**CORPORATE REPORT** 

2023

Year ended March 31, 2023

Only Ono

We believe there are challenges only we can take on.



# 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



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# Foundation for Value Creation

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#### **Editorial Policy**

The ONO Group has identified 18 material issues as "priority management issues" that have incorporated into the medium- and long-term growth strategy. This report provides comprehensive information on the Group's medium- and long-term targets, strategy, initiatives, and results, primarily regarding these material issues. For the 2023 report, we worked to further improve the quality of the report as a communication tool with stakeholders in various ways, including adding pages that offer an overview of the Group's important management resources (pp. 7–12) and pages that provide a view of indicators related to and progress with all material issues (pp. 27–30).

#### 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, 2022 through March 31, 2023 (some parts include activities since April 2023)

#### Reference Guidelines

ONO refers to the International Integrated Reporting Framework issued by the International Financial Reporting Standards (IFRS) Foundation, 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.

Web https://sustainability.ono-pharma.com/en/themes/111

#### **Publication Date**

September 2023

#### **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/en/ir/library/financial\_results.html

Corporate Governance Report

https://www.ono-pharma.com/sites/default/files/en/ir/corporate\_governance\_report\_en.pdf

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#### **External ESG Assessment**

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)

Selected for Pharmaceutical Sector World Index for third consecutive year Jointly developed by S&P Dow Jones Indices (US)

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



#### FTSE4Good Index Series

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

#### 2023 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX

#### MSCI Japan ESG Select Leaders Index

Designed to target companies that have relatively high ESG performance

#### **2023** CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

#### MSCI Japan Empowering Women Select Index

Selected as Japanese company with outstanding gender diversity in the industry from MSCI component stocks



#### 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



CDP2022 [Climate Change] [Water Security]

CLIMATE WATER

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



2023 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

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# Continually taking on the challenge of creating innovative 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 addressing the challenge of discovering our own innovative drugs.



1951 1955

1960 1965 1970 1975 1980

**Pursuing value creation** from our inception

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

#### 1717 Started business

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

#### 1934 Transformed modern management

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.



#### 1947 Launched drug manufacturing

After its establishment, ONO launched the manufacturing of drugs.

#### 1960'S Transformed to an ethical drug manufacturer

In our pursuit of whether it would be possible to transition from OTC drugs to ethical drugs, we launched various efforts, including the development of prostaglandins (PG). In 1968, we opened the Central Research Institute (Current the Minase Research Institute) (current Minase Research Institute) in order to fully launch our work to creation of ethical drugs.

#### 1970's-1980's

#### Successfully launched new innovative new drugs on the market

Starting with joint research with three PhDs, Sune K. Bergström, Bengt Samuelsson, and John R. Vane, who won the Nobel Prize in Physiology and Medicine in 1982, we quickly promoted industry-academia collaboration at a time when open innovation was not yet a word.







PROSTARMON-F

PROSTANDIN Injection

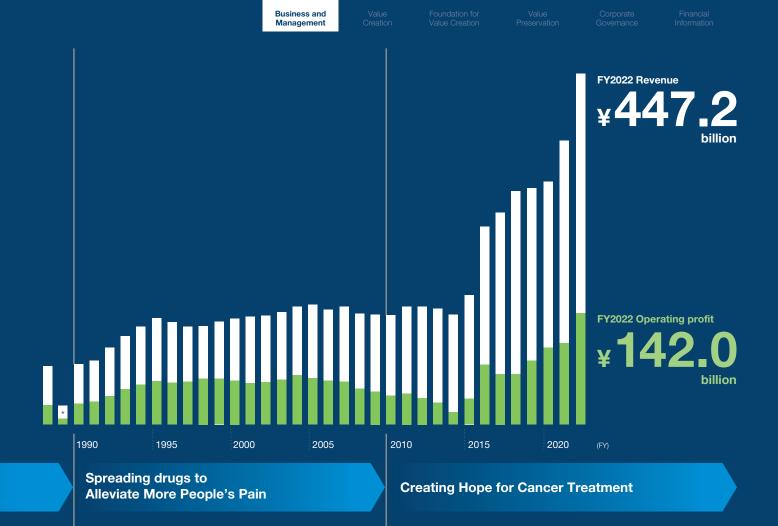
**FOIPAN Tablets** 

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

Prostaglandins (PGs) are called dream substances with enormous potential. After becoming the first company to succeed in the total chemical synthesis of PGs, we have not only poured our numerous resources, including researchers, into PG-related drug discovery research but also actively undertaken joint research and joint development with both academics and pharmaceutical companies in Japan and overseas. As a result, we successfully developed and launched a drug for the gynecology field in 1974 that was the world's first PG-related formulation. Since then we have broadened the fields of contributions to cardiovascular diseases, gastrointestinal diseases, and respiratory disease, resulting in twelve PG-related drugs that have been launched.

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







ONON Capsules (1995)



ONOACT for Intravenous Infusion (2002)



STAYBLA Tablets (2007)



RECALBON Tablets (2009)



GLACTIV Tablets (2009)



RIVASTACH Patches (2011)

#### 2010'S Full-scale entry into the oncology field

Our more than twenty-year challenge since discovering PD-1 (protein) in 1992 bore fruit, and we were able to launch sales of the anti-PD-1 antibody OPDIVO in 2014.



2014

World's First

# Launched the world's first anti-PD-1 antibody that provides new options for treating cancer: OPDIVO

Traditionally, there have been three core cancer treatments—that is, surgery, chemotherapy, and radiation therapy. With a mechanism to increase the body's ability to attack cancer cells by reviving the power of the immune system that people naturally have, OPDIVO is revolutionary because if offers a treatment approach based on a novel approach. We are new expanding indicated tumors for cancer immunotherapy, creating a fourth core treatment. After gaining manufacturing and marketing approval as a treatment for melanoma, it has been approved worldwide for eleven types of cancer, including non-small cell lung cancer, renal cell carcinoma, and gastric cancer to date. We are now continuing clinical trials to further adding indicated tumors.

# Innovation

Intellectual capital

# R&D abilities based on open innovation with world-class academic institutions and bio-venture companies

We are actively moving forward with open innovation in partnership with such entities as leading academic institutions and bio-venture companies to discover innovative new drugs. Our goal is to contribute to even more patients through drugs in the oncology, immune system disease, and specialty fields.

Note: Unless noted individually, data is for FY2022

#### **Active investment in R&D**

R&D costs

¥95.3 billion

(increase: 25.7%)

R&D cost-to revenue ratio

21.3%

#### Promoting open innovation

The number of research collaborations (as of March 31, 2023)

More 300 in Japan than overseas

FY2022

Launched
12 new drug
discovery alliances

#### **Pipeline Expansion**

The number of products in the clinical development stage (number of trials)

21

Number of new products launched and additional indications approved (FY2018 to FY2022)

32



Note: Unless noted individually, data is for FY2022. Market sales and class share rankings are based on external data.

**OPDIVO** 

Anti PD-1 antibody

Prescription drug sales in Japan (based on FY2022 drug price)

**NO.1** (¥158.8 billion\*)

Share of the Japanese market for anti PD-1/PD-L1 antibody-class products

**NO.1** (35.6%)

New patients prescribed OPDIVO

Breakdown by main types of cancer

- Gastric cancer
- Esophageal
- Non-small-cell lung cancer

About **36,000** 

about 18,000 about 5,600 about 5,400

FORXIGA SGLT2 inhibitor

Share of Japanese market for SGLT2 inhibitor-class products (excluding compounding ingredients)

**NO.1** (36.1%)

Number of new patients to whom our new drugs were delivered in FY2022

about **850,000** 

# Products

Intellectual property / Social capital

# **Actual delivery of** innovative drugs to more patients

Conditioned on a patient first perspective, we work to discover innovative new drugs and to maximize their product value. By sharing the opinions received from patients and the medical field, the whole company has united to improve the wellbeing of patients and their families.







# Focusing on training diverse talent who contribute to innovation

In order to continue to generate sustainable growth as a R&D-based pharmaceutical company that creates innovative drugs, we are not only accelerating the training and recruiting of talent who support the company but only working to foster an organizational culture with high employee engagement.

Note: Unless noted individually, data is for FY2022.

Versatile human resources who support the management foundation\*1

Total 542

Number of participants in Program to Train Innovative Talent

Total 3,309

Number of participants in HOPE Business Contest\*2

85

Annual number of hours of training per employee

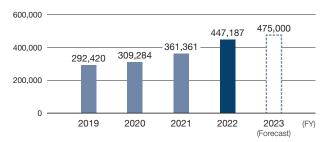
54.8

<sup>\*1</sup> Future executive talent, globally competent talent, digital talent, core innovation talent

 $<sup>^{*}2</sup>$  Venue for voluntary challenge of putting what employees have learned and experienced into practice

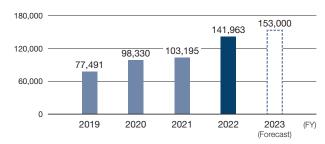
#### **Financial Information**

#### 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 23.8% year-on-year to 447.2 billion yen.

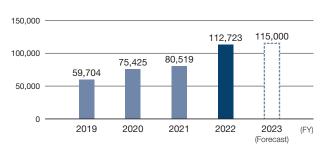
#### Operating profit (Millions of yen)



Although cost of sales, research and development costs, selling, general and administrative expenses all increased,, revenue also increased significantly, resulting in a 37.6% increase year-on-year to 142.0 billion yen.

#### Profit for the year

(attributable to owners of the parent company) (Millions of yen)



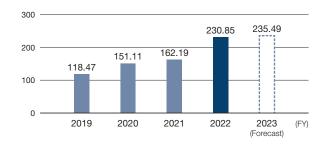
Current net income rose by 40.0% year-on-year, to 112.7 billion yen due to a decrease in corporate income tax in addition to higher pre-tax net income

#### 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 / %)

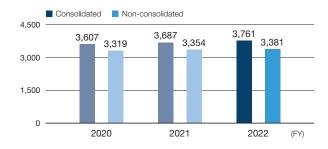


ONO considers the distribution of profits to shareholders as a vital management policy. ONO will prioritize stable dividend distribution, appropriately distributing its profits in line with its business performance.

#### **Non-Financial Information**

## **%**

#### Number of employees (people)

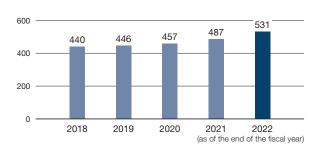


We recruit not only new graduates but also midcareer workers and others with a variety of different backgrounds to strengthen our corporate infrastructure.

Expansion of human capital, p.53

#### 88 (3)

# Number of mid-career hire employees (people)

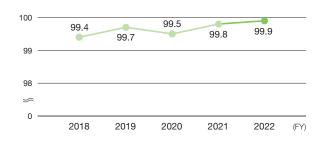


We focus on hiring people with the skills, knowledge, and experience necessary for our company.

Expansion of human capital, p.53



## Comprehensive medical examination rate (%)

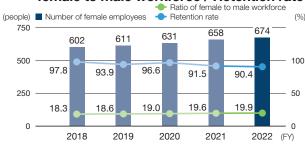


We take an approach to actively maintaining and improving the health of employees and their families. We have a support system in place for disease prevention, early detection, and treatment.

Eligibility: Insured employees aged 35 and over and their dependent spouses

Expansion of human capital, p.53

## 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.53

# Employee Health Age®\*—Average and Difference from Actual Age (Years)



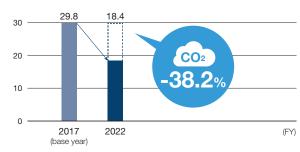
Health Age® is an indicator that expresses a person's state of health using an age calculated based on data obtained from comprehensive medical examinations and other sources. We are focusing on various measures related to maintaining and improving the health of employees so that they can maintain a health age that is less than their actual age.

Coverage: employees 35 or older (employees who received comprehensive medical examinations)

- \* Health Age® is a registered trademark of JMDC Inc.
- Expansion of human capital, p.53



#### CO<sub>2</sub> emissions (thousand tons-CO<sub>2</sub>)



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

Protection of environment, p.70



# Diligently advancing our growth strategies to generate sustainable growth for society and the Company

Question 01

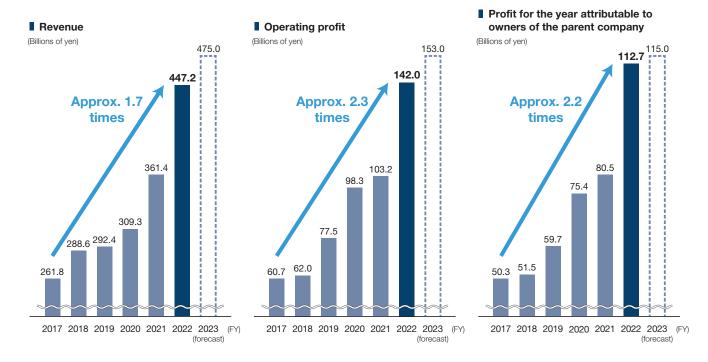
What is the Company doing to establish sustainable growth?

We are incorporating the material issues into our management strategies and accelerating Companywide initiatives to create value.

In FY2017, we set a long-term vision to build ONO into a Global Specialty Pharma that is investing 200 billion yen annually in R&D, which is on par with Japan's largest pharmaceuticals companies, and that is providing a continuous flow of innovative new drugs around the world. We set FY2031 as the date for fulfilling our vision and set three 5-year periods for which we would formulate specific medium-term management plans. We launched the second medium-term management plan in FY2022.

The current second period is critical to fulfilling our vision. In 2022, we reconfigured our four growth strategies (see pages 25-26) and fortified our management base for the DX and human resources needed to implement the strategies. We also recognized our material issues as management priorities (see pages 27-31).

With this change in perspective, we changed the description of materiality from "Important CSR Issues" to "Important Management Issues" encompassing both financial and non-financial issues requiring attention for the longer term. Implementing growth strategies and value creation measures that incorporate the material issues at a fundamental level will provide a solid base for sustainable growth.



#### Question 02

How did the Company perform in FY2022, and what is the status of the medium-term management plan?

# The plan is producing solid results as both revenue and operating profit reached record highs.

We set record highs in both revenue and operating profit in FY2022 with revenue growing 23.8% year on year to 447.2 billion yen and operating profit rising 37.6% to 142.0 billion yen. We increased R&D spending to 95.3 billion yen, which is approaching the halfway mark to our goal of 200 billion yen in FY2031.

We plan to increase R&D spending to 109 billion yen in FY2023, which will bring us half way to our target in the seventh year of our 15-year vision. Increasing our spending on R&D necessarily requires that we generate adequate resources. In FY2023, we expect to generate double the FY2016 amounts of both our revenue and profit for the year, with revenue growing 6.2% year on year to 475 billion yen and profit for the year rising 2.0% year on year to 115 billion yen.

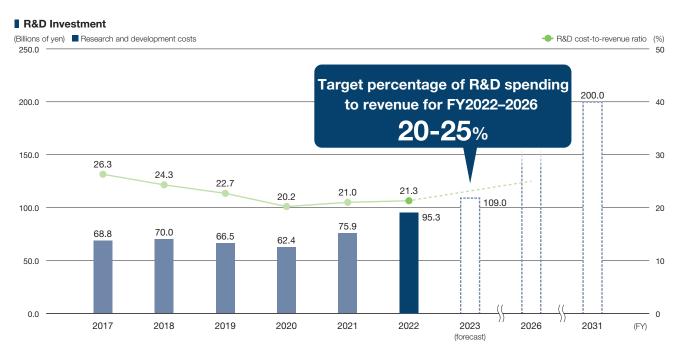
I believe these results and our outlook for next year represent solid progress for the first seven years of our long-term plan. Nevertheless, we are by no means complacent and will continue steadily implementing all of our growth initiatives.

#### Question 03

Please describe the growth strategies for the Value Creation associated with material issues.

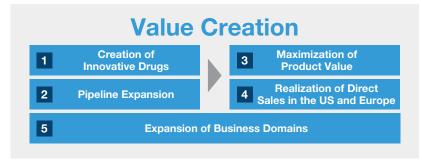
#### We will secure profit by continuing to maximize OPDIVO product value while creating innovative drugs and developing direct sales operations in the U.S. and Europe.

Our efforts to maximize the OPDIVO product value have boosted OPDIVO total sales and royalty income in Japan, South Korea, and Taiwan to close to 300 billion yen. We will continue to maximize OPDIVO product value by expanding the range of indicated cancer types, increasing treatment lines, and developing combination therapies. Sales of OPDIVO currently account for about 60% of the Group's total revenue, and we are preparing for the time when that patent expires by creating innovative drugs, expanding our product pipeline, and establishing direct sales operations in the U.S. and Europe. We are currently engaging in some 300 joint and commissioned research projects, including 110 new projects initiated in FY2022, of which nearly half are being conducted overseas. The pharmaceuticals market in the U.S. is five times larger and the European market is three times larger than the market in Japan. In other words, expanding our business into the U.S. and European markets offers potential to increase our revenue tenfold. That is why we are advancing a Group-wide initiative to establish direct sales operations in the U.S. and Europe. We are engaged in multiple projects in the U.S., including developing ONO-4059 (Velexbru tablets) and formulating the direct



#### Material Issues

18





#### Value Preservation (Value Damage Risk) Assurance of Product 12 **Reliability and Safety** 13 Stable Supply of Products 14 **Protection of Environment Respect for Human Rights** 16 **Thorough Compliance Supply Chain Management**

#### **Strengthening of Corporate Governance**

sales operation. We will need to develop and globally market at least three innovative drugs to offset the revenue impact from the OPDIVO patent expiration and ensure we continue to grow our business. We currently have 10 drugs in development around the world that we believe could be successors for OPDIVO and are aiming to have at least two or three of them on the market by FY2031. We also intend to actively pursue in-licensing activities for all of our proprietary drugs.

Another area of focus is expanding our business domain. Developing prescription drugs has been a primary way to expand business, but the success rate of drug discovery is diminishing as the scope of unmet medical needs becomes increasingly narrow. For us to achieve growth, in addition to marketing drugs, we also need to develop new businesses. One of the social issues we have been focusing on as a company is extending healthy life expectancy. We are accordingly allocating resources to the healthcare field where we believe we can effectively utilize the assets and expertise we have accumulated through our extensive experience in pharmaceutical R&D, sales, and production. One of our recent products in this field is the sleep supplement REMWELL, which we introduced in FY2021. REMWELL came out of our many years of research into lipids, and we

are continuing to apply our research assets to develop new products. In March 2022, we established Ono Digital Health Investment, GK to invest in venture companies engaged in healthcare businesses other than ethical drugs. We also established michiteku Co., Ltd. as a subsidiary to offer information processing and provision services in the healthcare field with a focus on providing tools for the treatment and daily support of cancer patients. We will continue seeking new areas in which to apply our experience and expertise to develop new business activities.





#### Question 04

Please describe the development of DX talent and human capital that are key parts of the growth strategy under the Foundation for Value Creation.

#### We are using digital and information technologies to completely transform our enterprise system and every aspect of our corporate operations.

Transforming our company with digital and information technologies is essential to increasing our future competitiveness as a pharmaceuticals company. We are doing this in three ways: by building a centralized enterprise system, by digitalizing all of our corporate processes, and by incorporating big data.

The enterprise system we are constructing will be the foundation for the globalization of our operations and used by all Group companies, including all subsidiaries and overseas bases. We have been using systems that were developed for specific businesses areas, and which were not always usable across the whole Group. The new fully integrated system will enable us to unify and control activities throughout the Group. We believe it is vital for us to lay the solid foundation now for us to become a truly global corporation in the future.

The second way we are increasing the Company's competitiveness is by digitalizing all of our processes from R&D to production and sales to boost both our operating efficiency and productivity. Each division is leading its own

activities with support from the Digital & IT Strategy Division Because it directly influences business growth, the sales division was one of the first to install an AI system to support its activities, and the results are already starting to appear. Leveraging the power of big data will be another key to ensuring our long-term growth. Big data is promising in many ways. For example, the cost of conducting clinical trials, which ordinally engage two groups of patients, one for testing the active drug and a control group that receives a placebo, can exceed 10 billion yen. That cost could be sharply reduced if the placebo group could be replaced with data collected from standard medical care services. Big data promises compelling benefits for the pharmaceuticals industry; however, there are many issues that still must be resolved, so we do not believe big data technologies will lead to an immediate leap forward for the industry. We are currently examining how the analysis of wide-ranging data can help boost productivity at each stage of research, development, sales, production, and M&A.

#### We are nurturing our human capital by fostering an environment that emphasizes taking on challenges, pursuing innovation, and diversity.

Japan's decreasing working population is a critical issue, and it is no exaggeration to say that nurturing the next-generation of human capital will be vital for companies to survive. We are making ONO an attractive company to work for by creating a corporate environment that fosters enthusiastic employees and encourages them to take on new challenges.

We are particularly focusing on encouraging projects that transcend conventional boundaries between departments. We expanded our internal open recruitment system enabling employees to move to positions in other departments, and in FY2022 the sales division started a trial of an "internal job challenge program" that enables employees to retain their position while working outside their department. We also support employee efforts to expand their networks and engage in activities to advance their careers, such as taking temporary positions in venture companies and other organizations. Measures to foster innovative talent include hosting an in-house business contest. The contest received 83 entries in FY2021, from which three were chosen to be developed for commercialization. Employee enthusiasm for innovation remained high in FY2022 with the number of entrants rising to 85.

We are also continuing to increase our employee diversity, including our drive to promote women to management positions. Increasing the diversity of our workforce has become an urgent issue with the vast expansion of our

business fields since the launch of OPDIVO and as celebrated the 300th anniversary of our founding in FY2017. We are advancing initiatives to increase the percentage of female managers from 4.1% in FY2022 to 10% by FY2026 and 20% by FY2031. We also revised the employee system to enable younger employees around the age of 30 to be appointed to leadership positions.

The environment and systems we are creating for fair training, promotion, and skill development of our human resources regardless of age or gender will give us an even stronger foundation for growth in the medium and long term.

#### Question 05

What are the main risk reduction measures that you focus on for Value Preservation?

#### We raised the targets in our mediumto long-term environmental vision to accelerate our efforts to address environmental issues.

As climate change and other environmental issues become more acute, companies are increasingly expected to take action. Protecting the environment is an urgent issue that affects all of mankind. For our company as well, not responding fast enough to protect the environment can become a factor that hinders our long-term growth. Our Environment Challenging Ono Vision (ECO VISION 2050) adopted in FY2019 set targets and outlined initiatives to realize a decarbonized society, a water recycling society, and a resource recycling society. We updated the targets in FY2022 and revised our environmental initiatives to make them more effective and put them on a faster schedule. We brought forward the target date for reducing our greenhouse gas emissions to zero from FY2050 to FY2035, and set new targets to achieve carbon neutrality by FY2025 and to use eco-friendly paper materials for our individual product packaging boxes by FY2030. Our primary mission is to pursue drug discovery that will positively impact the lives of patients and their families. At the same time, we also consider addressing the environmental issues cited in ECO VISION 2050 to be of equal importance. We are accordingly stepping up our activities to achieve our new environmental targets and to help address the issues facing society and the whole human race.

In addition, thorough compliance with laws and regulations is a fundamental requirement for all corporate activities, and as we globalize our business, we know that we will need to increasingly vigilant. In FY2022, we revised our existing Ono Pharmaceutical Code of Conduct to make it the Ono Group Code of Conduct applying to all Group companies, including affiliates and overseas subsidiaries. The new Code

of Conduct is framed from the perspective of a global organization to serve as a secondary document to each Group company's corporate philosophy that will provide a foundation for sincere behavior that accords with the high ethical standards required of companies upon which human lives depend.

We have also appointed compliance managers at every workplace and regularly hold informal meetings to create an environment that encourages employees voice any about compliance concerns.

Educating employees about past incidents of serious compliance violations remains an essential part of our compliance training. We have also reexamined how the Company provides donations and suspended the provision of scholarships and research endowments. All donations are disclosed on our website. We also take steps to prevent employees from engaging in inappropriate activities, such as with mechanisms to prevent individual employees from receiving or being solicited for donations.

