200%.

Overview of Performance Indicators for FY2022

Financial targets	Revenue	
	Operating profit	
Strategic targets	Initiatives for increasing corporate value over the medium-term (Set for each individual)	Maximization of product value
		Strengthening of the pipeline and acceleration of global development
		Realization of our own marketing in the US and Europe
		Expansion of business domains
		Management foundation that supports the growth strategy (expansion of intangible assets)
		Corporate transformation via digital and IT platforms
Non-financial targets	Initiatives for priority issues	
	State of adoption by ESG indexes	

Note: In FY2022, we will adopt indexes developed by Dow Jones Sustainability Indices (DJSI), FTSE Russell, MSCI, CDP.

Malus Clause and Clawback Provision

If, during the term of office of a Director or executive officer (hereinafter referred to as "Director, etc."), such Director, etc. violates laws, regulations, or internal rules in a material respect, or if the Board of Directors of the Company deems it appropriate, or if certain other circumstances determined by the Board of Directors of the Company occur, all or part of the shares with transfer restrictions held by such Director, etc. may be forfeited according to a malus clause established by the Company.
From the viewpoint of ensuring appropriate operation of the system, in addition to the malus clause for performance-linked restricted transfer stock, the Company has established a clawback provision that allows the Company to demand the return of the shares for a certain period of time after the termination of the restriction on transfer in the case of the same events as described above.

Contents Decided at the Annual General Meeting of Shareholders Regarding Director Compensation

The maximum total amount of compensation (annual) for the Company's directors was approved at the 74th Annual General Meeting of Shareholders (held on June 23, 2022) as follows:

Revision of the Maximum Total Amount of Compensation

		Before the revision (up to FY2021)	
		Directors (excluding Outside Directors)	Outside Directors
Monetary compensation	**Basic compensation**	¥450 million	–
	Bonus		
Stock compensation	**Stock-based Compensation-type Stock options**	¥100 million (equivalent to 75,000 shares)	–

		After the revision (from FY2022)	
		Directors (excluding Outside Directors)	Outside Directors
Monetary compensation	**Basic compensation**	¥700 million	(¥100 million)
	Bonus		–
Stock compensation	**Continuous service-type Restricted-transfer stock**	¥100 million (60,000 shares)	–
	Performance linked-type Restricted-transfer stock	¥300 million (180,000 shares)	–

The maximum total compensation of 100 million yen for the Company's auditors was approved at the 65th Annual General Meeting of Shareholders held on June 26, 2013.

4 Total Amount of Executive Compensation* (FY2021 actual)

Executive category	Number of recipients	Fixed compensation	Bonus	Stock options	Total amount to be paid
Members of the Board of Directors (excluding Outside Directors)	6	¥208 million	¥130 million	¥41 million	¥379 million
Outside Directors	4	¥50 million	–	–	¥50 million
Audit & Supervisory Board members (excluding Outside Audit & Supervisory Board members)	3	¥59 million	–	–	¥59 million
Outside Audit & Supervisory Board members	2	¥26 million	–	–	¥26 million
Total	15	¥342 million	¥130 million	¥41 million	¥513 million

* Includes directors who retired as of June 17, 2021 (one director, one outside director, and one Audit & Supervisory Board Member).

Policy on Cross-Shareholdings

The Company believes that it is essential to have partner companies with which the Company can maintain long-term collaborative relationships in order to discover innovative pharmaceutical products that truly benefit patients. The Company, therefore, holds shares that it deems necessary to hold for strategic purposes, after comprehensively considering the business relationship with the issuers of those shares and the synergies created, in light of a medium- to long-term perspective for increasing corporate value.
When judging whether cross-shareholding will lead to an increase in the corporate value of the Company from a medium- to long-term perspective, once a year the Board of Directors reviews the purpose of the holdings, the benefits and risks from cross-shareholding with respect to each issuer of the cross-held shares, and determines whether or not to continue holding those shares after comprehensively considering the business relationship with the issuers and synergies created. For the shares that the Company decides to reduce holdings of as a result of this review, the Company has discussions with the investees to obtain their understanding while implementing the reduction.
As part of an overall revision of cross-shareholdings, we have been systematically reducing them since fiscal 2018. By the end of March 2022, we had reduced our cross-shareholdings by 44 issues, bringing the total amount on the balance sheet to 114 billion yen and the ratio of cross-shareholdings to consolidated net assets to 17.2%. Going forward, we will continue to reduce these holdings with the goal of reducing the ratio to less than 10% over the medium to long term.

Status of Cross-Shareholdings

	As of the end of March 2018	As of the end of March 2022
Number of issues held	111 issues	67 issues
Amount reflected on the balance sheet	¥167.1 billion	¥114.0 billion
Percentage of consolidated net assets	31.6%	17.2%

Internal Control System

ONO has laid out its operational system in compliance with the internal control system set out at the Board of Directors meeting. We also strive to ensure compliance and detect internal control problems at an early stage through auditing by the Business Audit Department, which does internal audits, thereby maintaining and improving the appropriateness of organizational management. In addition, the development and operation status of the internal control system is reported periodically to the Board of Directors, and we work to constantly improve organizational operation.
Concerning antisocial forces, or organizations that may threaten social order or security, we communicate our firm stance to fight against them throughout our organization.