#### Question 06

Do you have a message you would like to communicate to stakeholders?

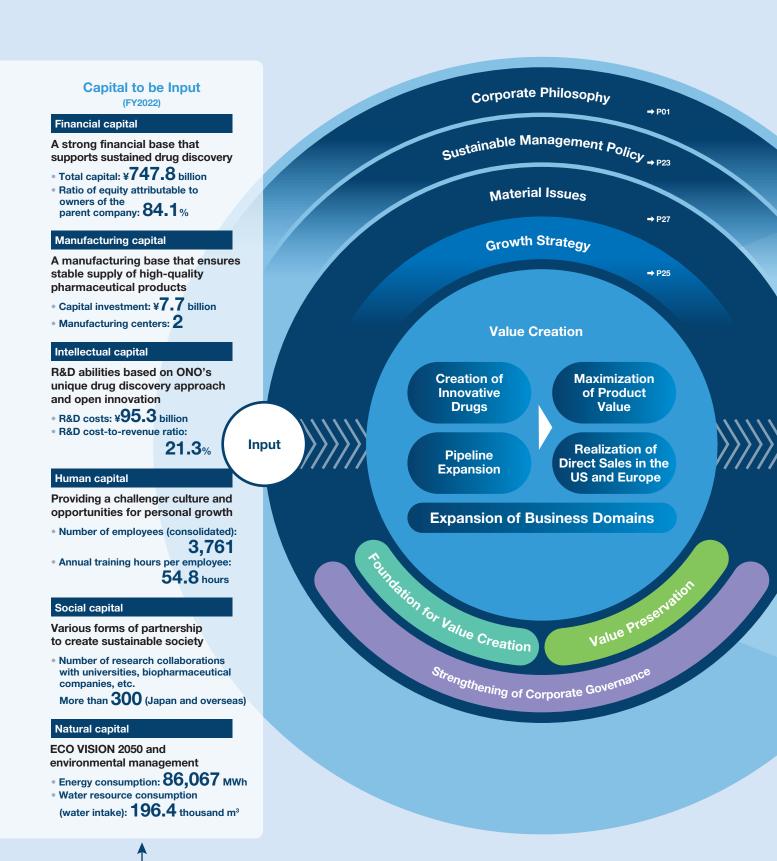
#### Our focus remains on establishing sustainable growth.

The Group's business environment does not necessarily support optimism. Nevertheless, I will continue executing strategies to drive our business growth and to make ONO an attractive presence for all stakeholders.

One by one, we will increase the number of people who are eager to work at our company, and that will lead us to the creation of new value. That is my objective for the future. All of our employees will continue working together with the aim of achieving sustainable growth.



# Delivering original and innovative new drugs as a Global Specialty Pharma







**Output** 

#### **Main products**

 OPDIVO Intravenous Infusion Cancer

¥142.3 billion

 FORXIGA Tablets Diabetes·Heart Failure·CKD

¥56.5 billion

• ORENCIA for Subcutaneous Injection Rheumatoid arthritis

¥24.8 billion

 GLACTIV Tablets Type 2 Diabetes

¥22.5 billion

**KYPROLIS** for **Intravenous Injection** Refractory multiple myeloma

PARSABIV Intravenous **Infusion for Dialysis** 

VELEXBRU Tablets

Waldenstrom macroglobulinemia and lymphoplasmacytic lymphoma

Parkinson's disease

¥5.0 billion

#### FY2022 results



#### **Economic Value**

#### Stable income

- Revenue: 447.2 billion yen
- Dividend per share: 70 yen (payout ratio: 30.3%)



#### **Societal Value**

#### Creation and provision of innovative drugs

- Number of patients to whom our new drugs are delivered: about 850,000
- Number of approvals received: Japan, 4; Korea, 4; Taiwan 7

#### **Training diverse talent**

 Versatile human resources who support the management foundation:

total **542** 



Outcome

#### **Environmental Value**

#### **Contributions to** decarbonized society

 Reduced greenhouse 38.2% gas emissions (scope 1 and 2, compared to FY2017)

#### **Contributions to** water-recycling society

- Water consumption: reduced 10.5% (year on year)
- ▶ See Materiality and KPI p. 27 for other indicators.

#### **Relevant SDGs**













¥8.4 billion

Primary central nervous system lymphoma

¥8.5 billion

ONGENTYS Tablets

# Aiming to achieve a sustainable society

Since our foundation in 1717 (Kyoho 2nd year of the Edo period), we have fully committed to the pharmaceutical business, under the corporate philosophy "Dedicated to the Fight against Disease and Pain" over many years. In FY2021, we formulated a new management policy to realize a sustainable society for the next 100 years.

#### **Sustainable Management Policy**



# 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.

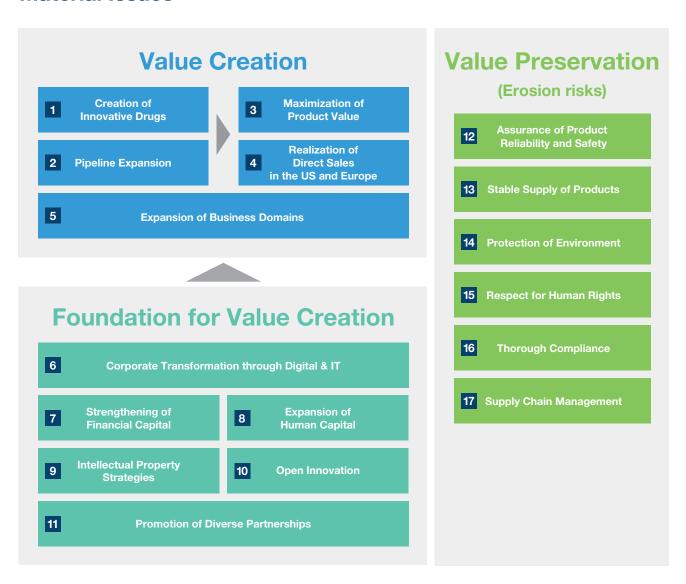
# Establishing a highly transparent and robust management foundation

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

In order to promote management that integrates financial and non-financial aspects based on our growth strategy and Sustainable Management Policy, we changed the name of material issues from "CSR material issues" to "material issues for management," and re-identified 18 material issues in FY2021.

By promoting initiatives for each of these material issues, we will work to improve the sustainability of both the ONO and society and increase corporate value in the long term.

#### **Material Issues**



Strengthening of Corporate Governance

Reason for identification, initiatives, indicators, etc. ▶ See p. 27

Process for setting policy ▶ See p. 31

# Four Growth Strategies and Management Infrastructures

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 the fields of new drug development and healthcare, 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 expand our intangible assets such as digital and IT infrastructure, human capital, and corporate brand, which are the management infrastructures supporting these growth strategies.

#### Management Targets (FY2022 -FY2026)

Revenue CAGR

# High single digits

(Compared to FY2021)

R&D cost-to-revenue ratio

**20-25**%

Operating income to revenue ratio

Maintain at 25% or higher



## 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 numerous clinical trials, the number of which is almost 100, mainly in our key strategic area of oncology. With OPDIVO, one of 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 primary area, we will work with our partner, AstraZeneca of the U.K., to quickly and surely 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. See p. 39



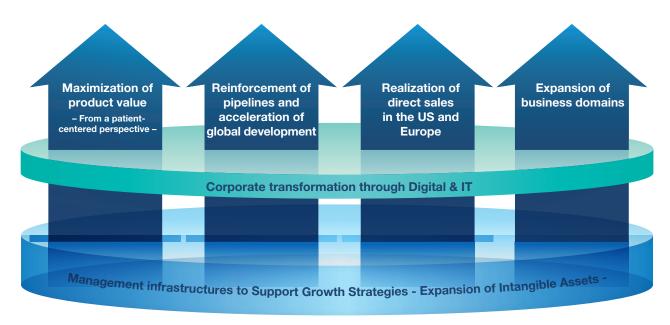
## Reinforcement of pipelines and acceleration of global development

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 research areas, and we will accumulate disease know-how in each area to create new drugs that will bring innovation to medicine on-site. We will strengthen and expand research and drug discovery alliances with world-leading universities, research institutions, and biotech startups, 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 nonclinical data from human-derived samples and data from clinical trials 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. As for global development, we will not only strengthen the system with an eye toward conducting our own sales in Europe and the U.S. and accelerate the development of numerous projects, including the Bruton's tyrosine kinase inhibitor ONO-4059 (Japanese name: VELEXBRU Tablets) in the US. ▶ See p. 35

#### ■ The Four Growth Strategies and Our Management Foundation

#### **Dedicated to the Fight against Disease and Pain**

#### Aiming to be a global specialty pharma





## Realization of direct sales in the US and Europe

In order to provide new drugs throughout 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 working to develop a sales structure for own sales with an eye on launching several projects, such as ONO-4059.

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, in light of the status of ongoing clinical trials, we are also moving forward with an examination of the establishment of our own sales organization, including medical affairs, marketing, sales, etc., in Europe. 
See p. 41



## Corporate transformation through Digital & 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 throughout the Group.

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. See p. 47



#### **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 addition to developing and commercializing products and services that take full advantage of the assets we have accumulated through research and development of prescription drugs , we launched REMWELL, which is a sleep supplement that has been approved in Japan as foods with function claims, in 2022. As a pioneer in lipid research, we will further work to solve various health issues in the future through Lipid-supply business.

We established michiteku Co., Ltd., in 2022 to 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 startups in the healthcare field by establishing Ono Digital health Investment, GK. ▶ See p. 43



#### Management infrastructures to Support Growth Strategies

- Expansion of Intangible Assets -

To support our four growth strategies and achieve dramatic growth, we will work to improve and expand our intangible assets: human capital, corporate brand, digital and IT infrastructure, etc. By increasing the human capital, we will work to develop talent to promote each element of the growth strategy while fostering talent throughout the Group. 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 of "innovative drugs," "Pharma," and "a corporation required by society."  $\triangleright$  See p. 53

# **Material Issues and KPI**

	Material Issues	Reason for being a priority issue	Vision over the medium to long term
	1 Creation of Innovative Drugs	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.	Cooperate with top scientists and accelerate the creation of new drugs that can change the world.
Valu	2 Pipeline Expansion	Our pipeline is the source of our sustainable growth. We continue enriching our pipeline to constantly provide innovative drugs to patients.	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 c
Value Creation	3 Maximization of Product Value	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.	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.
	4 Realization of Direct Sales in the US and Europe	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.	Aiming to become a globally competitive specialty pharmaceutical company, we are marketing new drugs in the U.S. and Europe.
	5 Expansion of Business Domains	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.	Contributing to solving social issues and realizing next- generation healthcare by leveraging digital technologies and our strengths.
ת	6 Corporate Transformation through Digital & IT	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.	A global IT infrastructure is being implemented and corporate transformation through digital is being realized.
Foundation	7 Strengthening of Financial Capital: financial strategy and policy on medium- to long-term investment	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.	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.
dation for Value Creation	8 Expansion of Human Capital	To achieve sustainable growth, it is essential to secure talent that can execute strategies as passionate challengers towards achievement of our corporate philosophy.	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.
מ	9 Intellectual Property Strategies	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 patiented and given concrete form as innovative drugs. Creating, maintaining, and utilizing IP are important issues for maximizing its value.	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.

Value Creation

Major initiatives	Indicators (items in blue are actual for FY2022)	
<ul> <li>Explore unique breakthrough drug seeds and creation of new drug candidate compounds through open innovation</li> <li>Improve the speed of creation of new drug candidate compounds by selecting optimal modalities, utilizing artificial intelligence (Al), etc.</li> <li>Promote drug discovery research based on human disease biology using the latest technologies, such as Al and informatics, as well as patient-derived samples</li> <li>Promote translational research by searching for biomarkers based on the mechanism of action</li> </ul>	The number of new products going to clinical trials: 3 (ONO-7018, ONO-1110, ONO-2020)	
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	<ul> <li>The number of products in the clinical development stage: 21</li> <li>The number of newly introduced products: 1 (exclusive option and asset purchase agreement for itolizumab</li> <li>Approvals received in the U.S. and Europe: Total of 12 projects at the clinical trial stage</li> </ul>	
<ul> <li>Engaging in effective marketing activities, using digital communications to provide information, and improving the expertise of MRs</li> <li>Obtaining approvals for drugs with indications and usage, dosage and administration that maximize the potential of developed compounds</li> <li>Identifying needs of patients and healthcare professionals and designing products to meet them</li> <li>Generating evidence focused on extension of the healthy life span (efficacy, safety, and QoL)</li> </ul>	<ul> <li>Number of patients to whom our new drugs are delivered: about 850,000</li> <li>Sales by major product: OPDIVO, 142,300 million yen; FORXIGA, 56,500 million yen</li> <li>Number of approvals received in Japan, Korea, and Taiwan: Japan, 4; Korea, 4; Taiwan, 7</li> </ul>	
<ul> <li>Establish a sales structure for the launch of ONO-4059 in the U.S.</li> <li>Carry out development in Europe and establish a sales structure according to the progress of the development</li> </ul>	<ul> <li>Start our own sales in the U.S. and Europe: increase of about 40 employees (total of about 100 employees) to reinforce development organization, sales organization, and infrastructure at ONO PHARMA USA increase of about 10 employees (total of about 60 employees) primarily for development at ONO PHARMA UK</li> </ul>	
<ul> <li>Creating and promoting new businesses utilizing digital technology, starting from customers' unresolved issues (needs)</li> <li>Develop and commercialize evidence-based products and services to solve social issues in the healthcare sector (Ono Pharma Healthcare Co., Ltd.)</li> <li>Invest in and create business for venture companies engaged in businesses aimed at solving healthcare issues (Ono Digital health Investment, GK)</li> </ul>	<ul> <li>The number of new businesses started: 1 (michiteku Co., Ltd.)</li> <li>The number of new products and services provided: 1*</li> <li>Released michiteku β-version in May 2023</li> </ul>	
<ul> <li>Implement cross-functional IT infrastructure based on the IT blueprint</li> <li>Implement a data utilization platform including internal and external data for important decision-making</li> <li>Improve robust information security management capabilities</li> <li>Develop the talent to plan and lead DX</li> </ul>	<ul> <li>Completion and utilization of the IT blueprint (big picture for IT infrastructure and related systems)</li> <li>Construction and use of a data utilization platform: Operate OASIS</li> <li>Establishment of a cross-functional DX promotion system: obtained DX certification</li> <li>Number of participants in the Digital Talent Development Training Program: 100 (FY2026 target of 500)</li> <li>Of these, the number capable of planning, managing, and executing DX projects: 15 (FY2026 target of 100)(achieved all FY2022 targets)</li> </ul>	
<ul> <li>Enhancing operating cash flow by expanding sales revenue</li> <li>Increasing asset efficiency by reducing cross-shareholdings</li> <li>Maintaining and increasing profitability and ROE by maximizing return on investment</li> </ul>	(FY2022 to FY2026)  Revenue CAGR: In the high single digits: 23.8% for FY2021  Operating income to revenue ratio: Maintain 25% or higher: 31.7%	
<ul> <li>Next executive talent: Promoting the training for selected employees and the strategic personnel transfers</li> <li>Globally competent talent: Promoting development plans based on global development and implementing global strategic personnel transfers</li> <li>Digital talent: Developing talent to plan and lead the digital transformation, and providing training programs for them</li> <li>Innovation talent: Providing programs to trigger innovations, and promoting innovation</li> <li>Other: Engaging in activities to disseminate mission statements, providing voluntary-participation type training, developing a self-development learning support system, etc.</li> </ul>	(Total number of persons up to 2026)  In next executive talent pool: 91 (goal of at least 250)  In globally competent talent pool: 153 (goal of at least 300)  Persons who will have participated in digital talent development and training program: 269 (goal of at least 500)  Including those who can plan, manage, and execute the DX project: 40 (goal of at least 100)  Core innovation talent: 29 (goal of at least 180)	
<ul> <li>Creating and maintaining IP to create innovative new drugs</li> <li>Strengthening the inventive process to lengthen the life of launched products and products in development, and filing patents effective for LCM*</li> <li>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.</li> <li>* Lifecycle management</li> </ul>	<ul> <li>Products and the R&amp;D pipeline: ▶ See p. 37.</li> <li>Amount of IP in use (IP landscape)</li> </ul>	

	Material Issues	Reason for being a priority issue	Vision over the medium to long term	
Foundation for Value Creation	10 Open Innovation	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.	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.	
dation for Creation	11 Promotion of Diverse Partnerships	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.	We strengthen company brands, etc. and accelerate business activities to promote partnerships with diverse stakeholders.	
	12 Assurance of Product Reliability and Safety	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.	A global specialty pharmaceutical company with established organizational systems for appropriate quality assurance and safety management.	
Value Preservation	13 Stable Supply of Products	The provision of a stable supply of our drugs to patients who need them is a basic duty of our business.	Our products are supplied stably to patients throughout the world.	
	14 Protection of Environment	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.	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.	
	15 Respect for Human Rights	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 problemsolving capabilities, we believe that we have a responsibility to contribute to this issue to the maximum extent possible.	Human rights risk management  Aim to construct a management system based on the UN Guiding Principles on Business and Human Rights  Aim to construct a governance system with adaptability to appropriately respond whenever human rights problems arise and establish a foundation of trust with society for the Group (including supply chain)  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.	
	16 Thorough Compliance	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.	Establish a compliance risk management system to support global business expansion and prevent compliance violations.	
	17 Supply Chain Management	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.	Strengthen collaborative relationships with business partners and manage sustainability-related risks such as the natural environment and human rights.	
Corporate Governance	18 Strengthening of Corporate Governance	To establish a highly transparent and robust management for sustainable growth, ONO focuses on enhancing the functions of the Board of Directors and the Audit & Supervisory Board to strengthen corporate governance.	Establish an effective corporate governance system to achieve our sustainable growth.	

Value Creation

Major initiatives	Indicators (items in blue are actual for FY2022)
<ul> <li>Promote collaborative research with world-class researchers, and drug discovery alliances and joint research with biopharmaceutical companies focusing on priority research areas</li> <li>Strengthen competitiveness in drug discovery and R&amp;D activities through strategic investments by Ono Venture Investment</li> </ul>	<ul> <li>The number of research collaborations: over 300 in globally (ones underway as of March 31, 2023)</li> </ul>
<ul> <li>Collaborating with partner companies in the research and development and sale of drugs</li> <li>Building relationships with local communities and municipalities</li> <li>Building cooperative relationships with the suppliers</li> <li>Building relationships with many partners for our business</li> </ul>	<ul> <li>The number of companies with which in-license and out-license agreements are concluded: 1</li> <li>The number of research collaborations: over 300 in globally (ones underway as of March 31, 2023)</li> <li>Other partnering results: See p. 65</li> </ul>
<ul> <li>Create appropriate global systems for product quality and safety management</li> <li>Establish an operation to study safety signals of investigational products</li> <li>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.</li> </ul>	<ul> <li>Construction of global quality and safety management system: Completed OPUS QA SOP proposal, reached agreement on policy among Japan, US, Europe, and constructing QMS system</li> <li>Zero significant findings from regulatory inspections: achieved</li> <li>Zero recalls of Ono products: achieved</li> </ul>
<ul> <li>Building a global product supply system</li> <li>Implementing risk management for overall operations related to product supply, such as strengthening response to BCP, maintaining proper inventory, etc.</li> <li>Examining mid- to long-term stable production systems, including increased production efficiency and the use of CMO, etc.</li> </ul>	No out-of-stock incidences: achieved
<ul> <li>Reduce greenhouse gas emissions and increase share of renewable energy in total electricity consumption</li> <li>Reduce use of water resources</li> <li>Recycling of unnecessary materials</li> </ul>	Achievement of medium- to long-term environmental goals linked to ECO VISION 2050  Realization of a decarbonized society: Reduced Scope 1 and 2 emissions 38.2% (compared to FY2017) and achieved renewable energy usage rate as a percentage of total electricity consumption of 21.5%  Realization of a water-recycling society: Reduced water resource consumption (water intake) 10.5% compared to previous year  Realization of a resource-recycling society: Achieved final landfill rate of industrial waste of 0.02%
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	Human rights risk management (up to 2026)  Conduct human rights due diligence within the Group: conducting risk assessment and impact assessment  Conduct human rights risk assessments for high priority suppliers: conducted risk assessment (conducted desktop surveys and held workshops to organize human rights risks)  Improving access to healthcare  Number of approved rare disease/pediatric indications: 1  Project outcome goals (new project to begin in FY2022): See ONO Bridge Project goals.
<ul> <li>Establish overall risk management (ERM) for global response, including compliance</li> <li>Comply with relevant laws and regulations of the pharmaceutical business, promote proper use of pharmaceuticals, prevent corruption and corrupt practices, protect information, etc.</li> <li>Foster a culture of proactive involvement in preventing compliance violations</li> <li>Strengthen governance of compliance risks by the Board of Directors</li> </ul>	<ul> <li>Number of significant compliance violations*: 0</li> <li>* Violations that have a great impact on sales and profits and have a great social impact</li> </ul>
<ul> <li>Share our code of conduct, get consent forms</li> <li>Assess risk</li> <li>Carry out on-site audits</li> <li>Confirm corrective action efforts</li> </ul>	<ul> <li>Establish a stronger risk management system (formulate policies and Sustainable Procurement Code, and create related system) (-2026): Constructed management system and revised Sustainable Procurement Code</li> <li>Comprehensive evaluations of companies in high-risk areas (-2026): Obtained consent forms and held partner explanatory meetings for companies in important and high-risk fields (3 times)</li> </ul>
<ul> <li>Improve function of the Board of Directors to enhance governance Continue taking measures to enhance function of the Board of Directors through communications with stakeholders and evaluation of the effectiveness of the Board of Directors</li> <li>Establish governance system for sustainable growth Continue monitoring risk management-related measures by the Board of Directors</li> </ul>	<ul> <li>Improve operation through evaluations of the effectiveness of the Board of Directors: Expanded support for outside directors and had Board of Directors review SR Activity Report (shared opinion of shareholders and investors) and agenda setting</li> </ul>

# Reidentify as important management issue

In FY2021, 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 medium-term management plan and have been developed into a more dynamic management system.

Steps in Material Issue Analysis

Step

Step 2

#### **Extract management issues**

#### Analyze the external and internal environment

- Analyze in conjunction with the formulation of the medium-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

#### **Define the 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 medium-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 management issues

In the material issue analysis conducted in FY2021, we analyzed the management environment in conjunction with the formulation of the medium-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.

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 priority 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.

# After identification: Run through management cycle

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 medium-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. Check pp. 32 and after for information on progress.

# Value Creation

Our mission is to provide new value to patients through the creation of innovative drugs. We are striving to create value required by companies and society, which includes strengthening R&D, expanding our pipeline, building our own marketing operations in U.S. and Europe to deliver medicines to more patients, and further expanding our business domain.

1	Creation of Innovative Drugs	33
2	Pipeline Expansion	35
3	Maximization of Product Value	39
4	Realization of Direct Sales in the US and Europe	41
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#### Material Issue

## **Creation of Innovative Drugs**

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 drug candidates going to clinical trials

# **ONO's History is the Challenge of Drug Discovery Achieving extremely aggressive open innovation**

We strive to create innovative drugs to succeed prostaglandin-related products and OPDIVO by valuing the ideas and teamwork of researchers and leveraging top science knowledge from throughout the world and bio-venture leading technology as much as possible. In order to link science and technology, which evolves at an astounding speed, to drug discovery, we actively promote such activities as study abroad in academia where we conduct research collaboration, and assignments in the U.S. and European bases, and raise the level of and engagement with each researcher. We will take on the challenge of creating an environment to promote quick drug discovery of world-class quality.



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



#### **Basic Approach**

# Contribute to society by developing pharmaceutical products that bring true benefit to patients

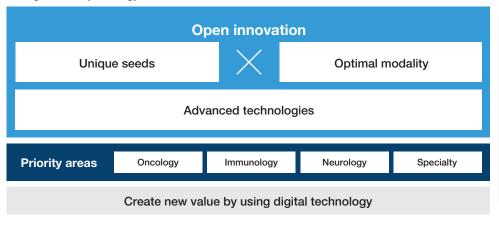
ONO aims to "contribute to society by developing pharmaceutical products that bring true benefit to patients". We are striving to create original and innovative drugs by taking on the challenges of diseases that have not yet been conquered and areas of high medical need where patient satisfaction with treatment is still low.

#### **Drug Discovery Strategy**

# Promoting open innovation in multiple fields and aiming to create innovative new drugs that meet medical needs

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 create breakthrough new drugs with medical impact by not only utilizing a variety of cutting-edge technologies, such as informatics, robotics, and genome editing, but also selecting the optimal modality (therapeutic

#### Drug Discovery Strategy



Create unique and innovative new drugs

approach), including small molecule compounds, antibodies, and cells for the unique drug discovery seed. In addition, we are working to improve the quality and speed of drug discovery research through the use of digital technology.

As of June 2023, a total of 10 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









The above photo is a supercomputer used for drug discovery. It is possible to process and analyze vast amounts of chemical data and biological information at high speed and search for drug candidates.

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 candidates in humans.

#### Strengthening technology platform

#### Making aggressive use of digital technology Promoting reforms to the drug discovery process

In recent years, there have been prominent advances in digital technology, which has resulted in innovative changes in the drug discovery process. At ONO, we use various advanced technologies to conduct rapid, detailed analysis of large volumes of data, such as genetic data of patients, and actively use that from the initial stages of drug discovery, including deciding on the value of our unique seeds. Furthermore, we use computer simulations to analyze molecular structure and predict mutual interactions between molecules. Through these efforts, we are working to quickly create new, high-quality drug candidates. In addition to building an Al model that uses high calculation capabilities, such as image analysis, video analysis, and natural word processing, we are taking on the challenge of revolutionizing the complex drug discovery process, a process that requires much time and labor.

Major Initiative(s) and Development Products in Each of the Four Priority Areas				
Major Initiative(s)	Candidates under Development	Target Diseases		
	ONO-4578	Solid tumor, Gastric cancer, Pancreatic cancer, Colorectal cancer, Hormone receptor-positive, HER2-negative breast cancer		
As a pioneer in cancer immunotherapy, ONO 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. We are also striving to find unique drug discovery seeds through open innovation and translational research. Furthermore, we are taking on the challenge of using new drug discovery modality.	ONO-7475	Solid tumor, EGFR-mutated non-small cell lung cancer		
	ONO-7914	Solid tumor		
	ONO-4685	T cell Lymphoma		
	ONO-7018	Non-Hodgkin lymphoma, chronic lymphocytic leukemia		
Based on many years of its experiences in immunology research, which contributed to creating OPDIVO, ONO is working toward drug discovery with a main focus on biopharmaceutical development. We are taking on the challenge of creating breakthrough new drugs for both autoimmune and allergic diseases.	ONO-4685	Autoimmune disease		
ONO conducts research focused on various topics, including not only neurons, a major components of the nervous system, but also glial cells, which maintain and	ONO-2910	Diabetic polyneuropathy Chemotherapy-Induced Peripheral Neuropathy		
support the environment necessary for the survival and function of neurons. We are dedicated to discovering innovative drugs to provide disease-modifying therapies, as	ONO-2808	Multiple system atrophy		
well as symptomatic treatment, to patients with neurodegenerative diseases, psychiatric disorders or chronic pain.	ONO-1110	Pain		
	ONO-2020	Neurodegenerative diseases		
ONO is working toward discovery of clinically valuable pharmaceutical products for diseases for which treatment is high in unmet needs, regardless of the disease indication. We have 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		
	As a pioneer in cancer immunotherapy, ONO 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. We are also striving to find unique drug discovery seeds through open innovation and translational research. Furthermore, we are taking on the challenge of using new drug discovery modality.  Based on many years of its experiences in immunology research, which contributed to creating OPDIVO, ONO is working toward drug discovery with a main focus on biopharmaceutical development. We are taking on the challenge of creating breakthrough new drugs for both autoimmune and allergic diseases.  ONO conducts research focused on various topics, including not only neurons, a major components of the nervous system, but also glial cells, which maintain and support the environment necessary for the survival and function of neurons. We are dedicated to discovering innovative drugs to provide disease-modifying therapies, as well as symptomatic treatment, to patients with neurodegenerative diseases, psychiatric disorders or chronic pain.  ONO is working toward discovery of clinically valuable pharmaceutical products for diseases for which treatment is high in unmet needs, regardless of the disease in patients, medical professionals, and society, and then leveraging this knowledge to	As a pioneer in cancer immunotherapy, ONO works toward discovering innovative drugs for cancer patients with the experience, expertise, and know-how we nurtured through R8AD of the immune checkpoint inhibitor OPDIVO. We are also striving to find unique drug discovery seeds through open innovation and translational research. Furthermore, we are taking on the challenge of using new drug discovery modality.  Based on many years of its experiences in immunology research, which contributed to creating OPDIVO, ONO is working toward drug discovery with a main focus on biopharmaceutical development. We are taking on the challenge of creating breakthrough new drugs for both autoimmune and allergic diseases.  ONO-4685  ONO-4685  ONO-4685  ONO-2910  ONO conducts research focused on various topics, including not only neurons, a major components of the nervous system, but also glial cells, which maintain and support the environment necessary for the survival and function of neurons. We are dedicated to discovering innovative drugs to provide disease-modifying therapies, as well as symptomatic treatment, to patients with neurodegenerative diseases, psychiatric disorders or chronic pain.  ONO-2020  ONO is working toward discovery of clinically valuable pharmaceutical products for diseases for which treatment is high in unmet needs, regardless of the disease indication. We have taken up the challenge of accurately identifying those needs in patients, medical professionals, and society, and then leveraging this knowledge to		

#### Material Issue 2

## **Pipeline Expansion**

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
- Obtain approval in the U.S. and Europe

#### Flexibly conducting clinical trials in Japan, the U.S., and Europe

We will continue to increase the number of new drug candidates by energizing in-house drug discovery research and conducting aggressive licensing activities. Efforts will also be made to obtain approval for these new drug candidates throughout the world, including the U.S. and Europe. To do that, it is first necessary to confirm that the safety and efficacy of the compounds are as expected, and we will quickly ascertain the potential value of the compounds by flexibly using bases in Japan, the U.S., and Europe to conduct clinical trials. Therefore, we are building a system to promote development between regions and countries so that we can deliver even more innovative new drugs to patients throughout the world even one day quicker.

#### Kiyoaki Idemitsu

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



#### Early establishment of PoC

## Undertaking speedy clinical development and improving the success rate

ONO is working to undertake speedy 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 infrastructure in Japan, the U.S., and Europe to quickly establish PoC to expediently identify the potential product value of candidates. 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 reinforcing our search for clinical markers through TR,\*1 we conduct rTR\*2 that links the results obtained from clinical trials to the launch of new discovery research projects by feeding those results back into research, creating an R&D virtuous cycle.

- \*1 Abbreviation of translational research. Method that applies knowledge obtained through basic research to various activities, including conducting diagnosis, treating, and determining efficacy during clinical trials.
   \*2 Abbreviation of reverse translational research. A method for feeding knowledge
- 2 Abbreviation of reverse translational research. A method for feeding knowledge obtained during clinical trials back into basic research.

#### **Licensing Activities**

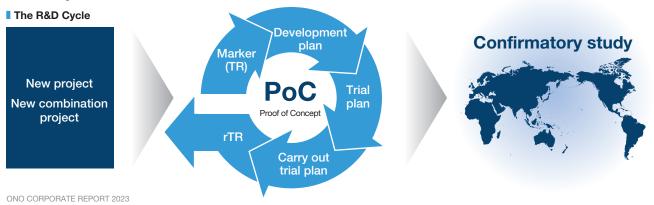
## Licensing with an eye toward global introduction

We are also actively pursuing licensing activities with the aim of in-licensing new candidates under development by pharmaceutical or bio-venture 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

## Maximizing product value and reinforcing pipeline

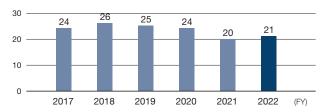
We are moving forward with clinical development to add functions to existing products in order to increase product value. For



OPDIVO, we are conducting clinical trials aimed at expanding the indications and usage for many cancers, using the drug at earlier lines of treatment, and establishing combination therapies to enhance therapeutic efficacy. We are also aggressively moving forward with global research on new compounds to reinforce our pipeline. In FY2022, there were 21 products at the clinical trial stage.

We will continue to aggressively pursue clinical development not only in Japan but also worldwide for the benefit of patients awaiting new therapeutic agents.

#### Number of Products in the Clinical Development Stage



#### **Global Pipeline and In-licensed Products**

### Creating and reinforcing system for quick decision making

In each of these fields, we are promoting development with an eye toward global commercialization. As for new drug candidates

in the field of oncology, there are 4 of our own products and 1 in-licensed product in addition to the VELEXBRU Tablets (BTK inhibitor), which are already on the market in Japan. In the field of neurology, we launched phase 1 trials for both ONO-2020 (epigenetic regulation) and ONO-1110 (endocannabinoid regulation), which means that a total of 4 compounds are in at the clinical trial stage. As for immunology and specialty fields, development of candidates is progressing on an individual basis. For a total of 12 projects, the goal of which is to commercialize globally, we are now conducting clinical trials. We are also moving forward with creating and reinforcing a system to make visible projects throughout the world and undertake quick decision making.

In addition, ONO-7913 (anti-CD47 antibody) and ONO-2017 (voltage-dependent sodium current inhibition/GABAA 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 addition to our own drug discovery, we are actively working to capture assets from overseas, and in December 2022, we obtained exclusive option rights related to development and commercialization of the anti-CD6 antibody itolizumab in the U.S., Canada, and several other countries. Development of itolizumab, which has therapeutic indications for acute graft versus host disease (acute GVHD) and lupus nephritis, is moving forward, and this will contribute to a broader pipeline for the immunology field.

#### I Global pipeline (As of July 27, 2023)

Development Area	Product Name	Mechanism	Target Disease	Develo	pment Stage	In-house / In-license
Development Area	(Development Code)	Mechanism	rarget Disease	(Japan)	(Overseas)	in-nouse / in-license
	Velexbru Tablets (ONO-4059)	BTK inhibitor	Primary central nervous system lymphoma	Launched	US : Phase2	In-house
	ONO-4578	EP4 antagonist	Solid tumor • Gastric cancer etc.	Phase1	_	In-house
Oncology	ONO-7475	AxI/Mer inhibitor	EGFR-mutated non-small cell lung cancer	Phase1	_	In-house
Cilcology	ONO-7914	STING agonist	Solid tumor	Phase1	_	In-house
	ONO-4685	PD-1×CD3 bispecific antibody	T-cell lymphoma	_	US : Phase1	In-house
	ONO-7018	MALT1 inhibitor	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	-	US : Phase1	In-license (Chordia)
	ONO-2808	S1P5 receptor agonist	Multiple system atrophy	_	US : Phase2	In-house
Neurology	ONO-2910	Enhancement of Schwann cell differentiation	Diabetic polyneuropathy, Chemotherapy-Induced Peripheral Neuropathy	Phase2	-	In-house
	ONO-2020	Epigenetic regulation	Neurodegenerative disease	_	US : Phase1	In-house
	ONO-1110	Endocannabinoid regulation	Pain	Phase1	_	In-house
Immunology	ONO-4685	PD-1×CD3 bispecific antibody	Autoimmune disease	Phase1	EU : Phase1	In-house
Speciality ONO-7684 FXIa Inhibitor		FXIa Inhibitor	Thrombosis	Phase1	EU : Phase1	In-house

#### In-licensed products (Phase 2 or later)

Product Name (Development Code)	Mechanism	Mechanism Target Disease		In-license	
ONO-7913	Anti-CD47 antibody	TP53-mutant acute myeloid leukemia	Phase 3	Gilead Sciences, Inc.	
ONO-2017	Inhibition of voltage-gated sodium currents/positive allosteric modulator of	Primary generalized tonic-clonic seizures	Phase 3	SK	
ONO-2017	GABA <sub>A</sub> ion channel	Partial-onset seizures	Phase 3	Biopharmaceuticals	
Braftovi Capsules	BRAF inhibitor	Thyroid cancer	Filed	Pfizer Inc.	
Mektovi Tablets	MEK inhibitor	Thyroid cancer	Filed	Pfizer Inc.	

### Development Pipeline (As of July 27, 2023)

#### Oncology

Product Name/ Development Code/	Mechanism	Dosage Form	Target Indication	Phase	Area	Licensor	
Generic Name			Malignant mesothelioma (Excluding Pleura)	1 II III Filed	JP		
		Injection	Epithelial skin malignancies	<b>———</b>	JP	In-house (Co-developed with BMS)	
Opdivo Intravenous Infusion	Anti-PD-1 antibody		Hepatocellular carcinoma	<b>———</b>	JP·KR		
illusion			Ovarian cancer	<b></b>	JP·KR·TW	with bivio)	
			Bladder cancer	<del></del>	JP·KR·TW		
Braftovi Capsules	BRAF inhibitor	Capsule	Thyroid cancer	<b>——</b>	JP	Pfizer	
Mektovi Tablets	MEK inhibitor	Tablet	Thyroid cancer		JP	Pfizer	
			Gastric cancer	<b></b>	JP·KR·TW		
Yervoy Injection*	Anti-CTLA-4 antibody	Injection	Urothelial cancer		JP·KR·TW	BMS	
			Hepatocellular carcinoma	<b></b>	JP∙KR		
	Anti-CD47 antibody	Injection	TP53-mutant Acute myeloid leukemia		JP	-	
			Acute myeloid leukemia	-	KR·TW		
ONO-7913/			Pancreatic cancer★	<b>→</b>	JP	- Gilead	
Magrolimab			Colorectal cancer★	<b>—</b>	JP		
			Solid tumor	<b>→</b>	JP	-	
			Myelodysplastic syndrome	-	JP		
ONO-4686*	Anti-TIGIT antibody	Injection	Solid tumor		JP	BMS	
ONO-4482*/ Relatlimab	Anti-LAG-3 antibody	Injection	Melanoma	-	JP	BMS	
ONO-7226*	Anti-ILT4 antibody	Injection	Solid tumor	<b>→</b>	JP	BMS	
ONO-7475/	Axl/Mer inhibitor	Tol-1-4	Solid tumor★	-	JP	la have-	
Tamnorzatinib	AXI/Mer Innibitor	Tablet	EGFR-mutated non-small cell lung cancer	<b>→</b>	JP	In-house	
			Colorectal cancer★	<b>-</b>	JP		
			Pancreatic cancer*	<b>→</b>	JP		
ONO-4578	PG receptor (EP4) antagonist	Tablet	Non-small cell lung cancer★	<b>-</b>	JP	In-house	
			Solid tumor • Gastric cancer★	<b>→</b>	JP		
			Hormone receptor-positive, HER2-negative breast cancer	<b>-</b>	JP		

Product Name/ Development Code/	Mechanism	Dosage Target Indication		Phase				Area	Licensor
Generic Name	iviecriariisiti	Form	rarget mulcation		I II III Filed		Alea	LICENSOI	
ONO-7119* Atamparib	PARP7 inhibitor	Tablet	Solid tumor					JP	Ribon
ONO-7122*	TGF-β inhibitor	Injection	Solid tumor	<b>-</b>				JP	BMS
ONO-7914*	STING agonist	Injection	Solid tumor	<b>-</b>				JP	In-house
ONO-4059	Bruton's tyrosine kinase (BTK) inhibitor	Tablet	Primary central nervous system lymphoma		<b>→</b>			US	In-house
ONO-4685	PD-1×CD3 bispecific antibody	Injection	T-cell lymphoma	<b></b>				US	In-house
ONO-7018	MALT1 inhibitor	Tablet	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	<b>→</b>				US	Chordia

#### Areas other than Oncology

Product Name/			Pha	200					
Development Code/ Generic Name	Mechanism	Dosage Form	Target Indication	I II III Filed		Filed	Area	Licensor	
Velexbru Tablets/ Tirabrutinib Hydrochloride	Bruton's tyrosine kinase (BTK) inhibitor	Tablet	Pemphigus			<b>-</b>	•	JP	In-house
ONO-2017/	Inhibition of voltage-gated sodium currents/positive	Tablet	Primary generalized tonic-clonic seizures			<b>-</b>		JP	SKBP
Cenobamate	allosteric modulator of GABAA ion channel		Partial-onset seizures			<b>-</b>		JP	JNDF
ONO-2910	Enhancement of Schwann	Tablet	Diabetic polyneuropathy		<b>→</b>			JP	In-house
ONO-2910	cell differentiation		Chemotherapy-Induced Peripheral Neuropathy		<b>-</b>			JP	- in-nouse
ONO-2808	S1P5 receptor agonist	Tablet	Multiple System Atrophy		<b>-</b>			US	In-house
ONO-4685	PD-1×CD3 bispecific antibody	Injection	Autoimmune disease	<b>→</b>				JP∙EU	In-house
ONO-7684	FXIa Inhibitor	Tablet	Thrombosis	<b>→</b>				JP·EU	In-house
ONO-2020	Epigenetic Regulation	Tablet	Neurodegenerative disease	<b>→</b>				US	In-house
ONO-1110	Endocannabinoid regulation	Oral	Pain	<b>-</b>				JP	In-house

<sup>★</sup>Combination with Opdivo.

\* In the case of clinical development of the oncology drugs in the same indication, the most advanced clinical phase is described.

### **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

### Maximization of product value from a patient-centered perspective

For us, a patient-centered perspective is indispensable. This is because patients bear not only physical but also mental and social concerns and worries. After gaining a deep understanding of various aspects of patients, including their symptoms, concerns, and worries, we promote the appropriate use of our drugs. We will further deepen cooperation between our numerous divisions. The whole company, particularly the Sales and Marketing Division, has united to maximize product value by sharing unmet medical needs in the medical field and opinions of patients with all divisions. Thus, we will take on the challenge of realizing the well-being of patients and their families there.



#### Satoshi Takahagi

Corporate Executive Officer / Executive Director, Sales and Marketing, Primary Care Business Division

#### **Basic Approach**

### Realizing the Well-being of Patients and Their Families

Working with healthcare professionals, we aim to maximize product value and thus realize the well-being 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**

### Conducting Awareness Activities With Healthcare Professionals

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' well-being by promptly delivering new drugs to patients who need them.

To this end, the Sales and Marketing promotes 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.

### Ascertaining Patient Needs and Providing Information with Digital Technology

### **Reinforcing the Omnichannel Information Provision System**

One of our initiatives to ascertain patient needs is to regularly hold "patient voice sharing meetings." Through these meetings, we deepen our understanding of the various problems faced by patients, not only physical ones but also mental and social ones, which leads to better communication with healthcare professionals. Gathering accurate information and providing appropriate information through channels required by healthcare professionals are important to enhance product value. The channels through which healthcare professionals obtain information are also growing increasingly diverse. Therefore, for information provision activities, we are promoting information provision via omnichannel that links the various real and digital channels based on accumulated data. With marketing automation, we are also moving forward with automating information provision in a manner appropriate for how healthcare professionals come into contact with digital content. In addition, for our members websites "ONO Medical Navi" and "ONO Oncology," we are implementing various measures, including expanding content such as personalized display and webinars and automatically linking member accounts with other companies' member sites.

Furthermore, we are reinforcing information provision that leverages digital technology, including expanding online meetings and email tools, assigning MRs who handle only the provision of information through digital channels (9 MRs as of March 2023), and providing free access to the side-effect search tool (Ae NAVI).

#### **Division Cooperation from the Patient's Perspective**

### Whole Company Moving Forward, Centered on Patients

The goal of Maximization of product value is not only to increase the number of patients using the product but also to realize the well-being 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.

### Reflecting the Needs of Patients and Healthcare Professionals

### **Introducing Side-Effect Management Application for all of Japan**

Patients who receive treatment with immune checkpoint inhibitors are often concerned that they cannot properly communicate their physical condition to healthcare professionals and health professionals want to quickly detect changes in patient's physical condition.

To resolve these issues, we launched the side-effect management application FukuSapo® throughout Japan in FY2022. Promoting interactive communication between patients and healthcare professions via FukuSapo® makes it possible to promptly discover immune-related adverse events and leads to appropriate response by healthcare professionals.

#### **Maximizing OPDIVO's Product Value**

### Four Perspectives, Including Adding Indicated Tumors

We are working with our partner Bristol Myers Squibb to maximize OPDIVO's product value, 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

#### **Leveraging the Opinions of Many Patients**

As part of our efforts to generate evidence (efficacy, safety, QOL) focused on extending healthy life expectancy, Medical Affairs conducts 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

collected data as scientifically objective data by using multiple statistical methods, such as sensitivity analysis, rather than simply tabulating patient questionnaires. In FY2022, we launched seven clinical studies along with publishing one research paper and presenting two papers at academic conferences.

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 FY2022, we applied for approval for malignant mesothelioma (excluding malignant pleural mesothelioma) in Japan, and it is currently under review On June 15, 2023, we will apply for approval for epithelial malignant tumors.
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 FY2022, we received approval for first line treatment of esophageal 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 FY2022, the drug was approved for neoadjuvant therapy for non-small cell lung cancer in Japan, Korea and Taiwan,.
Developing combination therapies	We are proceeding with development, searching for combinations with other drugs or treatments that boost OPDIVO's therapeutic effects. In FY2022, the drug was approved in Japan, Korea, and Taiwan 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.

# Realization of Direct Sales in the US and Europe

Vision over the medium to long term

Aiming to become a global specialty pharma, we are marketing new drugs in the U.S. and Europe.

Indicators

Start our own sales in the U.S. and Europe

#### I Three steps to becoming a global company



#### ONO's Global Business

## Working to establish our own marketing operations in the U.S. and Europe to become a true global company

We aim to be a true global company that competes internationally. Specifically, 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. We have defined three steps that will transform us into a global company. Currently, we are in step two working to establish our own marketing operations in the U.S. and Europe for our niche products that do not require large-scale sales organizations.



### Building a business foundation in the U.S. believing in Ono Pharma's R&D strength and limitless potential

In order to successfully establish operations in the U.S. for the first time, we drew up a medium- to long-term vision and strategy, and opened a new office in Cambridge, Massachusetts in 2021. In the U.S., we aim to continue to bring first-in-class products to market. Currently, we are hiring strong leaders, building our organization, and working on development and product launch preparatory activities. Believing in our R&D strength and limitless potential, we are establishing a platform for our business foundation in the U.S. in each value chain. We aim to be a global specialty pharma that truly benefits patients. This is a big dream that requires all hands on deck.

Kunihiko Ito President & CEO, ONO PHARMA USA, INC.

#### **Step1: Globalizing Our Marketing Organizations**

#### Steadily increasing presence in Asia with our own marketing organizations in South Korea and Taiwan

Our global expansion began in earnest with the establishment of ONO PHARMA KOREA CO., LTD. located in South Korea in FY2013 followed by ONO PHARMA TAIWAN CO., LTD. in FY2014, both of which are wholly owned subsidiaries of ONO. The subsidiaries established their own sales organizations, and we started our own sales operations for OPDIVO in South Korea in FY2015 and in Taiwan in FY2016, respectively.

To date, OPDIVO has been approved for 10 cancers in South Korea and 11 cancers in Taiwan (as of the end of June 2023). In addition, VELEXBRU received approval and began our own marketing in South Korea in FY2021 and in Taiwan in FY2022 for the indication of relapsed or refractory primary B-cell CNS lymphoma. Furthermore, since FY2021 BRAFTOVI has been marketed by our own sales organization in South Korea 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

#### Strengthening our systems for marketing and development

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 in an effort to build a related system.

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 our development structure for new compounds such as ONO-4059, we will strengthen our system for bringing products to market by hiring human resources from Commercial, Pharmacovigilance, and Medical to

establish our own sales system.

In the U.S. and Europe we are currently conducting clinical trials for 6 products and are aiming to establish a 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) for development products following ONO-4059. In Europe, we currently have an organization of about 60 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 system.

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

#### ONO PHARMA USA,INC.

The company aims to increase the number of employees from about 100 in FY2022 to at least 160 in FY2025. It has the following departments.