Operational Management Structure

For the maintenance and improvement of efficiency and accuracy of our decision-making and business operations, we hold Management Meetings and other meetings attended by the President, members of the Board of Directors, the corporate officers in charge of each division, and managers of relevant departments. At these meetings, we take a multifaceted approach to addressing important management issues, including those that are to be deliberated on at Board of Directors meetings. Also, we have a corporate officer system and promote the transfer of authority to maintain and improve management efficiency and make quicker decisions.
Audit & Supervisory Board Members are obliged to attend Management Meetings and inspect their minutes, as these meetings are also subject to auditing.

Information Disclosure

As specified in our Code of Conduct, we strive to establish transparent corporate management and recognize the importance of disclosing 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, promptness, fairness, and impartiality.
We disclose financial results and other information subject to timely disclosure rules 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 actively hold individual meetings and phone conferences in addition to a financial result briefing or a conference call at the time of each quarterly statement. In FY2021, due to the impact of COVID-19, we continued to use the Internet and held approximately 200 meetings in total. In normal circumstances we participate diligently in company briefings for individual investors sponsored by security firms, etc.; however, face-to-face briefings were difficult due to the impact of COVID-19 and therefore briefings were live-streamed. Under this environment, we continue to deepen investors' understanding of our business activities and business management strategies.

Risk Management

Basic Approach

We work to identify potential major risks to prevent them from occurring, and we have a structure in place to ensure that appropriate actions are taken in case they occur.
In addition, we have a company-wide risk management system with the President and Representative Director as the chief risk management officer and the Executive Director of Corporate Strategy & Planning (a member of the Board of Directors and a Senior Executive Officer) as the risk management director in charge. In this way, we tackle issues related to risk management, recognizing them as important issues for management strategy. Furthermore, we have an Audit & Supervisory Board and an Business Audit Department working to increase the effectiveness of audits in risk management.

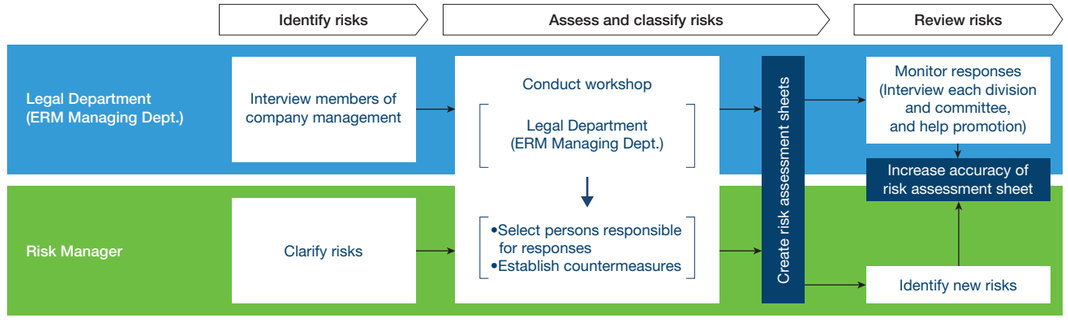
Establishment of an Enterprise Risk Management (ERM) System

We introduced Enterprise Risk Management (ERM) in FY2019, aiming for total, rather than partial, optimization of risk management. For implementation, we have appointed a Chief Risk Management Officer (President, Representative Director, and Chief Executive Officer) and a Head Risk Management Officer (member of the Board of Directors). In addition, we made the Legal Department the managing department for risk management, and established risk management regulations to promote ERM.

Basic Policy on ERM

1. With the aim of ensuring stable business continuity and achieving our business objectives, we have an enterprise risk management system to minimize losses to our company and its stakeholders, including customers, while fulfilling our accountability to society.
2. Each division assesses its risks using risk assessment sheets, and autonomously promotes risk management.
3. We identify the most important and urgent risks that could have a considerable impact on business management, and promote company-wide risk management activities.
4. In the event a risk materializes, we will take measures to minimize the damage and ensure prompt recovery in order to solve problems as quickly as possible.

Flow of ERM Promotion



ERM Promotion System

- **Basic Approach**
  1. Each Division Head uses the division's Risk Management Promotion Meeting to supervise the division's risk management.
  2. Office Managers conduct daily risk management.
  3. The Legal Department periodically monitors the risk management status of each division from the viewpoint of ERM.

  The results of monitoring are reported to the Management Committee (composed of directors, executive officers, division managers, etc.), the Board of Directors, and the Audit & Supervisory Board.

- **Risk Management Promotion Meeting**
  The Risk Management Promotion Meeting in each division assesses the division's risks and extracts issues using a risk assessment sheet, and develops prevention measures for identified risks according to their materiality and urgency, as well as risk responses. Thus, each division autonomously promotes risk management by considering, developing and implementing appropriate risk measures. The risk assessment sheet covers a wide range of risks, not only business risks, but also risks related to the environment, major disasters, human rights, pharmaceutical affairs laws and regulations, bribery, etc. In FY2021, each division extracted risks in a bottom-up fashion (bottom-up interviews) primarily by the division's risk manager, to see if there were any unidentified risks.