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

#### ONO PHARMA UK LTD.

The company had about 60 employees in FY2022. In addition to the following departments, it plans to build a network for its own sales, which includes marketing and sales

Clinical PV Development	QA	Company Infrastructure	Market Access	
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#### Step 3: Becoming a True Global Company

#### **Growing market share by continuously** introducing new drugs and expanding sales network to China and ASEAN

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.

#### "Aiming at a Global Specialty Pharma"

At ONO US, we believe that one of the key steps towards doing the best for patients with unmet needs is to hire passionate people. We have built a formidable US leadership team with extensive experience in Oncology and continue to hire exceptional talent to achieve our goals. We are leveraging Ono's leadership and commercial success in Japan to bring first-in-class drugs to the US and make them accessible to patients. We are building a robust commercial, access and operational infrastructure including best-in-class omnichannel strategy for effective stakeholder engagement. With our functional and market expertise, we feel confident in our capabilities to launch our drug pipeline in the US.

Archana Sondhi Vice President, Sales & Marketing, ONO PHARMA USA, INC.



### **Expansion of Business Domains**

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

#### For Sustainable Growth

### Focusing on developing new businesses that leverage research assets, etc.

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 startups. 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 leveraging our uniqueness and superiority and being 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.

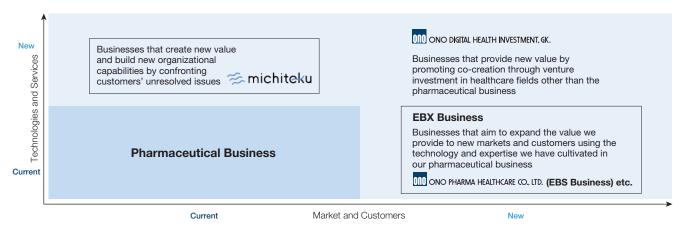
#### **Expanding the Scope of Value Provided**

### Contributing to greater QOL over the long term through prevention, post-treatment, etc.

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 support. 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 a long period of time to the improvement of quality of life (QOL).

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.

#### **■** Discovery of New Businesses



#### **Major Initiatives**

### Ono Pharma Healthcare Co., Ltd. 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. With the goal of further spreading the brand, 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/

## Ono Digital health Investment, GK Accelerating investments in startups engaged in the healthcare field

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.

In FY2022, we invested in Rehab for JAPAN Corporation (provides rehabilitation support that automatically suggests evidence-based goals and exercise program tailored to individual users) and aetherAl Co., Ltd., (develops and provides digital pathology image management systems that incorporate Al and a pathologic diagnosis support Al application). We will not only make investments but also support entrepreneurs through collaboration with our investment partners, aiming to expand our business domain and extend healthy life expectancy and realize a sustainable society.

\* A CVC (Ono Venture Investment Inc.) established in the US in 2020, invests in startups related to drug discovery

Web Ono Digital health Investment, GK

https://www.onodigitalhealth.com/en/

#### Investment partners (as of March 2023)

Investment partners	Business
Xenoma Inc. (Tokyo)	Provides healthcare services using the smart apparel e-skin
Rehab for JAPAN Corporation (Tokyo)	Plans, develops, sells, and operates the scientific nursing software Rehab Cloud
BMG Incorporated (Kyoto)	Develops products such as medical devices that make use of distinctive characteristic of the medical adhesive LYDEX®
aetherAl Co., Ltd. (Taipei, Taiwan)	Develops and provides digital pathology image management systems that incorporate Al

#### Focus of Ono Digital health Investment, GK investments



- 1 Business to meet patient needs
- 2 Business that pursues the health of people who support such patients
- Business that promotes ONO's CSR activities or that contributes to the SDGs

#### michiteku Co., Ltd. Promoting platform business

In the field of oncology (academic field related to various types of tumors, with the core of cancer), we focused on the physical, mental, and psychological problems of cancer patients that cannot be solved with drugs. To lessen the burden on cancer patients and solve social problems, it is necessary to expand information processing and information provision service businesses in the field of healthcare. Therefore, we established the wholly owned subsidiary michiteku Co., Ltd., in November 2022

As a company independent from our drug R&D and sales activities, michiteku will provide services to as many cancer patients and their families as possible by leveraging, to the greatest extent possible, the experience, know-how, and other assets we have acquired through our research and development in the field of immunology. As for particulars, the company will develop and provide information processing and supply activities in the field of healthcare.



#### TOPICS Introducing the $\beta$ version of the treatment life support tool michiteku on May 2023

Cancer patients can find it difficult to find reliable information appropriate for themselves from the sea of information. Many patients also have to quickly decide on a treatment method after receiving a diagnosis from the doctor while dealing with various worries. In addition, many also have to think about non-treatment issues, such as work and future life. The michiteku  $\beta$  version is a treatment life support tool that delivers information that patients need in this kind of situation and provides support that makes it possible to start treatment while minimizing concerns. The tool is now only for colorectal cancer and gastric cancer patients, but there are plans to expand the scope of value provided, which includes handling a broader range of cancers and extending support through post treatment decision (during treatment, follow-up, recurrence, etc.).



michiteku provides its services in Japan. The above image is taken from the michiteku official website.

#### Taking on the challenge of corporate philosophy of ONO in a new form

michiteku, a subsidiary of ONO primarily involved in software development, is taking on the challenge of solving problems faced by cancer patients. Despite required organizational capabilities and activities that differ from those for drugs, the basic idea of "for people's battle with disease and suffering" is the same. While valuing the value and life view of each individual patient, the company gives shape to the questions of what is the best decision making process and what is necessary. The work of michiteku to provide even one more patient with a fulfilling mindset and life has just begun.

Hitoshi Mito President, michiteku Co., Ltd.



# Foundation for Value Creation

A foundation for creating value is important to generate sustainable growth and provide society with value, such as innovative drugs.

We consider digital technology and IT that contributes to corporate transformations; stronger financial capital, the resource for growth; greater human resources who contribute to transforming the company into a Global Specialty Pharma; an intellectual property strategy, which is indispensable for a pharmaceutical company; and partnerships with parties outside the company, which includes open innovation, the lifeline for corporate growth, as this foundation, and focus on achieving each one.

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# Corporate Transformation through Digital & IT

Vision over the medium to long term

A global IT infrastructure is being implemented and corporate transformation through digital is being realized.

#### Indicators

- Completion and utilization of the IT blueprint (big picture for IT infrastructure and related systems)
- Construction and use of a data utilization platform
- Establishment of a cross-functional DX promotion system
- Number of participants in the Digital Talent Development Training Program: 500 (FY2026 target) Of these, the number capable of planning, managing and executing DX projects: 100 (FY2026 target)

### Corporate transformation through digital and IT moves to full introduction stage to improve the experience

It has been one year since we launched initiatives to promote a corporate transformation through digital and IT. During that year, following extensive discussions, we made steady progress toward becoming a Global Specialty Pharma, our vision for 2031. Business transformations are always major challenges, but they are also an exciting period for creating a future. By sharing digital and IT strategy, we are making steady progress in building a global IT infrastructure through productive discussions and laying the groundwork for our DX strategy, which includes training human resources in the digital field and data use foundation. In the second year, we will shift our focus to initiatives that lead to better experiences for all patients, their families, and healthcare professionals.



#### Satoshi Numata

Corporate Executive Officer / Executive Director, Digital & IT Strategy

Initiatives to Implement a Corporate Transformation by leveraging Digital and IT

### Designated DX-certified operators based on METI certification system

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. Based on this idea, we worked to create and reinforce the various aspects of our IT infrastructure, such as security, including the data use platform OASIS, which was built in August last year. This resulted in us being designated a DX-certified operators on January 1, 2023, based on the Ministry of Economy, Trade and Industry (METI) certification program. We will broadly expand these activities linked to corporate transformation.

#### Overview of DX vision and strategy

We will establish a position as a Global Specialty Pharma and deliver new value to patients around the world

ONO DX

- Challenge for well-being only Ono can provide –

1) Improve the experience of patients and their families

DX strategy

3) Improve the experience of the Ono Team

4) Strengthen the DX promotion platform

#### Global IT Infrastructure

#### Use with a focus on overall optimization

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 supports globally optimized business process, not division specific business process. 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.

#### **DX Promotion Strategy**

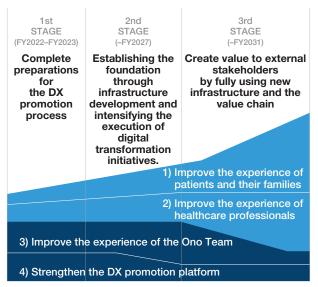
#### Increasing the vitality of people and improving productivity and creativity

We position DX as primarily related to human experience, not technology. To realize our corporate philosophy and accelerate our challenges 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. For DX, too, we aim to enhance the vitality of people and improve the productivity and creativity of the company.

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.

One important element for implementing a DX strategy is the speed of decision making. Separately from the ordinal budget process we have secured a budget that can be used for anything related to DX (challenge budget) so there are no worries about securing a budget for small, quick projects, and the funds will primarily be used for such activities as research and trial use of technology.

#### DX promotion process



#### **Development of DX talent**

#### Formulating a human resource development program, holding training for three layers

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 support. 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. After clarifying the DX promotion process and the DX talent needed to implement it, 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. As for conducting training for those three layers, the training classes for each layer were quickly fully booked, but we accepted additional applicants by expanding class size beyond what was initially envisioned, which has been positively received by employees.

#### Status of Data Use

#### **Establishing robust data governance**

The use of real-world data (RWD), which began four years ago, has spread throughout the company. Simple analysis is performed by each division using standard 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 & Marketing. 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. Furthermore, we have released the results of our pancreatic cancer database research outside the Company and aim to release information on various other types of research.

It is possible to conduct analysis using 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.

### Strengthening of Financial Capital:

financial strategy and policy on medium- to long-term investment

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

#### Strategically allocating cash to maintain and expand robust financial capital

In order to link current strong business performance to sustainable growth, it is indispensable to properly invest in independent drug discovery and licensing activities while also balancing profit and shareholder return. In addition, strategic investments to expand our business domain and strengthen our corporate infrastructure are important, and last year, we made public the overall image of these investment as the medium-term allocation. To increase cash flows that support investment, we not only strive to further expand revenue by maximizing product value, to maintain and improve profitability and effectiveness by maximizing return on investments, and to manage the balance sheet but also work to strengthen our financial capital.



#### Masaki Ito

Corporate Officer / Division Director, Business Management Division

#### **Basic Approach**

### Balancing growth investments and shareholder return

The medium- to long-term financial policy is to balance strategic investments, including R&D, and shareholder return in order to achieve sustainable growth.

While securing stable investment resources by continually expanding operating cash flows through greater revenue, we work to increase asset efficiency by reducing cross-shareholdings, and the cash flows we generate are used for growth investments, including R&D while considering return on investments. We will provide a stable shareholder return while generating additional growth and ensuring sound financial foundation.

#### Stable Creation of Investment Resources

### Generating cash through creation of new drugs and improved capital efficiency

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 continually 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.

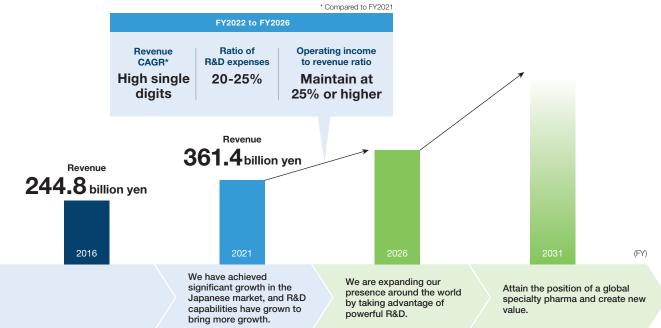
At the same time, the business environment surrounding pharmaceutical companies is becoming increasingly challenging, and the probability of success in new drug discovery remains low. By securing an appropriate level of internal funds, we will ensure the liquidity of funds necessary for smooth business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

### Maximizing Return on Investments and Maintaining Financial Soundness

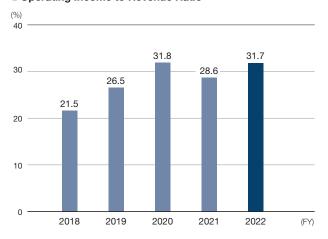
### Aiming for ROE that exceeds cost of shareholders' equity

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 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.

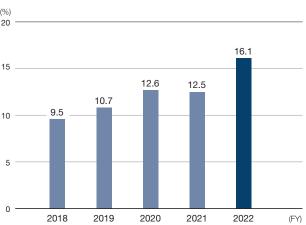
#### **■ Future Qualitative Objectives**



#### **■** Operating Income to Revenue Ratio

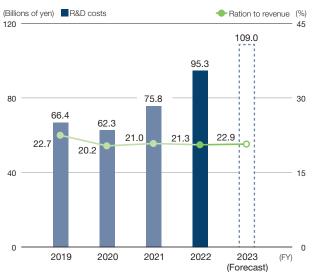


#### ■ ROE\*

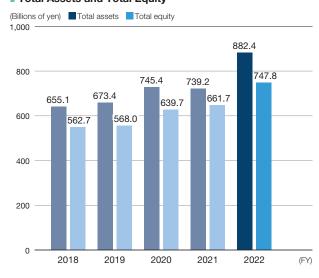


\* Profit for the year attributable to owners of the parent company / Equity attributable to ownersof the parent company (average of beginning and end of fiscal year)

#### R&D costs / Ratio to revenue



#### ■ Total Assets and Total Equity



#### Medium- to Long-term Investment Allocation

#### Making aggressive growth investments

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.

#### R&D investments of around 600.0 billion yen

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 FY2022 to FY2026, 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 FY2022, we were carrying out more than 300 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 starting in FY2022 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 construction of our own sales system with an eye toward introducing BTK inhibitor VELEXBRU Tablets in the U.S.. Furthermore, we will examine building an organization in Europe for our own sales, which includes marketing and sales, while keeping in mind progress in development. Ono Pharma Healthcare Co., Ltd., established in February 2021, Ono Digital health Investment, GK. in March 2022, and michiteku Co., Ltd., established in November 2022, plan to invest in new healthcare businesses, DX funds, and information processing and provision service businesses in the healthcare field, 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 five years, starting in FY2022.

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

#### Sources of cash Allocation of investments FY2022 initiatives Measures **Newly generated** cash . Capture global rights to pipeline products Priority investments in oncology, R&D Collaborate to expand immunology, neurology, research pipeline ¥600 в and specialty areas Invest in drug discovery startups Strategic investment to strengthen · Create overseas bases Strategic investments the drug discovery business, expand Create healthcare ¥250 в business areas, and strengthen businesses the corporate infrastructure • Invest in startup companies Stable dividends distribution and Increase in annual dividend Shareholder return flexibly considering stock per share of ¥14 . (¥56 → ¥70) repurchases share buybacks Funds on hand Capacity to invest to Multiple M&As for drug discovery further increase and technology ventures corporate value

#### **Shareholder Returns**

#### Increased dividend for third consecutive year

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 by 14 yen in FY2022, and is planning to increase the dividend by 10 yen in FY2023. 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.

#### Shareholder Returns Over Time



### **Expansion of Human Capital**

#### Vision over the medium to long term

The creation of corporate value is driven through talent development. In particular, the enhancement of future executive talent, globally competent talent, digital talent, and innovation talent have been set as important themes.

#### Indicators

(Total number of persons up to FY2026)

- In future 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: 180 or more

Aiming to create an organizational climate that makes it possible to simultaneously further increase diversity and create a sense of unity by expanding human capital

Expanding human capital, one of our goals, refers to creating not only a culture that extols people who take action themselves to achieve difficult targets and continue to take on such challenges even if they fail but also a company that continually expands its mechanisms to promote that. We are moving forward with creating an organizational climate that makes it possible to simultaneously promote diversity, equity, and inclusion (DE&I) and foster a sense of unity. We gain wisdom by all employees deepening their understanding of each other and different values colliding with each other. We aim to become a company that can always do this.

#### **Toshihiro Tsujinaka**

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



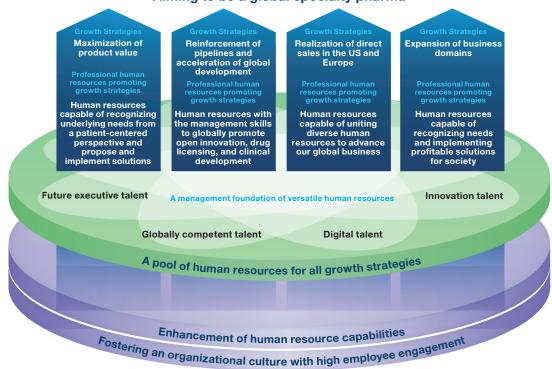
■ Growth and talent strategies to implement corporate philosophy and achieve the Vision

Corporate philosophy

#### **Dedicated to the Fight against Disease and Pain**

Vision

#### Aiming to be a global specialty pharma



#### Our thoughts on human capital

#### **Human Resource Strategy to Implement Corporate Philosophy and Vision**

One of our goals is expanding human capital, and this refers to recruiting and developing human resources who can contribute to growth and fostering an organizational culture of high employee engagement.

In regards to recruiting and developing human resources, we are focusing on human resources who can contribute to implementing the four growth strategies (see pp. 25-26) in order to achieve continuing growth as a pharmaceutical company oriented to the development of innovative drugs. We will concentrate on recruiting advanced human resources and professional human resources who will lead management, corporate transformation, and other activities, and human resource development programs to raise the level of each employee's capabilities.

A worker-friendly workplace in which diverse human resources can passionately work is indispensable for fostering this kind of organizational culture. We will work on various fronts, including introducing DE&I and diverse work styles, to achieve high employee engagement.

Under our management principals, we work to foster an organizational culture that contributes to the realization of a company in which all employees can passionately do their work.

#### Recruiting and training versatile human resources and professional human resources

#### A pool of human resources for all growth strategies

To achieve sustainable growth, it is essential to secure human resources that can execute strategies as passionate challengers towards achievement of our corporate philosophy and Vision. Therefore, in all our growth strategies, we have defined versatile human resources, employees who support the management foundation between divisions, and professional human resources, employees who possess skills and expertise to promote each growth strategy, and we think it is possible to achieve sustainable growth if these diverse human resources collaborate and drive organization and project members.

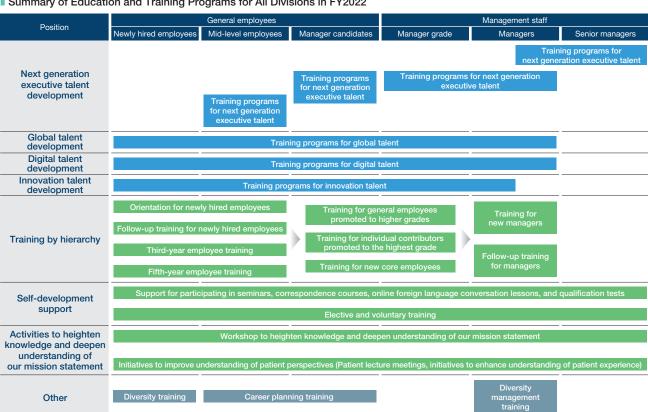
Versatile human resources, who support the management foundation between divisions, fall into one of four types (future executive talent, globally competent talent, digital talent, innovation talent), and we recruit and develop each type. Turning to professional human resources, who promote our growth strategy, we have defined the talent requirements and skills demanded for each strategy and recruit and develop such human resources.

#### **Human resource development**

#### **Enhancement of human resource capabilities**

In order to raise the skill level of all employees so that we continually create versatile human resources and professional human resources to promote and achieve our growth strategy,

#### Summary of Education and Training Programs for All Divisions in FY2022



we offer various types of training that employees can voluntarily participate in to provide the training required for each grade and support employees' autonomous career development.

### Activities to disseminate our mission statement through training

We have set Dedicated to the Fight against Disease and Pain as our corporate philosophy, 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 deepen understanding of this mission statement, we are working on two main activities: workshops to deepen understanding of our mission statement and efforts for improving the patient perspective. Workshops to deepen understanding of our mission statement promote deeper understanding of the mission statement and actual activities. As one effort to improve the patient's perspective, in FY2019 and FY2020, we held 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 only people with dementia have. 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.

Maximizing human resource and organization capabilities and achieve continuing growth

### Fostering an organizational culture with high employee engagement

In addition to "offering appealing work and providing appropriate treatment", we consider it important to create an environment in which "each employee can work with peace of mind while respecting different, diverse values" so that hired and developed human resources can actively participate for years into the future.

Human resources with different backgrounds and ways of thinking working together gives rise to new insights and ideas. We aim to become a company with a sense of unity by fostering a culture that is accepting of this diversity and to foster an organizational culture with high employee engagement. In particular, we are focusing on promoting our activities of diversity, equity, and inclusion (DE&I) based on the theme of "difference" x "unity." There are various approaches to promoting diversity, and we are initially aiming to "diversify management, etc.," "diversify individual experiences and perspectives," and "diversify work styles." At the same time, we are actively promoting health and productivity management in order to create workplaces in which all employees are physically and mentally healthy and can make the most of their capabilities.

#### Diversifying management, etc.

### Promoting the active participation of young and mid-career hires and female employees

We promote diversity in management, centered on young employees, mid-career hires, and women. In FY2022, we made it possible to fast track young employees to management positions. Furthermore, we actively hire mid-career managers, and they now account for 16% of managers, which means almost 100 mid-career hires are playing an active role as managers. As for women, only 4.1% of managers are women (FY2022), and this remains an issue for us. Until now, we first set and achieved the goal of "increasing the percentage of women in the section chief level to 15% or more" over two years starting in April 2021 based on the Act on the Promotion of Women's Active Engagement in Professional Life in order to increase the number of female manager candidates.

We are aiming to increase the percentage of female managers to 10% by FY2026 and 20% by FY2031. To achieve that, we will create systems and an environment that make it possible to impartially recruit, develop, and secure human resources regardless of gender.

#### Working to achieve high employee engagement

#### Fostering an organizational culture with high employee engagement



#### LGBTQ+ initiatives

We have implemented measures such as establishing an independent consultation counter and conducting e-learning to promote understanding of the LGBTQ+ community as initiatives to create a workplace in which such employees can work with psychological peace of mind.

#### **Employees with disabilities**

In order to arrange a workplace environment in which people with disabilities can make the most of their capabilities, we established Ono Pharma UD Co., Ltd., in April 2022, and the company was certified as a "special subsidiary" in October of the same year. There are now 55 people with disabilities playing an active role in various divisions.

#### Diversifying experiences and perspective of individuals

#### Initiatives to diversify experience and perspectives of individuals

We have created an open recruitment system and internal challenge job system (system that makes it possible to hold a concurrent job in another department) in order to diversify experience and perspectives of individuals. For the open recruiting system, 134 employees applied in FY2022, and 25 were actually transferred to another division, and in FY2023, 191 employees applied and 52 were transferred. As for the internal challenge job system, we have introduced it on a trial basis in only the Sales and Marketing Division, and in FY2022, 87 employees applied, and 20 of those will actually hold concurrent positions in other department, too. In this and other ways, we are moving forward with diversifying experiences and perspectives. In addition, we removed the prohibition on side and concurrent jobs for rehired non-regular employees in April 2023 and all employees in June 2023 so that employees can acquire new knowledge and experience that cannot be obtained in house. We aim to further increase productivity and generate creative innovation by promoting diversification whether in house or outside the company.

#### Supporting Employees' Taking on **Challenges with a Innovation Talent Training Program**

The Ono Innovation Platform is a program to develop innovation 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.

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. Through this program, we aim to create an environment where employees are excited to take on challenges and grow into innovators. Through FY2022, a total of 3,309 employees participated.

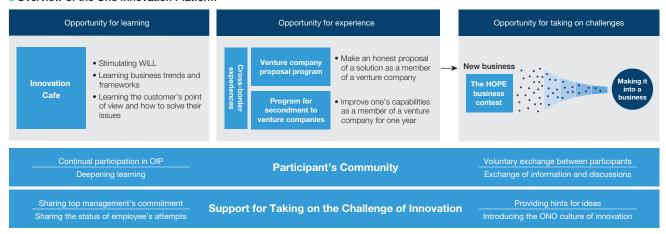
#### **Innovation Cafe**

The Innovation Cafe offers opportunities not only to acquire knowledge and skills but also opportunities for employees to accomplish what they want to do (WILL). In FY2022 we held 11 programs on themes such as learning the latest trends in business and healthcare, ways of thinking to create new ideas, uncovering one's own will, and how to solve customers' issues with a customer-oriented approach. A total of 1,499 employees participated.

#### FY2022 Innovation Cafe Contents (partial)

- Workshop on methods for developing and verifying hypothesis for customer problems based on design thinking
- Workshop on uncovering and verbalizing what employees want to accomplish (WILL)
- · Lecture on information gathering skills and ways of thinking to create value from information
- · Lecture on ways of thinking that create new ideas
- · Lecture on reskilling by outside expert
- · Lecture on latest technical trends in digital healthcare

#### Overview of the Ono Innovation Platform



#### ■ The Selection Process for HOPE



#### Venture company proposal program

The venture company proposal program "outsight" provides employees the opportunity to refine their problem solving skills regarding management issues that occur at various workplaces. This fosters creativity and thinking to solve unknown problems through serious debates with the managers of venture companies that possess abundant practical business experience. Since July 2022, 15 employees have participated in the yearlong program.

### Program for secondment to venture companies

We established a relocation program called V2V (Voyage to Venture) to provide employees an opportunity to gain experience that is not possible in the company. Employees 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 2022, four employees were dispatched to venture companies for one year.

#### "HOPE" business contest

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. During the contest in FY2022, the second year the contest was held, 101 topics were submitted by 85 employees, and the ideas included solutions to support the life of patients fighting a disease and nursing support service. With an eye toward commercialization, we are moving forward with an examination of topics selected after the final review.







New employees participating in Innovation Café (upper left)
Seconded to venture company (upper right)
Final screening of HOPE business contact (lower left)

#### **Diversifying work styles**

#### Establishing and maintaining an environment and work styles that make it possible for employees to make the most of their diverse individuality

As for DE&I, simply increasing diversity is not enough, it is important to establish a work environment and work styles that make it possible for employees to make the most of their individuality. Therefore, in May 2023, we introduced super-flex time system by eliminating core time.

In the same month, we started to set terms for each division such as maximum number of times members can work from home in order to achieve work styles and improve productivity for each division.

#### Supporting work-childcare balance

Our recent focus on encouraging female employees, of course, but also male employees to take childcare leave is one of our initiatives to support work-childcare balance. As a company that supports childcare, we were awarded Kurumin certification five times between 2008 and 2020 and the Platinum Kurumin certification in 2019.

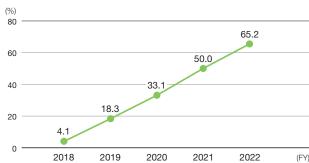
Moreover, the percentage of male employees taking childcare leave rose to 65.2% in FY2022 from 4.1% in FY2018. The fact that more than half of male employees are taking the opportunity to participate in childcare can be considered proof that we are creating a climate for work-childcare balance, regardless of gender.





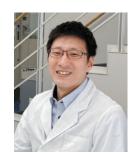
Kurumin certification mark

#### Percentage of male employees taking childcare leave



#### Taking about 3-months childcare leave supported by systems and climate

I took about three months leave so that I could dedicate myself to raising twins. Not only did my superior happily let me take the time off, but on account of job rotations and job sharing, which the Company is promoting, I handled my own work and could continue to smoothly do so. Consulting with the Human Resource staff who I got to know well, I was able to explain in concrete terms the leave that few people had taken and was difficult to imagine. Seeing the growth of my children firsthand during the leave was an irreplaceable, valuable experience. As a manager, I want to support subordinates who take leave on account of my own experience.



#### Masaya Hirobe

Chemical Substance and API Setting Group Head /Drug Discovery Chemistry Research Department

#### **Promoting Health and Productivity Management**

#### Aiming for the mental and physical health of all employees

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's health up declaration in FY2018 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. For example, on the health and productivity management portal site that we launched to communicate and share related information, we post various types of information, including interviews with the President and Representative Director regarding maintaining health, the results of health exams that employees can check whenever, information for correctly understanding the results of health exams and improving lifestyle, and summaries of health-related initiatives,

including health events independently held by offices. Through these efforts, we are promoting greater health literacy and selfcare.

These activities are being recognized, and in March 2023, we were recognized for the fifth consecutive year in the Health & Productivity Management Outstanding Organizations 2023 -White 500 (large enterprise category), promoted jointly by the Ministry of Economy, Trade and Industry (METI) and Nippon Kenko Kaigi. Also, for the third consecutive year we were in the top 50 companies among respondents (FY2022: 3,169 companies) and received high marks.

We will continue to engage in health and productivity management through various activities in order to achieve our target of a health and actual age difference of -3.0 years by FY2026, compared to a difference of -1.8 years in FY2022.



Certified Health & Productivity Management Outstanding Organizations mark

#### Health Management Theme

• Health Management Theme	
1. Prevent Passive Smoking	<ul> <li>Prohibit smoking at company sites (since April 2019)</li> <li>Raise awareness by conducting internal questionnaires, displaying original posters, etc.</li> <li>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.</li> </ul>
Lifestyle-related Diseases     and Cancer Measures	<ul> <li>Require employees to receive an annual health checkup (Employees over 35 years old undergo a complete medical checkup instead of a statutory health checkup)</li> <li>Establish contract facilities for complete medical checkups in prefectures throughout Japan →Percentage receiving complete medical checkups: 99.9% (FY2022)</li> <li>Support the cost of screening tests for each type of cancer</li> <li>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</li> </ul>
3. Mental Health Measures	<ul> <li>Provide internal training on mental health and have occupational health staff conduct individual consultations</li> <li>Provide stress checks to all employees once a year</li> <li>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</li> </ul>
4. Develop a Self-care Environment	<ul> <li>Operate a health and productivity management support website to communicate and share health information</li> <li>Provide healthcare application software for lifestyle correction and improvement</li> <li>Conduct a walking campaign every year in the company</li> <li>→ Employee participation rate: 52% (FY2022)</li> <li>Conduct an annual session to measure body composition, blood vessel age, bone density, and more at major workplaces</li> <li>Distribute health age notifications that are calculated based on the health checkup results and show the difference between health age and actual age</li> <li>→ Health age – actual age = -1.8 years (FY2022)</li> </ul>



Round-table Discussion of Diversity, Equity, and Inclusion (DE&I)

### Sustainable growth through "difference" × "unity"

ONO is promoting DE&I with the aim of becoming an "appealing organization that attracts people" so that it can generate sustainable growth.

We talked with an Outside Director with knowledge of DE&I, a female manager who has taken maternity and childcare leave, and two members of the Human Resources Planning Office regarding promoting women's participation and respect for diversity.

#### Diversity—current state and issues

**Seki** ONO's concept of DE&I is based on the idea of "difference" x "unity." Talent with different backgrounds and ideas working together will give birth to new insights and ideas. That is what ONO is aiming for.

Promoting the participation of women is not only one of the major elements for promoting DE&I but also the issue that we are most focused on. Despite only 4.1% of managers being women in FY2022, women account for 38.2% of the new graduate recruits. Furthermore, we have created systems that offer support for balancing work and childrearing so that women can work and participate for many years, which has resulted in almost all employees returning to the Company after taking childcare leave.

**Okuno** Ms. Kondo is a role model for promoting the participation of women as she became a manager in her thirties after returning to work following maternity and childcare leave.

What do you think about the current situation?

**Kondo** Over the past decade, the environment has changed so that women can work for many years, but there are still few female employees who want to become managers. Because many women in their thirties who are manager candidates returned to work after maternity and childcare leave, they probably feel "I am not qualified to be a manager."

**Okuno** A system in which more senior coworkers act as mentors and provide support when taking up a management post would probably provide women with peace of mind and make it possible for them to try to become managers. What is important is moving forward one step at a time, such as further expanding existing systems.

**Seki** I think that one such step is increasing the percentage of men who take childcare leave. While the actual figure depends on the department, 65.2% of male employees took childcare leave in FY2022. I think that making contributions so that women can

participate throughout society will also promote DE&I at ONO in a roundabout fashion.

#### What creative steps did you take when returning to work after maternity and childcare leave?

Hata I think that anyone would struggle to balance work and childrearing after returning to work following maternity and childcare leave. How was it for you, Ms. Kondo?

Kondo Although it depends on the person, I was able to find time for work by sharing childrearing responsibilities with my husband and making use of services such as babysitters and housework helpers. When a child is young, there are difficult situations such as having to quickly take time off from work, but I was able to have a normal life by not trying to do it all myself.

**Okuno** After returning to work, you worked reduced hours. Were there things related to work that you tried to do?

Kondo I was always conscious of making efficient use of my limited time. One valuable thing I learned from the experience was how to get the most performance out of limited time by getting creative.

Okuno A person creatively trying to efficiently conduct work will probably have a positive impact on those around them and increase productivity.

**Seki** We live in an era that stresses a rich private life. Therefore, when a person with time constraints becomes a manager, it probably creates major spillovers for the organization, such as transforming how people think about work styles.

Hata Some people have an image of female managers as being perfect people who can balance work and their private life. However, there are many women who struggle since they are unable to balance the two despite trying. Do you have any advice for them? Kondo Although there seems to be many women at ONO working hard to perfectly balance work and childrearing, I was unable to do that. When working, I want employees to make the most of the various company systems, including reduced work hours, telecommuting, and flexible working hours, to match the particular life event they are confronting. This does not apply only to childrearing.

#### Need to change the corporate culture

Okuno Society overall, too, is stressing efforts related to DE&I. If





there were a move to transform corporate culture and create systems, this would make it possible to not only generate sustainable growth for a company but also create value for society. Kondo For example, ideally, capable people, regardless of gender, would take part in management candidate training. To achieve that, too, it is probably necessary to give consideration to training programs and system design for people who find it difficult to participate for any of various reasons, such as their home situation. Okuno Some people hate lumping all women together, but there are many companies that have training for women. **Seki** That is right. It is necessary for the company to do more until they can get women to want to participate on their own.

#### Training diverse talent who possess a wide perspective

Kondo People with small children are encouraged to finish their work and quickly return home, and many of those are male employees. In recent years, for many married couples, both work, and if one of them leaves most of the housework and childrearing responsibilities to their partner, this places a work burden on their partner's company. It is necessary that ONO, of course, and all of society view this as an important issue.

Okuno Women will be able to participate throughout society precisely because of mutual help. I think that it would be wonderful if the statement "you should go home early" was not directed to individuals but made from a broader perspective as an "issue for society."

**Kondo** I do what I can to communicate that.

Okuno The participation of human resources who possess a broad perspective is indispensable for companies to generate sustainable growth in the long term, not simply pursue short-term profits. It is precisely because of this that it is necessary to possess a sense of unity and create an environment so both employees with childrearing experience, of course, and diverse human resources, regardless of nationality or handicap, can participate.

Seki ONO is creating various support systems related to DE&I, but I would like to see more focus on raising awareness and providing education so people make more active use of those systems.

**Okuno** It is great that we were able to uncover long-term hopes through today's dialogue. Let's all work together to promote DE&I so that ONO can achieve sustainable growth.

### **Intellectual Property Strategies**

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)

#### **Basic Approach**

### Utilizing Intellectual Property to Produce Innovative Pharmaceutical Products

We possess a rich lineup of proprietary intellectual property (IP), mainly related to lipids and cancer immunity, as a result of our experience manufacturing many innovative pharmaceutical products. We believe that new IP will emerge from open innovation based on highly unique IP, leading to the creation of innovative drugs. In addition, advances in techniques for analyzing information and the proliferation of big data have led to increasingly diverse ways of using IP, and important information can be obtained for considering M&As, the introduction of compounds and drug discovery technologies, and new businesses.

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

### Creating, Maintaining, and Utilizing Intellectual Property

At ONO, creating, maintaining, and utilizing IP are important ideas in our IP strategy.

Regarding the creation of IP, we contribute to enhancement in corporate value 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 increase the value of IP by acquiring, maintaining, and exercising 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 leads to the expansion of our IP.

#### **Initiatives for Realizing the Important Themes**

### Establishing a Cycle for Creating and Raising the Value of IP

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

#### Implementing Growth Strategies through IP Strategies



Value Creation and enhancement of intellectual property

#### Promoting the growth strategy

Maximization of product value
Reinforcement of pipelines and
acceleration of global
development

Realization of our own sales in the US and Europe

Expansion of business domains

also the information aspect, including the IP of other parties. 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 also make strategic investments in appropriate partners and technologies to more reliably monetize and maximize the value of our IP.

In order to do that and promote our growth strategy, 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**

#### Contributing to the Health of Mankind by **Giving Concrete Form to IP**

In this era of more complex, advanced industrial structure and 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, or course, 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

#### Creating IP From the Initial Stages of **Drug Discovery Projects**

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 drug discovery projects 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 Within Branding**

#### **Promoting IP Mix Strategy for New Businesses**

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.

#### **Approach Toward Patents in Countries with Limited Access to Drugs**

#### **Permitting the Exercise of Patent Rights Appropriate for the Particular Situation**

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, if there is the possibility that our patented compounds can be used as a treatment for such diseases as neglected tropical diseases, we examine various measures. including using existing patent pools and providing voluntary licenses to generic drug manufacturers.

In the case of a national public health emergency, such as the spread of an infectious disease, we understand that one option is to consent to compulsory licensing. In addition, in line with Article 31.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement), we recognize that compulsory licensing may be permitted to export drugs to countries that lack or have insufficient capacity to manufacture them, and examine the flexible and appropriate permitting of the exercise of patent rights for the particular situation. Moreover, compulsory licensing by itself is not a fundamental solution to improving access to drugs, and it is necessary to implement comprehensive measures, such as eliminating economic disparities, training healthcare professionals, and building a healthcare system, healthcare infrastructure, and drug

- \*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:

supply system.

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-in

### **Open Innovation**

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 candidates through drug discovery alliances with bio-venture companies.

#### Indicators

The number of research collaborations

#### The Characteristics of ONO's Open Innovation

#### Since the 1960s, we are now pursuing over 300 research collaborations

Since the 1960s, we have identified new drug discovery seeds through partnerships with universities and other research institutes in drug discovery research on prostaglandins, and have used these seeds as a starting point to create groundbreaking new drugs. This was more than 30 years before Professor Henry Chesbrough of Harvard University proposed the concept of open innovation in 2003.

The Discovery Research Alliance Department and the Business Development Department cooperating with Research Centers and Clinical Development Divisions are presently taking the lead in collaborating on research with world-class researchers and forming drug discovery alliances with bio-venture companies with a focus on our priority research areas, and are actively in-licensing various drug candidates.

Partnerships with a sense of urgency are required to obtain the latest research information ahead of competitors and quickly use this information in drug discovery. Toward this end, we have sent Ono's 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 bio-venture companies in the U.S. and Europe to launch more new partnerships. Currently, more than 300 research collaborations are in progress alobally.

#### **Progress in FY2022**

#### Initiated 12 new drug discovery partnerships

Since April 2022, we have launched 12 new drug discovery partnerships to create new drug candidate compounds in priority areas and for the development of new drug discovery technologies.

In November 2022, we exercised the option for the development and commercialization of ONO-8250/FT825, iPS cell-derived chimeric antigen receptor (CAR)-T cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors, created under the collaboration agreement with Fate Therapeutics, Inc. entered into in September 2018. By exercising the option, we will work with Fate to jointly develop and commercialize ONO-8250/FT825 in the U.S. and Europe. In

addition, we acquired the rights to exclusively develop and commercialize ONO-8250/FT825 in all territories outside the U.S. and Europe.

#### Overview of open innovation

#### **Discovery Research** Alliance Department

#### Research collaboration



#### **Academia**

- World-class researchers
- Unique drug discovery seeds

Alliance Department **Business Development Department** 

#### Drug discovery partnerships and in-licensing drug discovery programs | license

Compound



#### Start-up companies

- Proprietary drug targets
- New drug discovery technologies



#### Venture companies

- New drug candidates
- New drug discovery technologies

**Discovery Research** 

Strategic investments

Ono Venture Investment, Inc.

#### Drug discovery partnerships initiated since April 2022

Area	Collaborative research/ drug discovery partner	Start	Objective
	Fate Therapeutics (US)	June 2022	Expand drug discovery partnership for creating iPS cell-derived chimeric antigen receptor (CAR)-T cell product candidate initiated in September 2018  • Add option of CAR-NK cell therapy in addition to iPS cell-derived CAR-T cell product for solid tumors  • Newly add second target for solid tumors
Oncology	Memo Therapeutics (Switzerland)	November 2022	Discovery of therapeutic antibodies in the field of immuno-oncology
	KSQ Therapeutics (US)	January 2023	Acquisition of early drug discovery programs related to multiple DNA damage responses identified using CRISPRomics® platform technology, a proprietary drug discovery technology of KSQ Therapeutics
	Macomics (UK)	March 2023	Discovery of therapeutic antibodies newly targeting novel macrophage in the field of immuno-oncology
Immunology	Monash University (Australia)	January 2023	Discovery of therapeutic antibodies targeting G-protein-coupled receptors (GPCRs) in the field of autoimmune and inflammatory diseases
mmunology	Cue Biopharma (US)	February 2023	Collaboration and option agreement for CUE-401, a bispecific protein designed to induce and expand regulatory T cells (Tregs) in the fields of autoimmune and inflammatory diseases
	Captor Therapeutics (Poland)	November 2022	Discovery of targeted protein degraders in the field of neurodegenerative diseases
Neurology	PrecisionLife (UK)	December 2022	Identification of multiple novel therapeutic targets and patient stratification biomarkers in central nervous system diseases
Specialty	Domain Therapeutics (France) University of Montreal (Canada)	April 2022	Creation of novel small molecule compounds targeting GPCRs in metabolic diseases by applying Domain's proprietary GPCR drug discovery platform and expertise in medicinal chemistry and pharmacology for GPCR drug discovery
	Knowledge Palette (Japan)	August 2022	Establishment of a data-driven new drug discovery platform using large-scale transcriptome analysis technology
Technological development	PeptiDream (Japan)	March 2023	Discovery of macrocyclic peptide drugs for multiple drug targets
	MOLCURE (Japan)	March 2023	Utilization of MOLCURE's proprietary Al-driven drug discovery platform technology to discover therapeutic antibodies for multiple drug discovery targets

#### Ono Venture Investment, Inc.

#### Invested in three companies

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 FY2022, we invested in Casma Therapeutics Inc. of the U.S., which is developing new targeted protein degraders, Switch

Therapeutics Inc. of the US, which is developing new nucleic acid therapeutics, and one undisclosed company. As of March 31, 2023, we have invested in a total of seven companies since the company's establishment.



#### Using strategic returns to obtain innovative pharmaceutical products

Ono Venture Investment, Inc. makes investments in pursuit of synergies with Ono's drug discovery activities. Open innovation in collaboration with the world's top scientists and bio-venture companies with cutting-edge technologies is at the core of Ono's drug discovery strategy. Ono Venture Investment, Inc. launched in May 2020 to improve access to startup ventures that commercialize ideas from these top scientists. While exploring opportunities for drug discovery collaborations through venture capital networks, we hope to deliver new innovative medicines to patients around the world by connecting advanced drug discovery technologies and innovative drug candidate born from the growth of investee companies to Ono's drug discovery.

Hiroshi Yamamoto President and CEO, Ono Venture Investment, Inc.



### **Promotion of Diverse Partnerships**

#### 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
- The number of research collaborations
- Other partnering results

#### **Basic Approach**

#### Reinforcing cooperation with diverse partners

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. In addition to building stronger relationships of trust and cooperation

with our current partners, we will focus on constructing new networks and linking that to sustainable growth.

Open innovation is critical for ONO, and in terms of R&D, we are working to create innovative drugs through cooperation with academia and bio-venture companies. We will expand our development pipeline by forming partnerships with numerous companies to both in-license and out-license new drug candidate compounds. Furthermore, in each division, we aim to not only

grow our company but also co-create value with various

#### Licensing Activities (as of March 31, 2023)

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		Malignant melanoma, colorectal cancer	On sale in Japan and Korea (in Korea, only for colorectal cancer)
			License agreement to develop and commercialize BRAF inhibitor Encorafenib and MEK inhibitor Binimetinib in Japan and Korea	Thyroid cancer	Applied for approval in Japan
		MEKTOVI		Malignant melanoma, colorectal cancer	On sale in Japan
				Thyroid cancer	Applied for approval 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
ll 0040	Forty Seven (US) (currently Gilead)	ONO-7913	License agreement to develop and commercialize the anti-CD47 antibody	Blood cancer	In P3 in Japan · Korea · Taiwan
July 2019			ONO-7913/Magrolimab in Japan, Korea, Taiwan and ASEAN countries	Solid tumors	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	Primary generalized tonic-clonic seizures, 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	In P1 in US
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
Dec. 2022	Equillium Inc. (US)	-	Exclusive option and asset purchase agreement related to developing and commercializing the anti-CD6 monoclonal antibody itolizumab in the	Acute graft-versus-host disease	Conducting P3 trial globally
			US, Canada, Australia, and New Zealand	Lupus nephritis	Conducting P1 btrial globally

stakeholders by promoting coopetation with such entities as companies, local communities, NPOs, and NGOs.

#### **Main Initiatives**

#### Promoting licensing activities throughout the world

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. Through licensing activities over the past 15 years or so, we have succeeded in bringing 11 of the in-licensed compounds to market. Some of these compounds were in-licensed at an early stage of development, and subsequently, a major pharmaceutical company obtained the license for the compound in regions outside of Japan or acquired the company.

As for previous cases of in-licensing, we have built up trust with numerous companies, from major companies to bio-venture companies, and have promoted cooperation. We are focusing on development throughout the world, not only some areas of Asia, with a particularly strong focus on early entry in the U.S., and actively working on in-licensing and acquiring companies to capture items in the late stage of development to further reinforce our infrastructure. In the U.S., with a focus on our product lineup in the field of blood and blood cancer, the same field as that for VELEXBRU Tablets (BTK inhibitor), which is being developed to be introduced as our own product, we are aiming to form a franchise in that field based on our own products and alliance products. In FY2022, we concluded an exclusive option and asset purchase agreement related to developing and commercializing the first-in-class anti-CD6 monoclonal antibody itolizumab with U.S.-based Equillium Inc., which owns the related rights. Itolizumab is in phase 3 clinical trial as a treatment for acute graft-versus-host disease (aGvHD), a complication that occurs after hematopoietic stem cell transplants, and this is expected to be an important drug candidate under development to promote our expansion in the U.S. As for alliance activities, we are continuing to capture development and marketing rights throughout the world, not only in Asia, which involves searching for promising compounds by not simply relying on database search but directly interviewing more than 400 companies annually.

ONO has in-licensed new drug candidates in the early development stage making use of its so-called "good judgement" based on technology infrastructure. Leveraging those experiences, we are now aiming to capture development and marketing rights for both late-stage development product candidates and various other products, including early-development stage compounds, primarily in our three priority fields, with an eye toward medium- to long-term growth.

#### Launching joint transport of prescription pharmaceuticals in Japan

In January 2023, we launched joint transportation of prescription pharmaceuticals in Japan with Mitsubishi Tanabe Pharma Corporation, Shionogi & Co., Ltd., and S.D.COLLABO Co., Ltd. In addition to such issues as driver shortage, older drivers,

application of work style reform laws, and greater logistics costs due to higher fuel prices, the logistics industry faces the social issue of reducing CO<sub>2</sub> emissions to counter global warming. Therefore, after better ensuring quality, we will reduce the number of vehicles used to transport drugs by transporting our drugs with those of the other companies, which will reduce CO2 emission. We will also build a mechanism to safely and efficiently transport high quality drugs, which will make it possible to meet the needs of society. (See p. 69 Stable Supply of Products.)