- **Risk Management System for Environmental Issues**
  Business risks related to environmental issues are also managed within ERM. In terms of climate change in particular, associated risks and opportunities are identified and evaluated by the TCFD Working Group under the Environment Committee. The head of the Legal Department also participates in this working group, and progress is reported to the Company-Wide Risk Management Committee to ensure coordination with ERM. (See pp. 68)

- **Response to Major Risks**
  The Management Meeting identifies important and urgent risks as major risks every fiscal year, and considers, develops, and implements measures to control the identified risks, while monitoring the identified risks on a company-wide scale. In the event a risk occurs, we will take action in accordance with the response plan to minimize the damage and ensure prompt recovery, thereby solving problems as quickly as possible.

- **Crisis Management**
  In the event a major risk occurs, the President will establish an Emergency Response Committee as necessary, to take measures to minimize damage and facilitate speedy recovery.

- **Risk Management Education**
  We provide education on risk management for all employees to raise their awareness and sensitivity toward risks.

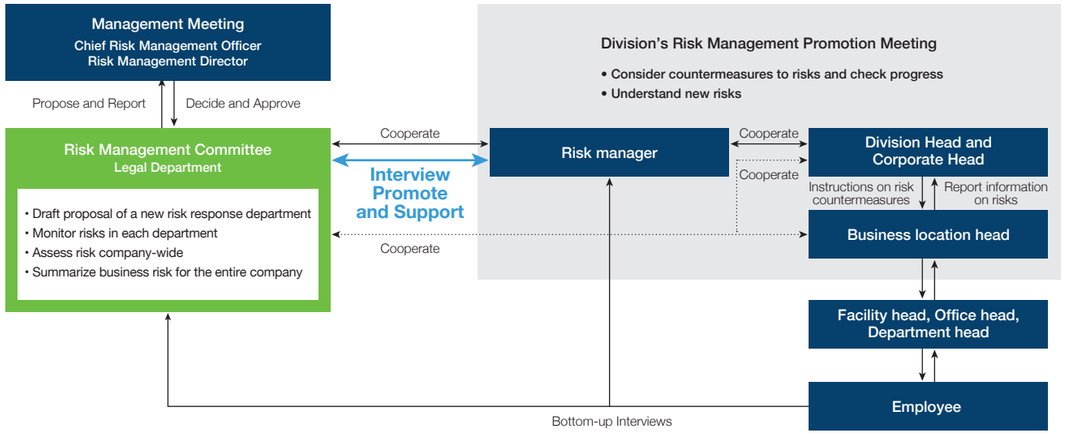
  Training for all employees:
  We had e-learning education on the basics of risk management and practical risk management skills (e.g., true cause analysis of risk issues and management techniques). (FY2020-2021)

  Training for risk managers and management:
  We conducted workshops on risk management techniques for internal directors, risk managers in each division, and leadership in some divisions. (FY2019-2020)

ONO Group's Risk Management

To promote risk management activities across the Group, we provide our subsidiaries with guidance and advice on risk management, while respecting their autonomy. We provide such guidance and advice through various opportunities including regular discussions where we receive reports from subsidiaries regarding their business operations and discuss important matters. We began to expand our ERM system to our subsidiaries in Japan and overseas in FY2020 to further enhance the risk management of the entire Group. In FY2021 we conducted risk assessments with risk assessment sheets.

Risk Management System



Business Continuity Plan (BCP)

We have set up a BCP Management Headquarters under the Emergency Response Committee, chaired by the President and Representative Director, and established a system designed to minimize the impact on operations even if a natural disaster or serious accident occurs, so that we can continue business activities, and even if they are suspended, recover promptly and resume them. And for management during normal times, we have a Business Continuity Management (BCM) Committee, which is chaired by the Executive Director of Corporate Strategy & Planning and is in charge of business continuity management, and a Management Office to maintain and strengthen our abilities to respond to crisis and continue our business operations, and promote relevant management activities.
We have prepared for disasters by installing systems such as emergency generators and duplicate power service in our Headquarters, the Tokyo Building, and all of our plants and research institutes, and we have also introduced seismic isolation systems to prepare for earthquakes in our Headquarters, the Tokyo Building, Minase Research Institute, and the Yamaguchi Plant. Also, because we have transferred some of the functions of the Headquarters in Osaka to the Tokyo Building, the development of a two-base system, improves our ability to continue our business operations. The BCM Committee conducts drills under the assumption of a large-scale disaster, identifies issues, and redoes plans to improve BCP response capabilities.

Web BCP System
https://sustainability.ono-pharma.com/en/themes/82#916

Financial Information

Financial Review

Results for FY2021

(Billions of yen)

	FY2017	FY2018	FY2019	FY2020	FY2021	Change rate FY2020/FY2021
Revenue	261.8	288.6	292.4	309.3	**361.4**	+16.8%
Operating profit	60.7	62.0	77.5	98.3	**103.2**	+4.9%
Profit for the year (attributable to owners of the parent company)	50.3	51.5	59.7	75.4	**80.5**	+6.8%

Revenue

Revenue totaled ¥361.4 billion, which was an increase of ¥52.1 billion (16.8%) from the previous fiscal year (year on year).