#### Working to create new value in collaboration with venture companies

As for collaboration with venture companies, we are actively investing not only in the field of prescription pharmaceuticals, but also in the field of healthcare.

In FY2022, we made an additional investment in Rehab for JAPAN, which offers rehabilitation support software that automatically proposes evidence-based goals and exercise programs for each individual user, and invested in aetherAI, a company that develops and provides digital pathology image management systems that incorporate AI and pathologic diagnosis support AI application. We are aiming to create new value in collaboration with venture companies that are taking on the challenge of unexplored fields. (See p. 43 Expansion of Business Domains.)

#### Promoting health and wellness in cooperations with local communities

We have concluded cooperative agreements with Osaka Prefecture and other local governments to promote health and wellness. On account of revisions to curriculum guidelines, we fully launched "cancer education" at high schools in FY2022. As a pharmaceutical company working to contribute to healthcare through R&D on therapeutic medicines for cancer, ONO works with Osaka Prefecture to support "cancer education" at high schools so that high school students can acquire proper information on cancer. During the first fiscal year of the program, we created a cancer survivors video and conducted travelling science classes at high schools in Osaka Prefecture. (See p. 83 Social Contribution Activities.) We also participated in the Ki-Do-U program, a program to support the creation and business growth of global startup companies from the Kansai Region operated by the Osaka Business Development Agency. As the World Expo 2025 Osaka, Kansai approaches, we are providing support to establish startups in growth fields that are attracting the attention of the world and achieve future society.

#### Contributing to healthcare and health throughout the world in cooperation with **NPOs and NGOs**

In regions with undeveloped healthcare infrastructure, ONO is striving to reinforce that infrastructure through partnerships with NPOs and NGOs, such as Japan Heart and People's Hope Japan. We will contribute to healthcare and health throughout the world and further promote efforts to embody our corporate philosophy "dedicated to the fight against disease and pain" by supporting such activities as training skilled healthcare professional, expanding advanced healthcare facilities, and training volunteer maternal and child healthcare promoters so that local communities can continue to deliver healthcare on their own. (See p. 75 Respect for Human Rights.)

# Value Preservation (Erosion risks)

We also consider protecting the value we have created as a pharmaceutical company and cultivated to date as an important initiative.

Ensuring the reliability and safety of our products and possessing a stable supply system are indispensable for delivering the innovative drugs we create to more patients.

We also recognize that the supply chain, human rights, compliance, and the preservation of the environment are major requirements for corporate activities.

We will steadily move forward with these initiatives to generate greater corporate growth.

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### Assurance of Product Reliability and Safety

[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 global quality assurance and safety management systems
- Zero significant findings from regulatory inspections
- Zero recalls of Ono products

#### **Supplying High-Quality Pharmaceutical Products**

### **Creating a Quality Assurance System Compliant With Global Standards**

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 standards, 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 but strive to provide high quality pharmaceutical products from the perspective of patients, caregivers, and healthcare professionals by creating a global quality manual based on the ICH Q10 Pharmaceutical Quality System Guidelines, and implementing continuous improvement of this system.

We strive to provide high-quality products through multiple measures, e.g. training for all employees engaging in production and quality assurance, enhancing the Pharmaceutical Quality System, and improving risk management systems.

To ensure that these quality assurance activities can be carried out throughout the entire group, including overseas, we are working to build systems and establish a global structure.

As a result of the above activities, there were no significant findings or recalls of our products based on FY2022 regulator inspection.

Web Quality System and Training System https://www.ono-pharma.com/en/company/business\_activities/manufacturing.html

#### **Initiatives to Ensure Safety**

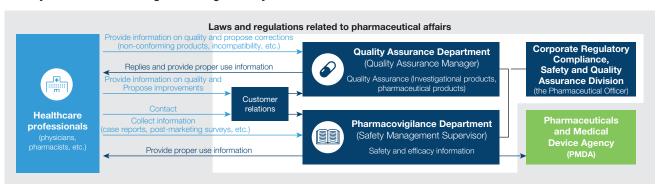
#### Creating a Risk Management Plan for Each Pharmaceutical Product and Undertaking Group-Wide Safety Management Activities

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.

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 take to heart patients' pain, the tragedy of drug-induced injuries, and the grave responsibility of a pharmaceutical company. In particular, after the launch of the anticancer drug OPDIVO, safety information in and outside Japan increased drastically. We evaluate this information based on the opinions of an external expert committee on proper use and other medical experts and then disseminate the information through various information delivery materials, academic societies, medical journals, etc., so that the drug is properly used.

For safety management activities, too, we have created global standard procedure manual and databases and constructed a Group-wide system that extends to overseas operations.

#### Safety Information Gathering and Management System



### **Stable Supply of Products**

[Vision over the medium to long term]

Our products are supplied stably to patients throughout the world.

#### [Indicators]

No out-of-stock incidences

#### **Management of the Supply Chain**

#### Thorough manufacturing and quality management

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 for each API and 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 We were able to avoid out-of-stock incidences and maintain a stable supply of products in FY2022, too.

#### **Maintaining facility operation**

#### Steady development and implementation of maintenance plan

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 Al 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

Al in the visual inspection process of products, which requires the recruitment of a large number of inspectors.

#### **Stable Supply of Products in Disasters**

#### Promoting training and multiple-base manufacturing

In preparation for a major disaster, we have formulated a crisis response and business continuity manual and conduct regular training. Furthermore, we try to diversify risk through the active use of multiple manufacturing bases and outsourcing plants. For our main product OPDIVO, we have already established a system in which the product is manufactured at both the Fujiyama Plant (Shizuoka Prefecture) and Yamaguchi Plant (Yamaguchi Prefecture). For other products, too, we are examining manufacturing at multiple bases, including outsourcing plants.

Even for API manufacturing bases, we are moving forward with using multiple outsourcing plants in order to diversify risk. We also conduct risk assessments of the supply chain unrelated to products and APIs.

#### **TOPICS**

### Launch of joint transportation compliant with guidelines

The Good Distribution Practice guideline requires strict distribution management for pharmaceutical products during the transportation and storage processes. There are also such issues as a shortage and aging of drivers, application of the Act on the Work Style Reform, and higher fuel costs.

In January 2023, we launched guideline-compliant joint transportation of pharmaceutical products with two companies in the same industry and a logistics outsourcing service provider. Maintaining transportation quality based on management standards and operating methods and improving transportation loading efficiency will not only help alleviate the shortage of drivers but also reduce CO<sub>2</sub> emissions

#### Joint transportation mechanism

Logistics outsourcing service provider S.D. Collabo



Pharmaceutical companies ONO, Shionogi, Mitsubishi, Tanabe Pharma Logistics warehouse (Medical terminal)

Pharmaceutical wholesalers

### **Protection of Environment**

[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 medium- and long-term environmental targets lined to ECO VISION 2050

- Realization of a decarbonized society
- Realization of a water-recycling society
- Realization of a resource-recycling society

See pp. 71-74 for actual results.

#### **Environmental Targets**

### Working to achieve the newly established medium- and long-term environmental targets

After setting individual targets for the "realization of a decarbonized society," "realization of a water-recycling society," and "realization of a resource-recycling society" based on the medium- and long-term environment vision "Environmental Challenging ONO Vision" (ECO Vision 2050), which was formulated in FY2019, we

have undertaken related initiatives.

In FY2022, we established new medium- and long-term environmental targets to reinforce and accelerate initiatives that contribute to the solution of various environmental problems that the world faces. These new targets are linked to realizing a healthy and sound society, which is given in ECO VISION 2050, and are recognized as targets to drive the industry.

Web New Medium- to Long-Term Environmental Targets https://sustainability.ono-pharma.com/en/themes/106

#### New Medium- to Long-Term Environmental Targets

Realization	Scope	Scope 3			
of a decarbonized society	FY2025 Achieve Carbon Neutrality (virtually zero carbon emissions by offsetti FY2035 Greenhouse gas emissions	ing with carbon offsets.) FY2050 Greenhouse gas emissions 60% reduction			
	Water Scarcity Risk	Water Pollution Risk		Supply Chain Risk	
Realization of a water recycling society	FY2030 Sales growth rate ≥ water consumption increase rate Coverage: ONO's operation sites Base year: 2017 Promote measures that lead to the conservation of rich water resources for local communities.	Control 100% of wastewater more strictly than applicable laws and regulations.  Coverage: ONO's manufacturing plants/research institutes  FY2025 Conduct an aquatic life impact assessment for 100% of wastewater  Coverage: ONO's manufacturing plants/research institutes  FY2030 Disclose the results of the aquatic life impact assessment for developing compounds.  Coverage: In-house drug candidates		FY2026 Conduct water related risk assessment and comprehensive risk management for important business partners.	
	Final Landfill Disposal Rate of Industrial Waste	Recycling F	ate	Reduce the Environmental Impact of Product Packaging  FY2030 100% correspondence  Prioritize the use of FSC® certified paper*, and use other recycled papers for materials that it is not possible to use FSC® certified paper.  Coverage: Individual packaging boxes for our market products	
Realization of a resource recycling society	≤ 1% Coverage: ONO's manufacturing plants/ research institutes, and logistics centers	FY2025 ≥ 60% FY2030 ≥ 6 Calculation: In accordance with the of the Federation of Pharmaceutic Associations of JAPAN, FPMAJ. Coverage: Unnecessary materials materials, etc.) generated from Ohle plants/research institutes, and log	e calculation rules al Manufacturers' (waste, valuables, free NO's manufacturing		

\* FSC®-certified paper is certified based on the standards of the FSC (Forest Stewardship Council®).

#### Revising targets and setting a roadmap

In ECO VISION 2050, which was formulated in FY2019, we stated that ONO will take on "the challenge of becoming a leading environmental company in the pharmaceutical industry." In light of this vision, we conducted numerous rounds of discussions to develop even more advanced targets and then set new targets. We have developed extremely challenging targets and a roadmap for the Group to unite and achieve those by having the CSR Promotion Section gather the opinion of parties outside the Company and sharing them throughout the Company and working in close collaboration with the Facility Management Section, which is confronting the direct environmental problems at manufacturing sites and research institutes.

Rena Nishizawa Director, CSR Promotion, Sustainability Promotion Department

Takashi Morimoto Associate Director, Facility Management of Minase Laboratory



#### Realization of a decarbonized society

### Medium- and Long-term Targets for Achieving a Decarbonized Society

Having adopted the target of "zero greenhouse gas emissions (Scope 1+2) for the company itself by 2050" in FY2019, we have worked toward decarbonization. The target was approved as a "1.5°C" target," the highest level at that time, by the international initiative Science Based Targets initiative (SBTi) in October 2019. Through the new medium- and long-term environmental targets, we aim to achieve carbon neutrality for greenhouse gas emissions (Scope 1 & 2) for the Company itself in 2025. In addition, we are accelerating our initiatives by bringing forward the target of achieving zero greenhouse gas emissions for the Company itself to 2035

from 2050.

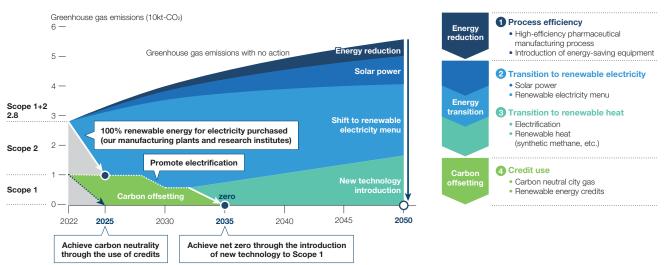
As for energy consumption, our efforts include joining the international initiative RE100 in June 2020. We will further increase our renewable energy use in the future.

#### Formulating a roadmap to achieve our targets

In FY2022, we formulated a roadmap to achieve our targets. When formulating that roadmap, we also incorporated such ideas as participating in environmental initiatives, including the GX League, and new technology through dialogue with companies developing next generation technology. We also set the timing for introducing measures for each base.

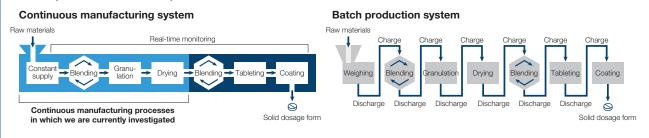
Web Greenhouse Gas Emission Reduction Policy, the Foundation of Approach to the Roadmap https://sustainability.ono-pharma.com/en/themes/122

#### ■ Company-wide roadmap



#### Example of opportunities related to climate change: Introducing a continuous manufacturing system

"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. 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 by approximately 13% by weight (compared with general batch system equipment). 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 as one of the opportunities related to climate change in our analysis based on TCFD analysis.



### **High CDP evaluation for Climate Change and Water Security**

The international environmental NPO CDP highly rated several of our activities, including climate change and water security-related initiatives and our active disclosure, and we were selected as A list, highest rating, for CDP2022 Climate Change and Water Security.

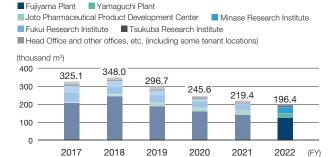


**Realization of a Water Recycling Society** 

### Promoting reduction in water intake

Quality water is indispensable for our research and manufacturing activities. It is important to properly manage risks regarding the negative impact our business could have on the environment, and we are working to realize a sustainable water-recycling society. Based on the medium- and long-term environmental targets set in FY2019, we have worked to reduce water intake for our offices by introducing water-efficient equipment and improving operations. Water intake in FY2022 was 196.4 thousand m³, 60.4% the water intake for FY2017, the base year for medium- and long-term targets. Since FY2018, our water intake has fallen each year on year-on-year basis.

### Water Intake (Water Resource Consumption)



### Introducing a risk-based approach

Through the new medium- and long-term environmental targets (see p. 70), which we have been trying to achieve since FY2023, we are working to implement more comprehensive water risk management. Out of consideration of differences in the issues that each water basin faces, we decided to employ a risk-based approach appropriate for the water-related risk for each region. As for water scarcity risk, we conducted verifications using the Water Resources Institute's evaluation tool (WRI AQUEDUCT) at our manufacturing sites and research institutes that consume large amounts of water. As a result, as of the end of FY2022, none of our company's major sites were deemed to be engage in operations in areas categorized as being extremely high risk for water stress. We are, however, aiming to generate dramatic growth, and have

set the target of "constraining the increase in water consumption at our offices to no more than the growth in net sales in 2030" in order to appropriately manage water resources in the future. Furthermore, we will promote measures linked to preserving the rich water resources of regions.

As for water pollution risk, we will continue to manage wastewater using control values that are stricter than those in laws and regulation. We will also reinforce the evaluation and management of wastewater from manufacturing plants/research institutes and the impact of developed compounds on aquatic life. Furthermore, we are working to evaluate and manage water-related risks at major partners.

Web Realization of a water recycling society https://sustainability.ono-pharma.com/en/themes/123

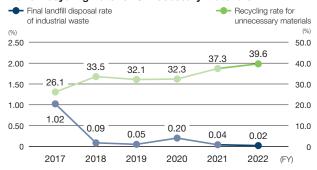
### Realization of a resource recycling society

### Promoting recycling and use of eco-friendly materials

In modern society, which is based on continual mass production and mass consumption as the global economy and population grows, environmental pollution and damage to ecosystems related to waste material processing have become a problem. There are also concerns about the depletion of limited resources.

Taking this into consideration, we revised our medium- and longterm targets in FY2022 to contribute to the creation of a circular society. We are aiming to achieve our targets related to final landfill disposal rate of industrial waste, recycling rate for unnecessary materials, and reduction in the environmental impact of product packaging.

### Final Landfill Disposal Rate of Industrial Waste and Recycling Rate for Unnecessary Materials



\* Coverage: Sites covered by this data: Fujiyama Plant, Joto Pharmaceutical Product Development Center, Yamaguchi Plant, Minase Research Institute, Fukui Institute, Tsukuba Research Institute, and logistics centers (added from FY2021).

### Expanding initiatives at various bases

In addition to striving to reduce waste produced throughout the Company, we are working to convert items such as waste wood, paper, metal, and plastics into valuable materials at manufacturing sites and research institutes. Other measures including research institutes selling off experimental equipment that is no longer needed so that the equipment can be reused.

Since FY2022, we have newly commissioned a recycling business to handle food waste from the Minase Research Institute

cafeteria, which is then reused as animal feed. Furthermore, we are accelerating initiatives at our various bases, including reusing wooden pallets that have been turned into chips at the Fujiyama Plant and recycling remains from incinerated infectious waste material as construction material at the Yamaguchi Plant. In regards to drugs, we are also moving forward with efforts to reduce the environmental impact at various stages from research to production, use, and disposal, by adopting manufacturing process simulations and a continuous manufacturing system, extending the period of use, and changing packaging materials and forms.

Food Recycling Process



Web Realization of a resource recycling society https://sustainability.ono-pharma.com/en/themes/124

### **Biodiversity**

### **Protecting rich ecosystem**

Rich ecosystems not only provide us with a stable supply of food, water, and other resources but also play an extremely important role in our health, including mitigating climate change and disasters, inhibiting the production of infectious pathogens, parasites, etc., and providing psychological and cultural stability.

We evaluate the impact of our business activities on the environment and implement various measures to minimize that

impact. Furthermore, we support the Kunming-Montreal Global Biodiversity Framework, a framework adopted at the 15th Conference of the Parties to the Convention on Biological Diversity (COP 15), which was held in Montreal Canada in December 2022, and want to partner with such stakeholders as local governments and NPOs/NGOs and make contributions to generate a nature positive and halt the loss of biodiversity.

Using the most recent disclosure framework released by the Taskforce on Nature-related Financial Disclosures (TNFD) as reference, we are also beginning to examine using the same definition of reliance on, impact on, and risks related to nature, including the supply chain, and setting targets and indicators based on science.

Web Biodiversity Conservation

https://sustainability.ono-pharma.com/en/themes/125

Web The details of our environmental initiatives and environmental data are on our sustainability web page.

https://sustainability.ono-pharma.com/en/themes/118

### Information Disclosure Based on the TCFD Recommendation

### Climate change-related disclosure

ONO has expressed its support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) in October 2019. Out of consideration of those recommendations, we are not only moving forward with appropriate disclosure by evaluating and managing climate change–related risks and opportunities but also actively working to respond to climate change through targets that contribute to the Paris Accord, an international target.



Task Force on Climate-related Financial Disclosures (TCFD)

Web Information Disclosure Based on the TCFD Recommendation https://sustainability.ono-pharma.com/en/themes/121

### Impact on and Main Initiatives Related to Biodiversity

Factors that impact nature	Negative impact	Main initiatives
Change in habitat  Use of land due to business expansion	Shrinking habitats Deforestation	Confirm that the Company's land is not nature conservation area Collaborate with stakeholders regarding such issues as conserving habitats and undertaking clean-up activities
Excessive use of eco-system services  • Water use	Competition for water resources in regions Deterioration in water quality due to drought	For manufacturing plants/research institutes that consume a lot of water, confirm that water consumption does not have a major impact on the region's water resources and are not in regions with extreme water stress
Climate Change • Greenhouse gas emissions	Global warming's impact on ecosystems Spread of disease and insect pests More severe natural disasters, including typhoons	Achieve zero greenhouse gas emissions earlier than planned through our activities*
Pollution     Chemical substances     Drugs and metabolites     Waste     Living modified organisms	Impact of water quality and soil and air pollution on organisms	Adopt wastewater management standards that are stricter than laws and regulations and evaluate impact on aquatic life* Aquatic Life Impact Evaluation for our drugs and new drug candidates* Promote recycling of waste and reduce environmental impact due to packaging* Examine efficient resource use and high-efficiency manufacturing process Comply with the Cartagena Act through the operation of a management committee
Alien organisms	Impact on habitat of native species	Comply with international rules and laws related to issues such as use of wood pallets with a "plant inspection passed stamp" in order to prevent the inflow of non-native species

<sup>\*</sup> See New Medium- to Long-term Environmental Targets (P70).

### Governance

We are aware that our response to environmental problems, including climate change, is a material management issue. The President and Representative Director was appointed as the chief person in charge of environmental management and the Member of the Board of Directors, Senior Executive Officer and Executive Director, Corporate Strategy & Planning as the person in charge of environment coordination.

Material issues related to our sustainability strategy, including our response to climate change, are deliberated on at the Sustainability Strategy Meeting, which is chaired by the person in charge of environment coordination and attended by many of the members of the Management Meeting. Items deliberated on and decided at the meeting are reported to the Board of Directors at least once every six months, and Directors supervise the implementation of decisions. Furthermore, the person in charge of environment coordination chairs the Environmental Management Committee, which manages and promotes environmental initiatives throughout the Company, and the Sustainability Promotion Committee, which deliberates on important issues related to workplace-level sustainability activities and submits proposals to the Sustainability Strategy Meeting. In this way, our climate change-related initiatives are thoroughly coordinated and managed by the person in charge of environment coordination (Member of the Board of Directors and Senior Executive Officer) and supervised by the Board of Directors.

### Strategy (Analysis and evaluation of risks and opportunities)

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. When conducting scenario analysis, information such as scenarios based on the Intergovernmental Panel on Climate Change (IPCC) and International Energy Agency (IEA) are used as reference. The results of the analysis are reported to the various meetings, including those of the Environmental Management Committee and Sustainability Promotion Committee, and there are deliberations on whether a response is necessary and if a response is necessary, mitigation and adaption measures. In our FY2022 analysis, no financially significant risks were recognized in either the 1.5°C or 4°C scenarios.

### ■ Risk and Opportunity Management

When ascertaining the risks and opportunities related to climate change's impact on our finances, the timing, probability of occurrence, and the extent of the consequences are analyzed, details of responses to them are evaluated, and then the priority of countermeasures is 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.

In addition, The Company-Wide Risk Management Committee considers measures to alleviate and respond to the identified risks, and proposes them to the Sustainability Strategy Meeting or the Management Meeting for approval. When the responsible person

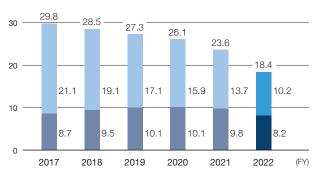
at locations such as manufacturing sites and research institutes implement approved measures, risks due to climate change, including flood risks, are comprehensively managed, and the state of progress is shared at the various meetings, including those of the Environmental Management Committee and Sustainability Promotion Committee.

### Indicators and Targets

To minimize risks and maximize opportunities due to climate change, we continually set medium- and long-term and annual targets and monitor progress in achieving those targets. As for the new targets set in FY2022, we brought forward the target of zero greenhouse gas emissions for the Company itself to FY2035 from FY2050 with an eye toward becoming carbon neutral (effective zero using carbon offsets) for our emissions (Scope 1 and 2) in FY2025. Even for greenhouse gas emissions for the supply chain (Scope 3), our calculations cover offices in Japan in line Ministry of the Environment guidelines. We are also working to reduce CO2 emissions through greater transportation efficiency by launching joint transportation of prescription pharmaceuticals in Japan in January 2023.

### ■ Greenhouse Gas Emissions (Scope 1+2)





Note: Coverage is ONO

Note: Greenhouse gas emissions (Scopes 1 + 2) do not include CO2 offset by voluntary credits (carbon neutral city gas purchased). If these voluntary credits are included, GHG emissions (Scopes 1+2) would be 17.7 kt-CO2 in FY2022.

Web Details regarding climate change-related risks and opportunities, greenhouse gas emissions, etc.(CDP account required as it is a CDP website) https://www.cdp.net/en/saml/new

Web GHG Emissions in the Supply Chain (Scope 3) https://sustainability.ono-pharma.com/en/themes/122

### Material Issue 15

# **Respect for Human Rights**

### **Human rights risk management**

### [Vision over the medium to long term]

- We aim to build a management system based on the United Nations Guiding Principles on Business and Human Rights.
- By building a flexible governance system that can appropriately respond whenever a human rights issue arises in the Group (including supply chain), we aim to establish a foundation of trust with society.