Opdivo Intravenous Infusion for Malignant Tumors

While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to first-line treatment for non-small cell lung cancer, esophageal cancer, and first-line treatment for gastric cancer, resulting in sales of ¥112.4 billion, an increase of ¥13.6 billion (13.8%) year on year.

Other Main Product

With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥36.7 billion (64.0% increase year on year), sales of Glactiv Tablets for type-2 diabetes were ¥24.5 billion (3.8% decrease year on year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥22.9 billion (4.5% increase year on year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.9 billion (10.2% increase year on year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥8.4 billion (17.5% increase year on year).

Long-term Listed Products

Sales of long-term listed products were affected by the impact of generic drug use promotion policies, etc. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥4.7 billion (13.4% decrease year on year), sales of Rivastach Patches for Alzheimer's disease were ¥2.9 billion (56.6% decrease year on year), respectively.

Royalty and others

Royalty and others increased by ¥20.7 billion (21.8%) year on year to ¥115.4 billion.

(Billions of yen)

	FY2020	FY2021	Change rate FY2020/FY2021
Revenue of goods and products	214.5	**246.0**	+14.6%
Royalty and others	94.7	**115.4**	+21.8%

Profit and Loss

Operating profit was ¥103.2 billion, an increase of ¥4.9 billion (4.9%) year on year.

Profit attributable to owners of the Company increased by ¥5.1 billion (6.8%) year on year to ¥80.5 billion in association with the increase of the profit before tax.

Cost of Sales

Cost of sales increased by ¥7.9 billion (9.3%) year on year to ¥93.5 billion mainly due to an increase in revenue of goods and products.

Research and Development Costs

Research and development costs increased by ¥13.5 billion (21.6%) year on year to ¥75.9 billion, due to increases in research expenses, expenses for collaborative development with alliance partners, and expenses for preparation of investigational products, as well as the recording of impairment losses in relation to intangible assets associated with compounds under development.

Selling, General, and Administrative Expenses (except for research and development costs)

Selling, general, and administrative expenses (except for research and development costs) increased by ¥7.8 billion (11.3%) year on year to ¥77.1 billion mainly due to expenses related to the launch of new products and additional indications, an increase in co-promotion fees associated with expanding sales of Forxiga Tablets, and investments in information infrastructure related to IT and digital technologies.

Other Income

Other income decreased by ¥7.2 billion year on year to ¥1.0 billion, due to the absence of the upfront payment received under the license agreement with Roche in the previous fiscal year for the patent relating to the anti-PD-L1 antibody.

Other Expenses

Other expenses increased by ¥10.8 billion year on year to ¥12.7 billion. The increase is attributable to factors that include the Company having recorded a ¥7.3 billion difference because the total consisting of ¥5.0 billion associated with settlement of litigation on patents relating to the PD-1 antibody and donations of ¥23.0 billion paid to Kyoto University exceeded the provision for royalties on patents of ¥20.7 billion that had already been recorded; along with the Company also having recorded expenses associated with the collaboration agreement relating to Opdivo with Bristol-Myers Squibb Company.

(Billions of yen)

	FY2020	FY2021	Change rate FY2020/FY2021
Cost of sales	85.6	**93.5**	+9.3%
Research and development costs	62.4	**75.9**	+21.6%
Selling, general, and administrative expenses	69.2	**77.1**	+11.3%

Cash Flows

Cash and cash equivalents at the end of the fiscal year totaled ¥69.1 billion, which was an increase of ¥8.1 billion from ¥61.0 billion at the end of the previous fiscal year, mainly due to ¥61.8 billion provided by operating activities, ¥6.0 billion provided by investing activities, and ¥60.2 billion used in financing activities.

Net Cash Provided by Operating Activities

Net cash provided by operating activities at the end of the fiscal year was ¥61.8 billion, as a result of profit before tax of ¥105.0 billion, etc., while income taxes paid of ¥34.3 billion and a decrease in provisions of ¥20.7 billion, etc.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the fiscal year was ¥6.0 billion, as a result of proceeds from sales and redemption of investments of ¥22.8 billion, etc., while purchases of intangible assets paid of ¥6.8 billion and purchases of property, plant, and equipment paid of ¥5.5 billion.

Net Cash Used in Financing Activities

Net cash used in financing activities for the fiscal year was ¥60.2 billion, as a result of purchases of treasury shares of ¥30.0 billion and dividends paid of ¥27.7 billion, etc.

(Billions of yen)

	FY2020	FY2021
Cash flows from operating activities	74.0	**61.8**
Cash flows from investing activities	-57.6	**6.0**
Cash flows from financing activities	-24.8	**-60.2**
Cash and cash equivalents at the end of the fiscal year	61.0	**69.1**

Investment in Plant and Equipment

Plant and equipment investment at the end of the fiscal year totaled ¥9.3 billion. This included investment in enhancing and maintaining research facilities (¥5.2 billion), business facilities (¥2.9 billion), and manufacturing facilities (¥1.2 billion).
There was no disposal or sale of significant facilities during the fiscal year.

Future Outlook

Revenue

Revenue of goods and products are expected to be ¥290.0 billion, an increase of ¥44.0 billion (17.9%) year on year. Among new main products, sales of Opdivo Intravenous Infusion are expected to be ¥155.0 billion, an increase of ¥42.6 billion year on year, due to its expanded use in first-line treatment for non-small cell lung cancer and gastric cancer, urothelial carcinoma and cancer of unknown primary, despite the intensifying competitive environment. In other new main products, the Company expects sales of Forxiga Tablets, which were approved for additional indications of chronic kidney disease last year, to increase by ¥10.3 billion year on year to ¥47.0 billion, as well as anticipating higher sales of Kyprolis for Intravenous Infusion, Velexbru Tablets, and Ongentys Tablets. Furthermore, royalty and others are expected to continue to grow and to increase by ¥19.6 billion (17.0%) year on year to ¥135.0 billion.
Revenue is therefore forecast to be ¥425.0 billion, an increase of ¥63.6 billion (17.6%) year on year.

Profit

Cost of sales is expected to be ¥104.0 billion, an increase of ¥10.5 billion (11.2%) year on year, due to an increase in revenue of goods and products.
Research and development costs are expected to be ¥87.0 billion, an increase of ¥11.1 billion (14.7%) year on year, due to aggressive investment for the realization of sustained growth through further expansion of collaborative research with advanced companies and academia with cutting-edge technology and research themes; global development study; and collaborative development.
Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥88.0 billion, an increase of ¥10.9 billion (14.2%) year on year, due to an increase in co-promotion fees associated with expanding sales of Forxiga Tablets, active investments in information infrastructure related to IT and digital technologies, and active investments to strengthen global businesses including the USA.
Other expenses are expected to decrease by ¥11.2 billion year on year to ¥1.5 billion, due in part to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody, and other costs recorded in the fiscal year ended March 31, 2022.
Therefore, operating profit is expected to be ¥145.0 billion, an increase of ¥41.8 billion (40.5%) year on year, and profit attributable to owners of the Company is expected to be ¥110.0 billion, an increase of ¥29.5 billion (36.6%) year on year.

(Billions of yen)

	FY2022 (forecast)	Change rate FY2021/FY2022
Revenue	**425.0**	+17.6%
Revenue of goods and products	**290.0**	+17.9%
Royalty and others	**135.0**	+17.0%
Operating profit	**145.0**	+40.5%
Profit for the year (attributable to owners of the parent company)	**110.0**	+36.6%

Note: We assume that restrictions on certain activities will continue due to COVID-19, but the impact on financial results will be immaterial. Going forward, if any revisions to financial forecasts are necessary, the Company will promptly announce them.

Consolidated Financial Summary

(Millions of yen)

IFRS	2014.3	2015.3	2016.3	2017.3	2018.3	2019.3	2020.3	2021.3	2022.3
Operating Results									
Revenue	143,247	135,775	160,284	244,797	261,836	288,634	292,420	309,284	**361,361**
Cost of sales	32,746	35,136	41,524	65,524	65,391	83,829	79,063	85,573	**93,511**
Selling, general, and administrative expenses	38,377	42,222	43,979	62,049	68,055	70,033	67,679	69,230	**77,057**
Research and development costs	44,413	41,346	43,369	57,506	68,821	70,008	66,497	62,384	**75,879**
Operating profit	26,429	14,794	30,507	72,284	60,684	62,010	77,491	98,330	**103,195**
Profit for the year (attributable to owners of the parent company)	20,344	12,976	24,979	55,793	50,284	51,539	59,704	75,425	**80,519**
Financial Position									
Total assets	486,141	524,588	540,450	617,461	609,226	655,056	673,444	745,428	**739,203**
Total equity	451,724	475,213	476,255	524,211	529,619	562,736	568,022	639,743	**661,674**
Cash flows from operating activities	28,422	31,579	12,842	74,450	15,727	66,774	74,157	73,977	**61,829**
Cash flows from investing activities	6,926	(12,756)	13,037	(17,989)	(34,189)	(49,763)	(10,234)	(57,586)	**6,038**
Cash flows from financing activities	(19,636)	(19,603)	(19,465)	(20,552)	(62,549)	(22,279)	(54,721)	(24,754)	**(60,237)**
Investment in plant and equipment	7,492	16,031	15,771	9,532	18,593	21,351	9,520	9,100	**9,336**
Depreciation and amortization	5,109	6,100	6,534	7,821	9,213	10,621	14,214	15,820	**17,721**
Amount Per Share*1									
Basic earnings (Yen)	38.38	24.48	47.13	105.27	97.00	100.25	118.47	151.11	**162.19**
Equity attributable to owners of the parent company (Yen)	843.93	887.81	889.38	979.42	1,019.97	1,084.08	1,126.95	1,270.45	**1,343.40**
Cash dividends (Yen)	180.00	180.00	180.00	40.00	45.00	45.00	45.00	50.00	**56.00**
Other Indicators									
Operating income to revenue ratio (%)	18.4	10.9	19.0	29.5	23.2	21.5	26.5	31.8	**28.6**
R&D cost-to-revenue ratio (%)	31.0	30.5	27.1	23.5	26.3	24.3	22.7	20.2	**21.0**
Equity ratio (%)	92.0	89.7	87.2	84.1	86.1	85.1	83.5	85.1	**88.7**
ROA (%)*2	6.1	3.6	6.2	12.9	10.4	10.3	12.0	14.2	**14.1**
ROE (%)*3	4.6	2.8	5.3	11.3	9.6	9.5	10.7	12.6	**12.5**
Payout ratio (%)	93.8	147.1	76.4	38.0	46.4	44.9	38.0	33.1	**34.5**
Number of employees	2,858	2,913	3,116	3,290	3,480	3,555	3,560	3,607	**3,687**