### Improving access to healthcare

### [Vision over the medium to long term]

- 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]

- Conduct human rights due diligence within the Group (up to 2026)
- Conduct human rights risk assessments for high priority suppliers (up to 2026)

### [Indicators]

- Number of approved rare disease/pediatric indications
- Project outcome goals (new project to begin in FY2022)
- → See ONO Bridge Project target

### Perspective on Human Rights

### Adherence to international standards

The Group also upholds and respects the International Bill of Human Rights, the International Labour Organization's Declaration on Fundamental Principles and Rights at Work, conventions on the human rights of workers, such as wages and working hours, etc., the OECD Guidelines for Multinational Enterprises, the United Nations Declaration on the Rights of Indigenous Peoples, and other

international codes of conduct related to human rights, and the Ten Principles of the United Nations Global Compact. In July 2020, we established the Ono Group Human Rights Global Policy based on the United Nations Guiding Principles on Business and Human Rights based on this concept. For the entire ONO Group, to fulfill our responsibility to respect the human rights of our stakeholders, the Ono Group Human Rights Global Policy applies to all executive officers and employees of our group, and we also encourage all of our business partners involved in the businesses, products, and services of ONO Group to comply with the policy.

### Respect for human rights demanded by the world and our response

### Ono Group Human Rights Global Policy (Established in July 2020)

### Human rights due diligence

# 1. Assessment of impact on human rights Identify, analyze, and assess adverse impacts on human rights Identified risks (September 2022) Human rights impact assessment (scheduled to be completed in FY2023) 4. External information disclosure Report action status and results internally and externally Information will be disclosed on our website and in corporate reports. 2. Implementation of preventive and corrective actions Actions for appropriate treatment We will start identifying the actual status. 3. Follow-up assessment Implement follow-up assessment on whether the actions are appropriate Measures will be examined.

### Access to relief

Moreover, although our former policy satisfies international rules to a certain degree, it was not sufficient to promote activities related to respecting human rights as a material issue. Therefore, we revised the policy to satisfy international rules. In March 2023, this Policy has been revised and disclosed after obtaining the approval of the Board of Directors meeting held.

Web ONO Group Human Rights Global Policy

https://www.ono-pharma.com/en/company/policies/human rights.html

### Human rights due diligence

### Assessment of impact on human rights

We recognize that we may have adverse impacts on human rights directly or indirectly through our business activities and our supply chain. In accordance with the United Nations Guiding Principles on Business and Human Rights, we have established a human rights due diligence system to prevent or reduce adverse impacts on human rights that we may cause to society, will continue to implement the system, and will disclose the progress and results externally.

In FY2022, we conducted an impact assessment of risks to human rights (human rights risk assessment) in our group and supply chain in cooperation with the Caux Round Table (CRT Japan Committee) and specified priority human rights that we will address.

First, we conducted a desktop survey\* and identified potential human rights risks associated with our business activities, including our supply chain. In addition, we also identified themes and areas with high potential risks and held a human rights due diligence workshop to identify our risks. The human rights due diligence workshop was held for two days with 25 participants in total from relevant departments. In the workshop, we considered the needs of society and social changes, and then we identified potential human rights issues that may have an impact on our business and that may occur among rights holders and the overall value chain. As a result, we incorporated "working environment at production sites of procured articles, including raw materials" and "vulnerable workers (temporary workers, foreign workers, etc.) in Japan, including in our group companies and in our supply chain" as human rights topics because we could not ascertain the detailed risks and will now move forward with ascertaining the actual state in partnership with Group companies and partners.

In addition, we will work to implement preventive and corrective actions as well as establish a system where high priority human rights issues and new human rights issues can be promptly

Assessment report by PSCI (Pharmaceutical Supply Chain Initiative) and survey by CRT Japan Committee, Nippon CSR Consortium "Important Human Rights Issues for each Industry (Pharmaceutical Industry), etc.

### Scope of risk identification, etc.

### Target value chain

Research and development - Procurement

- Manufacturing Logistics Selling Consumption
- Discardina

### Rights holders who may be impacted

Workers in the supply chain, workers of our business partners, our employees, and the local community (including the supply chain)

### Risks of concern

- Access to healthcare and pharmaceutical drugs
- Pharmaceutical safety and health damage
- Risks during development
- Human rights issues related to the environment and climate change
- Pharmaceutical distribution
- Human rights issues under supply chain
- Provision of appropriate pharmaceutical information
- Industrial safety and health
- Waste treatment
- Discrimination
- · Race, age, sex
- Gender (including sexual minorities)
- Various forms of harassment
- · Excess and unfair working hours
- Foreign worker rights
- Child labor and forced labor
- Privacy rights
- Equal pay for equal work
- Impact on indigenous peoples and local residents
- Compliance
- Human rights issues related to technology and Al

### Identified risks

### Working environment at production sites of procured articles, including raw materials

We will identify the actual status of the working environment of raw material suppliers, such as producers and manufacturers, etc., in particular, the working environment of raw material producers and outsourcing manufacturing companies, identify and assess specific adverse impacts on their human rights during our procurement activities, and implement prevention and mitigation actions.

### Vulnerable workers (temporary workers, foreign workers, etc.) in Japan, including in our group companies and in our supply chain

We will identify the actual status of vulnerable workers in our group companies in Japan and in our supply chain, identify and assess specific adverse impacts on their human rights during our procurement activities, and implement prevention and mitigation actions.

### Preventive and corrective measures

We are creating worker-friendly environments by strengthening the compliance system to prevent any harassment and providing training every year.

In addition, in association with the revision of the Ono Group Human Rights Global Policy, we provided training on the United Nation Guiding Principles on Business and Human Rights for persons in charge from the Business Audit, Legal, Corporate Planning, Sustainability Promotion, Procurement and Purchasing, Compliance Promotion, and Human Resources Departments in FY2022, as a preliminary exercise prior to training for all employees.

# Actions for urgent matters related to human rights

We have established a system to take action promptly for high priority human rights issues in cooperation with CRT Japan Committee.

In 2022, Kimberly-Clark Corp (U.S. company) and Ansell Ltd (Australian company) were sued by International Rights Advocates (IRA), a legal support group in Washington, D.C., on the grounds that they knowingly profited from forced labor at Brightway Holdings, a rubber glove manufacturing company and supplier in Malaysia. We investigated through our agents since we have purchased rubber gloves sold by Kimberly-Clark. As a result, we confirmed that, as of the investigation date (September 15, 2022), Kimberly-Clark had discontinued transactions with Brightway, no longer handled Brightway's products, and is conducting third-party audits regularly with all outsourcing manufacturing companies. We determined that we would continue to use the products of Kimberly-Clark while watching the progress of the lawsuit, and decided to reexamine the use of substitutes if further concerns arise in the future.

### Improving access to healthcare

# Providing innovative drugs for more patients

Even today as we see remarkable developments in the medical field, there are many diseases against which no effective treatment exists. 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 creation of innovative drugs. 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 drugs for rare diseases. In FY2022, we gained approval for the use of ONOACT for Intravenous Infusion for pediatric patients with low cardiac function and tachyarrhythmia (supraventricular tachycardia, atrial fibrillation and atrial flutter).

Furthermore, we do not exercise our patent rights in least developed countries as defined by the United Nations and low income and lower middle income countries as defined by the World Bank, except for some, in order to provide our innovative drugs to even more patients. We also give consideration to providing consent for the flexible, appropriate use of patents on an individual case when there are national public health emergencies, including spread of infectious disease.

# Support for reinforcing healthcare infrastructure

Throughout the world, there are many people without access to necessary healthcare because of undeveloped healthcare infrastructure. Based on the idea that it is important to reinforce healthcare infrastructure so that local communities can continue to deliver healthcare on their own, we have worked to solve this problem since FY2018 by partnering with NGOs and similar entities. See the following for information on ONO Bridge Project (project for Myanmar and Cambodia), which is currently underway.

Web Efforts Made for Improving Access to Healthcare https://sustainability.ono-pharma.com/en/themes/102#928

### **ONO Bridge Project**

Under the "ONO SWITCH Project" that was implemented from FY2018 to FY2021, we have provided support in Cambodia, Myanmar, Bangladesh, and Bhutan for the training of local healthcare personnel, educating local citizens on diseases, and assisting with scarce healthcare facilities and supplies (for more details, see "ONO SWITCH Project (FY2018 to FY2021)" on this page below).

We have achieved steady results in strengthening healthcare infrastructure through the activities of the NGOs and NPOs that we supported.

In consideration of the lessons learned from the ONO SWITCH project, we started a new healthcare access improvement project, the "ONO Bridge Project," in FY2022, and launched the program in Cambodia and Myanmar.

With the new project, and not only through financial support necessary for NGO measures, we will also increase the social recognition of issues related to access to healthcare, have our employees participate in volunteer activities, take measures for collaboration using our know-how, etc. At the same time, we will increase the input of non-financial capital into the project and thereby maximize our social impact and strengthen our human resources, etc.

Web ONO SWITCH Project (FY2018-FY2021) https://sustainability.ono-pharma.com/en/themes/102#ONO-SWITCH\_2018-2021

Web ONO Bridge Project

https://sustainability.ono-pharma.com/en/themes/102#1069

# ■ Myanmar: Maternal and child health service improvement program NPOs supported: People's Hope Japan

Business and Management

The maternal mortality rate in Myanmar is considered to be 250/100,000 live births There is a big gap from the goal: "SDGs 3.1: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births." Through this program, we support work to reinforce regional health service networks, which includes local residents and midwives, in order to improve access to mother-child health services for pregnant women.

Initiatives	Targets (FY2022-FY2024)	FY2022 progress
Training mother and child health promoters In various (farming) villages of Lewe Township, Nay Pyi Taw, People's Hope Japan not only undertakes such activities as providing health education and making house calls to pregnant women but also trains mother and child health promoters, who serve as a bridge between local residents and health services.	Newly train 600 mother and child health promoters  Conduct two-day training stipulated by the Ministry of Health  Assign mother and child health promoters (1 promotor for every 5 pregnant women) to all 178 villages in the covered territory  Conduct retraining for 300 mother and child health promoter	<ul> <li>Newly trained 121 mother and child health promoters</li> <li>Selected 401 new candidates for next training session</li> <li>Provided trainer education for 55 local healthcare professionals so they can train mother and child health promoters</li> </ul> Mother and child health promoter trainer education

# ■ Cambodia: Program to Improve Access to Advanced Pediatric Medical care Supported NGO: Japan Heart

In Cambodia, there are many pediatric patients who do not have access to advanced healthcare. In high-income countries, the survival rate for pediatric cancer patients is 80%, but in low and medium income countries, the rate is extremely low, 30%. This is primarily because of a shortage of medical institutions and physicians, insufficient financial means of residents, and local customs. Through this program, we work to improve pediatric patient's access to advanced healthcare by supporting the activities of Japan Heart Children's Medical Center in Cambodia.

Initiatives	Target (FY2022-FY2026)	FY2022 progress
Training skilled healthcare professionals We conduct training for local healthcare professionals who will provide advanced healthcare, including diagnosis, surgeries, post-surgery management, primarily related to cancer	Training physicians: Training in Japan: 1 person Training at other medical facilities in Cambodia: 2 persons Participation in international academic conference of cancer: 5 persons Training nurses: Training at other medical facilities in Cambodia: 5 persons Participation in international academic conference of cancer: 5 persons Employing radiology technicians: 1 person	<ul> <li>Physician training         <ul> <li>One physician received five months of clinical training at a Japanese medical institution.</li> <li>One physician attended Singapore academic conference.</li> </ul> </li> <li>Nurse training         <ul> <li>Two nurses attended Singapore academic conference.</li> </ul> </li> <li>Launched recruiting efforts for radiologist</li> </ul>
Free mobile clinics for villages In Cambodia, we operate mobile clinics in rural regions of the Ponnel District, Kandal Province, where there is poor physical access to medical institutions and little tradition of receiving such exams.	Plan to hold 51 times (once a month) during the program period (Jan. 2023–)	Held free mobile clinics three times, providing 143 people with free medical exams  Mobile clinics
Enhancement of advanced medical devices We will add a new X-ray fluoroscopy room to Japan Heart Children's Medical Center.	Added exam room for X-ray fluoroscopy	Completed construction of an operating room in order to add X-ray fluoroscopy equipment

### **Material Issue 16**

# Thorough Compliance

[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

### Aiming to build a compliance system tailored to the ONO Group

As a company that carries pharmaceuticals for human health and medical care, we are required to act in good faith based on high ethical standards. Based on our Corporate Philosophy, we established the ONO Group Code of Conduct as a basic shared concept in order to pursue the same direction while respecting diversity in an environment with different laws and cultures. Based on this Code, our corporate actions will ensure that each Group company continues to be trusted by society and contributes continuously. In our day-to-day operations, we will foster a culture that encourages our people to raise a voice against any questionable action, and strive to prevent compliance violations. In this manner, we are working on compliance as the cornerstone of our business activities.

**Takehiro Yamada** Corporate Officer / Senior Director, Compliance Management Department



### **Compliance System**

# Thorough compliance based on high ethical standards

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 Group 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 that should be adhered to when conducting corporate activities and the Compliance Global Policy that contains our approach and management structure for promoting 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.

Web Corporate Philosophy / ONO Group Code of Conduct https://www.ono-pharma.com/en/company/mission.html#CodeOfConduct Web Compliance Global Policy

https://www.ono-pharma.com/en/company/policies/compliance.html
Web Ono Pharmaceutical Code of Practice

https://www.ono-pharma.com/en/company/policies/cop.html

### ■ Compliance System

# Corporate Philosophy ONO Group Code of Conduct Research and Development Transparency Manufacture and Marketing Participation in Society Comply with Law and Regulations Values Working Environment Human Rights/Discrimination Compliance Global Policy

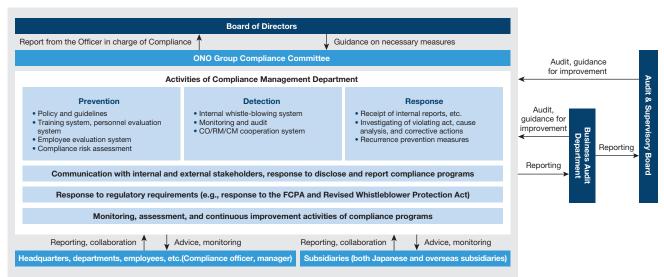
### **Compliance Promotion System**

### Strengthening compliance promotion system

To strengthen our compliance promotion system, we have appointed an Officer in charge of Compliance and set up a Compliance Committee. This Committee has a system in place to examine and deliberate on compliance-related issues, plan and promote training and other activities as well as to examine and deliberate on reports, etc., from subsidiaries. It also cooperates with the internal auditing department and checks the status of initiatives at each business location. In addition, the Compliance Committee manages risk in cooperation with the Risk Management Committee.

In response to serious compliance violations in FY2020, since October 2021, we have appointed a compliance officer in each division as the person responsible for strengthening compliance operations, and a compliance manager in all departments as a consultation point for workplace matters related to compliance. They work to coordinate with the risk manager who manages the overall risk of the organization. Through this system, we are taking prompt measures in response to matters that have been escalated

### ■ Compliance Promotion System



up within the organization.

Information on consultation cases is also shared with the Compliance Promotion Department, 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 require that group companies create systems and rules to prevent the occurrence of noncompliance.

### **Reporting and Consultation System**

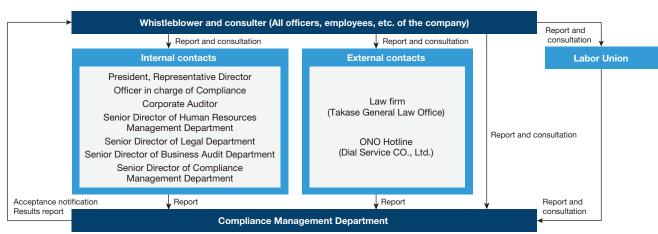
# Development of reporting and consultation system

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 President, Representative Director; the Officer in charge of Compliance; 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 took effect in FY2022, and are thoroughly communicated to all employees.

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

### Reporting and Consultation System



Investigation and corrective action

### Compliance Education

### Ongoing compliance training

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, including covering the topic of bribery prevention taking into account serious compliance violations of

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 are based on actual compliance issues. In addition to regular training, 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.

### **Ethical Considerations in R&D**

### Considerations for human samples, animal experimentation and clinical testing

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 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.

\* 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/en/company/policies/respect\_human\_rights.html

https://www.ono-pharma.com/en/company/policies/ethical\_considerations\_in\_ animal\_experiments.html

### **Fair and Transparent Business Activities**

### Preventing fraud/corruption and communication

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 Officer in charge of Compliance. Amid globally mounting interest in compliance with laws governing unfair and corrupt practices, we established the Anti-Bribery and Corruption Global Policy and the Anti-Bribery Policy 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

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

://www.ono-pharma.com/en/company/policies/public\_research.html

Web Ono Pharmaceutical Global Tax Policy

https://www.ono-pharma.com/en/company/policies/tax\_policy\_jp.html PDF Tax Reporting by Country

research projects.

https://sustainability.ono-pharma.com/data/pdf/tax/Country\_Report\_(Summary)\_

FY\_Ended\_March\_31\_2022\_en.pdf

PDF Anti-Bribery and Corruption Global Policy

https://www.ono-pharma.com/sites/default/files/en/company/ anti-bribery-and-corruption-global-policy\_en.pdf

### Material Issue 17

# **Supply Chain Management**

[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]

- Establish a stronger risk management system (formulate policies and sustainable procurement code, make the system well established) (–2026)
- Comprehensive evaluations of companies in high-risk areas (-2026)

**Approach Towards Sustainable Procurement** 

# Promoting fair, impartial, and transparent procurement activities

As the social structure changes with technological innovation and globalization, the supply chain is becoming increasingly important for maintaining business activities.

Also, to respond to social problems related to human rights violations, labor environment, and other issues that have arisen and to achieve a sustainable society, it is important to work with all of our suppliers in the supply chain to establish a management system and strengthen our efforts together.

In addition to gaining a new recognition of the importance of these topics, we promote sustainable procurement under the leadership of a member of the Board of Directors and a senior executive officer. With the goal of resolving social issues in collaboration with suppliers, we are leveraging our sound network of suppliers, established to ensure the quality of and stable supply of pharmaceutical products, and creating a sustainability management system related to such issues as human rights, labor environment, and the natural environment. To ensure fair, impartial, and transparent procurement, we require that all employees involved in procurement activities adhere to the Basic Policy for Procurement Activities. Having formulated the ONO Sustainable Procurement Code for Business Partner (hereinafter, "the Code"), which summarizes items that suppliers are asked to cooperate with, we request the cooperation of suppliers.

Web Basic Policy for Procurement Activities https://www.ono-pharma.com/en/company/policies/procurement.html PDF Ono Sustainable Procurement Code for Business Partner https://sustainability.ono-pharma.com/data/pdf/en/2022/ono\_sustainable-procurement-code\_for-business-partner.pdf

### **Collaboration with Business Partners**

### **Obtaining Consent with the Code**

Until now, we have run through a cycle of sharing our approach towards sustainable procurement at explanatory meetings, which are mainly held for direct material suppliers, conducting risk assets based on the EcoVadis's sustainability assessment system, and then implementing corrections.

Taking into consideration changes in the external environment and the importance of sustainable procurement, we have strengthened related activities by setting this again as a materiality issue in FY2021, too, and subsequently conducting risk analysis based of such factors as monetary amount of the purchase, type of business, whether there is an alternative supplier, and country of origin.

With an eye toward giving priority to concluding agreements with suppliers that collaborate with our sustainable procurement activities in the future, we took such steps as establishing an in-house promotion system and formulating operating standards in FY2022. In addition, we identified 180 suppliers that should be given priority based on a risk analysis conducted in FY2021. After holding an explanatory meeting for identified suppliers and taking other steps, we obtained consent forms regarding collaborating with our activities. As of March 31, 2023, consent forms have been obtained from 132 companies. In FY2023, we plan to conduct risk assessments of companies that have submitted a consent form and broaden the companies that we obtain such forms from. Moreover, we select risk assessment targets, taking into consideration the sustainability risks for each type of company based on the impact on our business and third-party data. We will continue to meticulously communicate with suppliers to obtain their understanding and cooperation with our activities and work with them to contribute to the realization of a sustainable society.

# **Expanding Sustainable Procurement to the Whole Supply Chain and Connecting the Present to the Future**

In addition to having implemented checks of and initiatives related to sustainability issues with direct material suppliers, we created the Ono Sustainable Procurement Code for Business Partner, which summarizes the items and initiatives we want a broader range of partners to adhere to in order to further accelerate the realization of a sustainable society. As for indirectly supplied materials, we provide explanations to and obtain consent from both outside contractors and indirect material suppliers. With the cooperation of EcoVadis, we are moving forward with checks and analysis of sustainability issues and the formulation of measures to actually solve those problems. We will also reinforce risk management related to safety and health, human rights, labor, environmental preservation, ethics, and information management.

Shigeru Saito Procurement and Purchasing Department Manager



# **Social Contribution Activities**

See below for details.

Web Social contribution activities

https://sustainability.ono-pharma.com/en/themes/131

### **Basic Approach**

# Setting priority fields taking into consideration business resources

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

### **Supporting the Advancement of Medicine and Pharmacy**

# **Supporting Research for the Advancement of Medicine and Pharmacy**

We offer research grants and scholarships for researchers to study abroad through public interest incorporated foundations, related associations, and other entities, and make other efforts to meet unfulfilled medical care needs and contribute to the advancement of medicine. Our aim is to create a foundation for innovation by promoting research through these activities.

### **Supporting Patients and Their Families**

### **Dissemination of Medical Information**

We continue to communicate the latest medical care information for patients and their families through such activities as operating a website that provides useful medical care information, providing content apps, and holding public seminars.

### Support for Solaputi Kids' Camp

We became a supporting member of the public interest incorporated foundation Solaputi Kids' Camp in FY2014. Since FY2021, our MRs have served as "snow delivery volunteers" for the Snow Gift program, which delivers snow to children in hospitals in areas where snow does not fall. In FY2022 these MRs delivered snow to ten facilities and subsequently received comments of joy and letters from the children who played with the snow, their parents, and medical care staff.





Delivering snow (left) and children playing with the snow (right)

### **Participation in Relay For Life**

We participate in activities that support patients with cancer and their families, deal with cancer throughout an entire community, since FY2014 and aim to overcome cancer. After thoroughly implementing measures to prevent infections, we took part in these activities in FY2022, the first time in three years.

This provided opportunities to hold dialogues with cancer patients, which included having survivors and caregivers write their hopes for our employees on prepared message flags.





Employees taking part in the Relay For Life (left) and message flag (right)

### **Supporting Education for Children**

### **Cancer education for high school students**

Following the revision of the Curriculum Guidelines, cancer education has officially started in high schools since FY2022. Based on the opinions of cancer specialists, government officials, and educators, we created a Cancer Survivor Message video for high school students and conducted traveling classes at high school in FY2022.





Miki Yakata who appeared in the video (left) and traveling class (right)

Web Cancer survivor message video https://youtu.be/ElslzChm6kg

# Travelling science workshop for elementary school students

Through the Minase Research Institute and Joto Pharmaceutical Product Development Center, we conduct travelling science workshops for 6th graders at elementary schools near those facilities with our researchers as lecturers in order to raise interest in science and teach the children about careers.





Travelling workshops at Hoei Elementary School (left) and Shimamoto Daisan Elementary School (right)

# **Corporate Governance**

To enhance corporate value and generate sustainable grow, we must strengthen corporate governance that is centered on reinforcing the functions of the Board of Directors and Audit & Supervisory Board.

As for the Board of Directors and Audit & Supervisory Board, we are working to improve their effectiveness through various measures, moving forward with various initiatives, including those related to ensuring diversity of Directors and Audit & Supervisory Board members and reforming the remuneration system, and building a strong governance system.

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### Masao Nomura

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

### Shusaku Nagae

Member of the Board of Directors, Outside Director Special Corporate Advisor, Panasonic Holdings Corporation Outside Audit & Supervisory Board Member, Nikkei Inc.

### Yasuo Hishiyama

Outside Audit & Supervisory Board Member 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 Representative, Akiko Tanabe CPA office Outside Director, OIE SANGYO CO., LTD. Partner of Midosuji Audit Corporation



Round-table Discussion with Outside Officers

# Reinforcing the governance system and accelerating sustainable management to achieve sustainable growth

ONO continually strives to reinforce corporate governance by actively incorporating the opinion of outside officers. Two Outside Directors and two Outside Audit & Supervisory Board members discussed the governance system, compliance, and outlook for achieving sustainable growth.