*1 The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for "Basic earnings" and "Equity attributable to owners of the parent company," these are calculated assuming that the stock split was conducted at the beginning of the fiscal year ended March 31, 2014. Also, "Cash dividends" for the fiscal year ended March 31, 2014 to the fiscal year ended March 31, 2016 indicate the amounts before conducting the stock split.
*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)

	2018.3	2019.3	2020.3	2021.3	2022.3	2023.3 (Forecast)
Revenue of Major Products						
OPDIVO Intravenous Infusion	90.1	90.6	87.3	98.8	**112.4**	155.0
FORXIGA Tablets	11.1	14.5	18.1	22.4	**36.7**	47.0
GLACTIV Tablets	27.4	26.9	26.1	25.5	**24.5**	23.0
ORENCIA for Subcutaneous Injection	14.1	17.4	19.8	21.9	**22.9**	23.0
PARSABIV Intravenous Injection	3.4	5.7	7.1	8.1	**8.9**	8.0
KYPROLIS for Intravenous Infusion	5.5	4.9	6.0	7.1	**8.4**	9.0
ONOACT for Intravenous Infusion	5.6	4.6	4.9	4.7	**4.9**	4.5
OPALMON Tablets	14.4	10.4	8.3	5.5	**4.7**	3.5
VELEXBRU Tablets	—	—	—	2.1	**6.3**	7.0
RIVASTACH Patches	8.9	8.9	8.5	6.6	**2.9**	*
BRAFTOVI Capsules	—	—	*	1.1	**2.7**	3.5
MEKTOVI Tablets	—	—	*	1.0	**2.2**	2.5
ONON Capsules	5.5	4.4	3.5	2.9	**3.6**	2.5
ONGENTYS Tablets	—	—	—	0.3	**2.9**	5.0

Note: Based on ex-manufacturer prices
* Not disclosed.

Breakdown of Revenue						
Revenue of goods and products	205.9	208.9	205.6	214.5	**246.0**	290.0
Royalty and others	55.9	79.7	86.8	94.7	**115.4**	135.0
OPDIVO Intravenous Infusion	39.8	58.5	61.6	59.8	**69.9**	*
Keytruda® (Merck)	*	12.8	19.3	24.3	**30.8**	*
Other	*	8.4	5.9	10.6	**14.7**	*

* Not disclosed.

Revenue by Region						
Japan	204.0	207.4	202.9	212.9	**242.0**	
Americas	52.5	72.3	81.5	85.6	**105.9**	
Asia	5.1	7.4	7.5	7.4	**8.9**	
Europe	0.2	1.6	0.5	3.4	**4.6**	

Consolidated Financial Statement

Consolidated Statement of Financial Position

(Millions of yen)

	2021.3	2022.3
Assets		
Current assets:		
Cash and cash equivalents	61,045	**69,112**
Trade and other receivables	84,269	**99,788**
Marketable securities	2,978	**60**
Other financial assets	40,952	**47,797**
Inventories	39,151	**41,817**
Other current assets	19,246	**22,692**
Total current assets	247,642	**281,266**
Non-current assets:		
Property, plant, and equipment	113,866	**112,131**
Intangible assets	68,285	**64,734**
Investment securities	146,796	**125,046**
Investments in associates	112	**108**
Other financial assets	131,888	**127,302**
Deferred tax assets	34,242	**25,074**
Retirement benefit assets	7	**377**
Other non-current assets	2,590	**3,165**
Total non-current assets	497,787	**457,937**
Total assets	745,428	**739,203**
Liabilities and Equity		
Current liabilities:		
Trade and other payables	39,163	**49,689**
Lease liabilities	2,023	**2,301**
Other financial liabilities	616	**716**
Income taxes payable	19,047	**1,526**
Provisions	20,721	**—**
Other current liabilities	12,163	**11,694**
Total current liabilities	93,733	**65,926**
Non-current liabilities:		
Lease liabilities	7,030	**6,501**
Other financial liabilities	0	**0**
Retirement benefit liabilities	3,056	**3,322**
Deferred tax liabilities	1,052	**1,009**
Other non-current liabilities	813	**771**
Total non-current liabilities	11,952	**11,603**
Total liabilities	105,685	**77,529**
Equity:		
Share capital	17,358	**17,358**
Capital reserves	17,231	**17,241**
Treasury shares	(44,705)	**(74,683)**
Other components of equity	62,299	**51,236**
Retained earnings	581,950	**644,754**
Equity attributable to owners of the parent company	634,133	**655,906**
Non-controlling interests	5,610	**5,768**
Total equity	639,743	**661,674**
Total liabilities and equity	745,428	**739,203**

Consolidated Statement of Income

(Millions of yen)

	2021.3	2022.3
Revenue	309,284	**361,361**
Cost of sales	(85,573)	**(93,511)**
Gross profit	223,711	**267,850**
Selling, general, and administrative expenses	(69,230)	**(77,057)**
Research and development costs	(62,384)	**(75,879)**
Other income	8,165	**980**
Other expenses	(1,932)	**(12,698)**
Operating profit	98,330	**103,195**
Finance income	2,693	**2,710**
Finance costs	(137)	**(874)**
Share of profit (loss) from investments in associates	4	**(6)**
Profit before tax	100,890	**105,025**
Income tax expense	(25,392)	**(24,340)**
Profit for the year	75,497	**80,684**
Profit for the year attributable to:		
Owners of the parent company	75,425	**80,519**
Non-controlling interests	72	**166**
Profit for the year	75,497	**80,684**
Earnings per share:		(Yen)
Basic earnings per share	151.11	**162.19**
Diluted earnings per share	151.09	**162.16**

Consolidated Statement of Comprehensive Income

(Millions of yen)

	2021.3	2022.3
Profit for the year	75,497	**80,684**
Other comprehensive income (loss):		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	17,273	**(2,094)**
Remeasurement of defined benefit plans	2,370	**199**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	3	**2**
Total of items that will not be reclassified to profit or loss	19,646	**(1,893)**
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	424	**814**
Total of items that may be reclassified subsequently to profit or loss	424	**814**
Total other comprehensive income (loss)	20,070	**(1,079)**
Total comprehensive income (loss) for the year	95,567	**79,606**
Comprehensive income (loss) for the year attributable to:		
Owners of the parent company	95,488	**79,444**
Non-controlling interests	78	**161**
Total comprehensive income (loss) for the year	95,567	**79,606**

Consolidated Statement of Changes in Equity

(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, 2020	17,358	17,229	(44,737)	48,030	524,605	562,484	5,538	568,022
Changes in Accounting Policies					(1,414)	(1,414)		(1,414)
Restated balance	17,358	17,229	(44,737)	48,030	523,191	561,071	5,538	566,609
Profit for the year					75,425	75,425	72	75,497
Other comprehensive income (loss)				20,064		20,064	6	20,070
Total comprehensive income (loss) for the year	—	—	—	20,064	75,425	95,488	78	95,567
Purchase of treasury shares			(5)			(5)		(5)
Retirement of treasury shares		(38)	38			0		0
Cash dividends					(22,461)	(22,461)	(6)	(22,467)
Share-based payments		40				40		40
Transfer from other components of equity to retained earnings				(5,795)	5,795	—		—
Total transactions with the owners	—	2	32	(5,795)	(16,666)	(22,426)	(6)	(22,432)
Balance at March 31, 2021	**17,358**	**17,231**	**(44,705)**	**62,299**	**581,950**	**634,133**	**5,610**	**639,743**
Profit for the year					**80,519**	**80,519**	**166**	**80,684**
Other comprehensive income (loss)				**(1,074)**		**(1,074)**	**(4)**	**(1,079)**
Total comprehensive income (loss) for the year	—	—	—	**(1,074)**	**80,519**	**79,444**	**161**	**79,606**
Purchase of treasury shares			**(30,009)**			**(30,009)**		**(30,009)**
Disposition of treasury shares		**(31)**	**31**			**0**		**0**
Cash dividends					**(27,703)**	**(27,703)**	**(4)**	**(27,707)**
Share-based payments		**41**				**41**		**41**
Transfer from other components of equity to retained earnings				**(9,988)**	**9,988**	—		—
Total transactions with the owners	—	**10**	**(29,978)**	**(9,988)**	**(17,714)**	**(57,671)**	**(4)**	**(57,675)**
Balance at March 31, 2022	**17,358**	**17,241**	**(74,683)**	**51,236**	**644,754**	**655,906**	**5,768**	**661,674**

Consolidated Statement of Cash Flows

(Millions of yen)

	2021.3	2022.3
Cash flows from operating activities		
Profit before tax	100,890	**105,025**
Depreciation and amortization	15,820	**17,721**
Impairment losses	2,307	**3,404**
Interest and dividend income	(2,462)	**(2,349)**
Interest expense	73	**70**
(Increase) decrease in inventories	(6,107)	**(2,464)**
(Increase) decrease in trade and other receivables	(7,179)	**(15,283)**
Increase (decrease) in trade and other payables	6,361	**8,177**
Increase (decrease) in provisions	—	**(20,721)**
Increase (decrease) in retirement benefit liabilities	410	**54**
(Increase) decrease in retirement benefit assets	—	**130**
Other	(4,468)	**70**
Subtotal	105,645	**93,835**
Interest received	63	**40**
Dividends received	2,401	**2,317**
Interest paid	(73)	**(70)**
Income taxes paid	(34,060)	**(34,293)**
Net cash provided by (used in) operating activities	73,977	**61,829**
Cash flows from investing activities		
Purchases of property, plant, and equipment	(7,018)	**(5,497)**
Proceeds from sales of property, plant, and equipment	2	**14**
Purchases of intangible assets	(13,275)	**(6,780)**
Purchases of investments	(760)	**(1,127)**
Proceeds from sales and redemption of investments	14,033	**22,782**
Payments into time deposits	(80,939)	**(57,486)**
Proceeds from withdrawal of time deposits	30,800	**55,800**
Other	(429)	**(1,667)**
Net cash provided by (used in) investing activities	(57,586)	**6,038**
Cash flows from financing activities		
Dividends paid	(22,449)	**(27,666)**
Dividends paid to non-controlling interests	(6)	**(4)**
Repayments of lease liabilities	(2,296)	**(2,560)**
Purchases of treasury shares	(3)	**(30,007)**
Net cash provided by (used in) financing activities	(24,754)	**(60,237)**
Net increase (decrease) in cash and cash equivalents	(8,363)	**7,631**
Cash and cash equivalents at the beginning of the year	69,005	**61,045**
Effects of exchange rate changes on cash and cash equivalents	403	**436**
Cash and cash equivalents at the end of the year	61,045	**69,112**

Corporate Information / Stock Information

Profile (as of March 31, 2022)

Company Name	ONO PHARMACEUTICAL CO., LTD.
Founded	1717
Date of Incorporation	1947
Paid-in Capital	17,358 million yen
Number of Employees	3,687 (Consolidated) 3,354 (Non-consolidated)
Total Number of Authorized Shares	1,500,000,000
Number of Shares Issued and Outstanding	528,341,400 (Including 40,031,712 shares of treasury stock)
Number of Shareholders	64,637
Stock Exchange Listing	Tokyo Stock Exchange (Code number: 4528)

Principal Shareholders

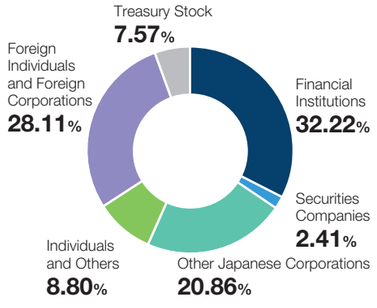
Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	76,107	15.58
Custody Bank of Japan, Ltd. (Trust account)	26,807	5.48
STATE STREET BANK AND TRUST COMPANY 505001	21,645	4.43
Meiji Yasuda Life Insurance Company	18,594	3.80
Ono Scholarship Foundation	16,428	3.36
KAKUMEISOU Co., LTD	16,161	3.30
MUFG Bank, Ltd.	8,640	1.76
Aioi Nissay Dowa Insurance Co., Ltd.	7,979	1.63
STATE STREET BANK WEST CLIENT – TREATY 505234	7,806	1.59
SSBTC CLIENT OMNIBUS ACCOUNT	7,086	1.45

Note: 1. The Company is excluded from the principal shareholders listed in the table above, although the Company holds 40,031,712 shares of treasury stock.
2. The shareholding percentage is calculated by deducting treasury stock (40,031,712 shares).

Major Offices (as of March 31, 2022)

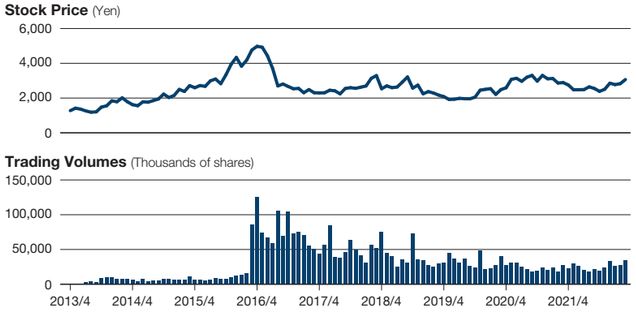
Head Office	8-2, Kyutaromachi 1-chome, Chuo-ku, Osaka 541-8564, Japan Tel: +81-6-6263-5670 (Registered Office) 1-5, Doshomachi 2-chome, Chuo-ku, Osaka, Japan
Tokyo Building	9-11, Nihonbashi-Honcho 4-chome, Chuo-ku, Tokyo 103-0023, Japan
Branches in Japan	Sapporo, Sendai, Tokyo, Yokohama, Nagoya, Kyoto, Osaka, Takamatsu, Hiroshima, Fukuoka, and other branches in major cities
Research Institutes, etc.	Minase Research Institute, Osaka, Japan Tsukuba Research Institute, Ibaraki, Japan Joto Pharmaceutical Product Development Center, Osaka, Japan
Manufacturing Plants	Fujiyama Plant, Shizuoka, Japan Yamaguchi Plant, Yamaguchi, Japan
Domestic Subsidiaries	TOYO Pharmaceutical Co., Ltd. Bee Brand Medico Dental Co., Ltd. Ono Pharma Healthcare Co., Ltd. Ono Digital health Investment, GK
Overseas Subsidiaries	ONO PHARMA USA, INC., Cambridge, USA ONO PHARMA UK LTD., London, UK ONO PHARMA KOREA CO., LTD., Seoul, South Korea ONO PHARMA TAIWAN CO., LTD., Taipei, Taiwan Ono Venture Investment, Inc., California, USA Ono Venture Investment Fund I, L.P., California, USA
Related Party	Namicos Corporation

Shareholders by Category



Note: The ratio by shareholders listed above is rounded down to two decimal places. Therefore, their total do not amount to 100%.

Stock Price and Trading Volumes



Note: The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. Note that the stock price is translated on a post-stock split basis.

ONO PHARMACEUTICAL CO.,LTD.

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