# Steadily reinforcing the corporate governance system and related activities

**Nomura** When I took up the position of Outside Director in FY2018, the number of Outside Directors was raised to three from two, resulting in three of the eight Directors being Outside Directors. Two years later, in FY2020, a female director was appointed, and in FY2021, the following year, I replaced the President as the chairman of the Executive Appointment Meeting and Executive Compensation Meeting. Even regarding cross-shareholdings, we have reduced their weight to 14.4% as of March 2023 from 31.6% five years earlier.

Looking back over the five years since I took up my position, one can probably argue that efforts related to our corporate governance have steadily moved forward.

Nagae I feel that the Company has created a system to support Outside Officers. Despite becoming an Outside Director only two years ago, I have had many opportunities to deepen my understanding of the Company, which has included visiting various bases such as research bases and interacting with employees. As an Outside Director, I try to make statements without worrying about what people will think. For example, the President currently serves as the Chairman of the Board of Directors, but I have made several proposals, including "it may be good to separate supervision and execution in the future" and "it may be good to allocate time for open discussions on topics set by the Board of Directors," and I was able to do that because of the firm support that makes it possible to deepen my understanding of the Company.

**Hishiyama** I have served as an Outside Audit & Supervisory Board member for seven years, and by always possessing a perspective of "making the Company better," the full-time Audit & Supervisory Board members work extremely close to the workplace,

which includes collecting information through direct contact with more than several hundred employees each year.

As an attorney, I am sometimes in charge of the helpline, and the opinion of employees play a key role in improving the organization. In that sense, it is very meaningful that Audit & Supervisory Board members directly hear the opinions of employees. If the business expands overseas in the future, it may become more difficult to do that for various reasons, but I will continue to do so as much as possible.

**Tanabe** I have been involved in three evaluations of effectiveness, and I think that the operation of the Board of Directors has gradually improved. Full-time Audit & Supervisory Board members also look at issues related to the operation of the various bases and provide penetrating proposals to the President from an independent perspective, which leads to lively deliberations by the Audit & Supervisory Board, too, which I think is wonderful.

# Aiming to create an effective compliance system

Nomura Taking into consideration previous serious compliance violations, we have worked to reinforce the compliance system, which has included appointing a Compliance Officer as the responsible person for each department in FY2021 and installing a Compliance Manager in all departments as a consultation counter. However, I think it is important to take care so that employees do not feel they are being monitored in their work. We will create an open worksite in which anything can be said. It is important to move forward with the creation of the system by having people take to heart the idea that this is directly linked to preventing scandals.

Nagae There was a focus on how to promote the creation of a

system to prevent recurrences, and I got the impression that decision-making was quick, and things were moving forward smoothly. In addition to being a size that makes it easy to demonstrate its maneuverability, the foundation of a strong desire for compliance makes this possible.

Hishiyama Japan Exchange Regulation released its "Principles for Preventing Corporate Scandals," which states that "companies should establish this cycle of early detection (of compliance violations), swift response, and subsequent corrective action and embed the process into their corporate culture." Having reinforced our compliance system, we now quickly detect speech and actions that could lead to violations, and efforts to contribute to prevention have taken root. I see this as truly being in line with that principle. Furthermore, in the message from the President to new recruits in FY2023, he stated that he wants them to take the following three points to heart—"be honest and comply with laws and regulations," "have a dream, continually take on challenges to achieve the dream, and enjoy the process," and "make decisions from a patient perspective." It is extremely significant that top management communicated a message that compliance should be given the greatest priority.

Opportunity, motive, and justification are the three bases of the so-called "fraud triangle," and one can argue that motive and justification, the psychological factors, are deeply rooted in the corporate culture. Therefore, it is important that the attitude of valuing compliance not become an empty idea. I want to properly conduct monitoring as an Outside Audit & Supervisory Board member.

**Tanabe** Examining the compliance monitoring results report, one cannot miss that there were compliance violations for reasons other than lack of integrity. There were many cases when the act was not recognized as a violation, but was actually considered good. Even so, the person was, of course, disciplined. Because a company has a responsibility to protect its employees, it is important to know where the risk of compliance violations lie. One issue that should be examined is employing creative ways, such as training, so that reinforcing compliance does not become a burden for employees.





**Nomura** Because of my experience as manager I think that compliance is the lifeline, the last line of defense, for companies. A small compliance violation can snowball into a big problem, and shake even massive companies. Furthermore, as Outside Audit & Supervisory Board member Tanabe pointed out, there have been cases when compliance violations occurred with the person not realizing that what they did was a compliance violation, and it is important to continue to foster a corporate culture in which employees immediately ask if they are not sure or have a concern.

**Tanabe** The Company has added compliance initiatives as an item for employee evaluations. It is only natural that a violation lowers an employee's score, but in the future, it may be important to examine what activities should raise a score. A mechanism in which the Company positively evaluates employees working on compliance would increase employee's awareness of the issue, and make it easier for this to take root as corporate climate.

# Issues that should be tackled when implementing the global strategy

**Nomura** As for promoting a global strategy, the Company first moved forward with efforts to implement governance, compliance, and sustainability within Japan, our home base. For the U.S., the country we are focusing on the most, we are undertaking such efforts as expanding training, because it is necessary to instill an awareness of harassment related to religion and race.

While accepting the values of local people is the most important point when expanding overseas, there are limits to what can be done by dispatching leaders from Japan. It is also necessary to simultaneously promote initiatives to quickly train leaders who can handle management locally.

**Tanabe** It is extremely important that we implement global governance when expanding overseas and business domains. Having formulated the code of conduct "Ono Pharmaceutical Code of Practice" and "Compliance Global Policy," we are moving forward with such efforts as reviewing the various provisions, and I think

we must conduct further deliberations and make preparations regarding such issues as to what extent to delegate authority to local subsidiaries, to what degree should headquarters supervise this, and what type of monitoring should be used.

Nagae As for compliance training, it is critical to expand the content of training from a perspective of our global expansion. When promoting the global expansion at Panasonic, I truly saw the importance of "localization." If aiming to implement a business model based on local production and local sales, there are many things that must be taken into account, including properly ascertaining local conditions, such as demand, culture, and prices, which are completely different than those of Japan, and taking into consideration exchange rate risk, other risks, trends among competitors, and other factors.

There are many companies that have been forced to withdraw from markets if insufficient groundwork is done, particularly research on competitors, and this must be taken to heart. For ONO, the business expansion is limited to the U.S., Europe, Korea, and Taiwan, which means sufficient research can be conducted; therefore, it is important to always firmly understand the Company's position. It is necessary to envision both an optimistic and pessimistic scenario, and if things start to look even slightly negative, to quickly decide to withdraw.

# Accelerating sustainable management and generating sustainable growth

**Tanabe** Having changed the name of material issues from "CSR material issues" to "material issues for management" based on the Sustainable Management Policy newly formulated in FY2021, employees, too, can probably understand that sustainability-related activities are important initiatives tied to our Corporate Philosophy. All eighteen of the material issues are important, but I am particularly focused on expanding human capital. We are moving forward with an examination of a global human resources system, which Outside Director Okuno is providing advice on, and we will gradually expand the scope of human resources needed as we expand the business





domain and promote sustainability activities, not simply promote existing businesses. On the other hand, as Japan's labor force shrinks, an important issue is whether we can capture outstanding human resources. I also think that it is necessary to further examine the ideal state for the Company's finance to maximize corporate value.

Nagae I always say that employees are the most important stakeholders. First of all, unless employees are autonomous, business performance will not improve and corporate governance and compliance will not properly function. As Outside Audit & Supervisory Board member Tanabe has pointed out, the existence of the Company will be in danger if it cannot attract outstanding human resources. When I see the lively exchange between employees at such venues as the Medium-term Management Plan Announcement Meeting and in-house Business Contest, I truly feel that ONO values employees.

I think that to further promote globalization of the business, it is important for all employees to take on more challenges on various front. For this, too, the Company must continue to have an open atmosphere.

**Hishiyama** As for sustainability-related initiatives, they are important not only to reduce risk but also to link them to continued earnings. For example, one possible idea is to examine creating additional new businesses linked to well-being, such as "extension of healthy life expectancy," through the use of digital IT.

**Nomura** People have been talking about our being in a time of 100-year lifespans for a good while now, but after that, there will likely be "a time of healthy lifespans of 100 years." I want ONO to become a corporate group that can take on the challenge of achieving "a time of healthy lifespans of 100 years." It would probably be best if both management and employees unite to learn while firmly ascertaining global trends.

# Directors, **Audit & Supervisory Board Members**

(as of July 1, 2023, shares held as of March 31, 2023)

### **Members of the Board of Directors**



**Gyo Sagara** 

President, Representative Director, and Chief Executive Officer

Number of the Company's shares held: 103,100

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)

### Kiyoaki Idemitsu

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

Number of the Company's shares held: 10.400

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 Developme
	(to date)
June 2020	Corporate Executive Officer
June 2021	Member of the Board of Directors,
	Executive Officer (to date)



### Toshihiro Tsujinaka

June 2004

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

> Joined the Company Senior Director, Koshinetsu Branch

Number of the Company's shares held: 21,500

	Sales Division
November 2007	Senior Director, Sales Operations
October 2012	Senior Director, Sendai Branch Sales
	Division
October 2015	Senior Director, Oncology Planning &
	Promotion
April 2016	Division Director, Oncology Business
	Division
June 2016	Corporate Officer
October 2018	Executive Director, Corporate Strategy
	& Planning (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)

### Masao Nomura

Member of the Board of Directors Outside

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 data)

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



### **Toichi Takino**

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

Number of the Company's shares held: 22,000

April 1995 April 2006 April 2008	Joined the Company Senior Director, International Business 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

Number of the Company's shares held: 0

April 2002	Associate Professor, Faculty of Economics, Osaka University of
April 2004	Economics and Law 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

### **Audit & Supervisory Board Members**



Shusaku Nagae

Member of the Board of Directors Outside



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 th Board, Panasonic Corporation
June 2017	Director, Chairman of the Board, Panasonic Corporation
June 2021	Member of the Board of Directors,
June 2021	Outside Director (to date) Special Corporate Advisor, Panasonic
	Corporation (currently Panasonic Holdings Corporation) (to date)
March 2023	Outside Audit & Supervisory Board Member, Nikkei Inc. (to date)

[Status or important concurrent holding of positions] Special Corporate Advisor, Panasonic Holdings Corporation Outside Audit & Supervisory Board Member, Nikkei Inc.



Katsuyoshi Nishimura

Full-time Audit & Supervisory Board Member

Number of the Company's shares held: 12,100

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

Member (to date)

Full-time Audit & Supervisory Board



Hironobu Tanisaka

Full-time Audit & Supervisory Board Member

Number of the Company's shares held: 1,800

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



Yasuo Hishiyama

June 2011

Audit & Supervisory Board Member Outside

Number of the Company's shares held: 0

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

Audit & Supervisory Board Member Outside

Number of the Company's shares held: 0

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

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

Member (to date)

### Material Issue 18

# Strengthening of Corporate Governance

[Vision over the medium to long term]

Establish an effective corporate governance system to achieve our sustainable growth.

### [Indicators]

Evaluation of the effectiveness of the Board of Directors (evaluated by all members of the Board of Directors and the Audit & Supervisory Board)

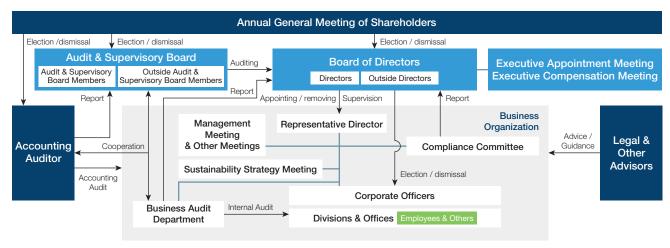
### **Corporate Governance Structure**

### **Basic Approach**

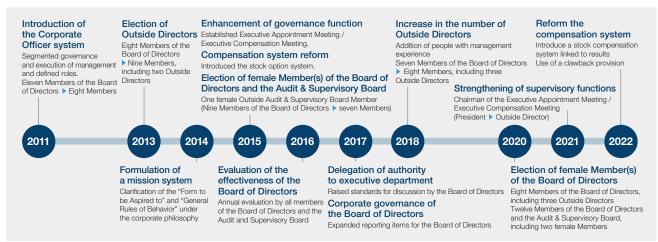
As part of our endeavors to strengthen corporate governance, ONO has adopted an organizational framework with an Audit & Supervisory Board, whose task is to focus on enhancing the functions of the Board of Directors and the Audit & Supervisory Board. ONO has established an Executive Appointment Meeting 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



### Response to the 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.

PDF 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 seven members of the Board Directors are Outside Directors, and one member is female [14.3% of Directors are female]). 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 (one member is female) 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.

### Attendance at the Meetings of the Board of Directors and the Audit & Supervisory Board One year from June 23, 2022 (the end of the 74th Annual General Meeting of Shareholders)

	Name	Board of Directors	Audit & Supervisory Board	Executive Appointment Meeting	Executive Compensation Meeting
	Gyo Sagara	<b>0</b> 100%	_	100%	100%
Member of the	Toshihiro Tsujinaka	100%	_	66.7% *1	_
Board of	Toichi Takino	100%	_	_	_
Director	Isao Ono *2	100%	_	_	_
	Kiyoaki Idemitsu	100%	_	_	_
	Masao Nomura	100%	_	O 100%	O 100%
Outside Director	Akiko Okuno	100%	_	100%	100%
Director	Shusaku Nagae	100%	_	100%	100%
Audit &	Katsuyoshi Nishimura	91.7%	O 93.3%	_	_
Supervisory Board Member	Hironobu Tanisaka	100%	100%	_	_
Outside Audit &	Yasuo Hishiyama	100%	100%	_	_
Supervisory Board Member	Akiko Tanabe	100%	100%	_	_

<sup>:</sup> Chairperson

Number of meetings held since appointment: Board of Directors meetings: 12, Audit & Supervisory Board meetings: 15, Executive Appointment Meetings: 3, and Executive Compensation Meetings: 2

<sup>1</sup> Director Toshihiro Tsujinaka was absent from one of the Executive Appointment Meetings held during the fiscal year, but this because of the objectives and purpose of the meeting and the approval of all other members was obtained.

<sup>\*2</sup> Isao Ono resigned as Director as of the conclusion of the 75th Annual General Meeting of Shareholders held on June 22, 2023.

### 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.

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

### **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 bonus, performance-related compensation, etc. 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.

### **Evaluation of the Effectiveness of the Board of Directors**

### **Basic Approach**

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 FY2022 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

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

Major improvements in FY2022					
Operation of the Board of Directors	<ul> <li>Regular items and similar issues were reorganized and schedule set.</li> </ul>				
Corporate governance of the Board of Directors	<ul> <li>Directors and broadened discussions regarding medium- to long-term management issues</li> <li>Reinforced cooperation between Outside Directors and Audit &amp; Supervisory Board members</li> </ul>				
Support for Outside Directors	Greater provision of information to Outside Directors     Conducted inspection of bases by Outside Directors				
Directors	<ul> <li>Conducted inspection of bases by Outside Directors</li> </ul>				

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. Evaluations of the effectiveness of the Board of Directors will be more objective starting next fiscal year because third parties will take part, which will lead to further improvements.

### 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.

**Outside Directors and Outside Audit & Supervisory Board Members** 

### **Roles of Outside Directors and Audit & Supervisory Board Members**

Possessing extensive experience and broad knowledge, 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. In FY2022, in addition to Cooperation Meetings, Outside Audit & Supervisory Board members inspected bases (Tsukuba Research Institute and Yamaguchi Plant) during onsite audits by Audit & Supervisory Board members that they were present for, and exchanged opinions from diverse perspectives.

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

The Company aides Outside Directors' execution of duties by providing information to and receiving information from them through the Corporate Governance Office, which serves as the secretariat of the Board of Directors. Furthermore, support is provided to promote Outside Directors' understanding of business content and business activities, and this includes providing not only explanations of such issues as business but also opportunities for exchanges of opinions outside of Board of Directors meetings. 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.

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

	Name	Expected roles
	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.
Outside Directors	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 &	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.
Supervisory Board Members	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**

### **Basic Approach**

- 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.

### **Decision-making process**

- 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.

### Composition of officer compensation

	Monetary co	ompensation	Stock compensation		
	Basic compensation	Bonus	Continuous service-type Restricted-transfer stock	Performance linked-type Restricted-transfer stock	
Directors (excluding Outside Directors)	•	•	•	•	
Outside Directors	•	_	_	_	
Audit & Supervisory Board members	•	_	_	_	

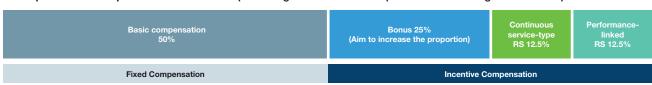
### ■ Compensation system

	Types of compensation		Purpose/summary				
Fixed	Fixed compensation Basic compensation		Monthly fixed compensation				
	Short-term Bonus		Incentive compensation to increase awareness of performance goals for each fiscal year  Amount paid: Calculated taking into consideration individual performance evaluation after reflecting degree that performance indicator targets were met  When paid: Lump-sum payment immediately after each fiscal year				
Incentive	Restricted stock remuneration*1		Incentive compensation to provide incentive to enhance medium- and long-term corporate value and work even more to share value with shareholders  • In principle, stock restrictions shall be released and the stock delivered in a lump sum after the retirement of a director.				
		Continuous service-type	Number of shares to deliver: Calculated according to the level of responsibility in making decisions  When shares are delivered: Delivered after the end of the annual general meeting of shareholders following Director's appointment (pre issuance)				
ensation	Medium- and long-term  Perform		Number of shares to deliver: Calculated based on the degree of achievement of performance targets (including ESG targets) set on a fiscal year-by-fiscal year basis, which are linked to medium-term management targets and management issues, and the degree of achievement of target figures for performance indicators for each fiscal year.  Number of shares to be delivered to each Director = the base number of shares' x percentage to be delivered's  When shares are delivered: Delivered after the end of the annual general meeting of shareholders based on results of the performance evaluation at end of the performance evaluation period (one fiscal year) (post issuance).  Moreover, if the delivery of restricted stock is not appropriate for any of various reasons, including the Director resigning at end of term, cash may be paid in lieu of stock.				

- \*1 There is a "Malus Clause" to the effect that all or some restricted stock can be seized for such reasons as major violations of laws, regulations, or internal rules during the term.
- \*2 The same number of performance-linked restricted transfer shares will be issued to executive officers who do not concurrently serve as Directors.

  \*3 In addition to \*1, there is a "clawback clause" to the effect that for such reasons as violation of laws, regulations, in-house rules during the term, the Company can demand return of stock compensation (amount equivalent to the value disposed of) even after a set amount of time following the lifting of restrictions on transfer.
- \*4 The Board of Directors shall determine the amount of the compensation based on the position, responsibility, etc. of the Director
- \*5 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%.

### Composition of Compensation for Directors (excluding Outside Directors (when reference target is 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

The proportion of each type of remuneration 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. RS stands for restricted transfer stock.

Creation

### Performance-linked remuneration, etc.

### (1) Bonuses

The targets and results related to the main evaluation indicators for bonuses FY2022 are as given below.

	Evaluation items	Targets	Results
	Consolidated revenue	425.0 billion yen	447.2 billion yen
Company performance*1	Consolidated operating profit	145.0 billion yen	142.0 billion yen
performance	Consolidated profit (attributable to owners of parent)	110.0 billion yen	112.7 billion yen
Individual performance	Individual performance targets	Individually set	Individual evaluation*2

- \*1 The target figures for company performance are the consolidated earnings forecast set at the beginning of the fiscal year. Results are evaluated at the Executive Compensation Meeting based on special factors that were not anticipated when targets were set at the beginning of the fiscal year, performance evaluations, and the like.
- \*2 The President evaluates the individual performances of members of the Board of Directors other than the President, and the validity of the evaluation is reviewed at the Executive Compensation Meeting. In addition, the performance of the President is evaluated only by Outside Directors at the Executive Compensation Meeting.

### (2) Performance-linked restricted stock remuneration

The targets and results related to the main evaluation indicators for FY2022 performance-linked restricted stock remuneration are shown in the table below.

		Evaluation items	Targets	Results	Composition	
Financial	Consolidated re	venue	425.0 billion yen	447.2 billion yen	10%	
targets*1	Consolidated op	perating profit	145.0 billion yen	142.0 billion yen	10%	
		Maximization of product value				
	Initiatives for	Strengthening of the pipeline and acceleration of global development				
	increasing corporate	Realization of our own marketing in the US and Europe	Individually set	Individual evaluation*2	70%	
	value over the medium -term	Expansion of business domains	iridividually Set	ii laividuai evaluatioi i		
Strategic		Management foundation that supports the growth strategy (expansion of intangible assets)				
targets		Corporate transformation via digital and IT platforms				
		Consolidated revenue trend	Revenue growth trend	Revenue growth		
	Medium-term	Consolidated operating profit trend (before R&D expenses)	Profit increase trend	Profit increase		
	growth – value creation	Consolidated R&D expenses trend (excluding impact of impairment)	Increase	Increase	10%	
		Consolidated ROE change/trend	Evaluate standard in Medium term	Current period: 16.1% 5-year average: 12.3%		
Non- financial	Materiality initiat	ives	Status of initiatives for identified challenges	Achieve goals set by the Company	100/	
targets	Status of inclusion	on in ESG indices	Status of inclusion in identified indicators, etc.	Achieve goals set by the Company	- 10%	

<sup>\*1</sup> The target figures for financial targets are the consolidated earnings forecast set at the beginning of the fiscal year.

### **Total Amount of Executive Compensation (FY2022)**

	_		-	-				(IVIIIIIONS OF YEN)
	Total amount to be paid	Fixed compensation	Bonus	Stock-based Compensation- type Stock options <sup>-1</sup>	Restricted transfer stock compensation			Number of
Executive category					Continuous service-type	Performance- linked	Transition measures <sup>2</sup>	recipients
Members of the Boardof Directors (excluding Outside Directors)	538	216	134	10	36	46	96	5
Outside Directors	58	58			_			3
Audit & Supervisory Board members (excluding Outside Audit & Supervisory Board members)	61	61	_	_	_	_	_	2
Outside Audit & Supervisory Board members	29	29	_	_	_	_	_	2
Total	685	364	134	10	36	46	96	12

<sup>\*1</sup> Although stock-based remuneration-type stock options have not been newly granted in FY2022, the expense amount for FY2022 out of the amount granted in previous fiscal years is indicated in the stock-based remuneration-type stock options column.

\*2 Accompanying the passage of a resolution to grant continuous service-type restricted-transfer stock and performance linked-type restricted-transfer stock to Directors (excluding Outside Directors) at the

Results are evaluated at the Executive Compensation Meeting based on special factors that were not anticipated when targets were set at the beginning of the fiscal year, performance evaluations, and the like.

2 The President evaluates the efforts of individual members of the Board of Directors other than the President to enhance medium- to long-term corporate value, and the validity of the evaluation is reviewed at the Executive Compensation Meeting. In addition, the performance of the President is evaluated only by Outside Directors at the Executive Compensation Meeting.

Accompanying the passage of a resolution to grant continuous service-type restricted-transfer stock and performance linked-type restricted-transfer stock to Directors (excluding Outside Directors) at the 74th Annual General Meeting of Shareholders held on June 23, 2022, the provision regarding stock acquisition rights as stock-based remuneration-type stock options for Members of the Board of Directors, excluding Outside Directors, approved at the 67th Annual General Meeting of Shareholders held on June 26, 2015, was abolished. As a transitional measure, it was decided to have Directors surrender all unexercised stock acquisition rights granted as stock-based remuneration-type stock options and grant Directors the same number of restricted stock as the number of surrendered shares (for compensation, etc., to implement the transitional measure, a resolution was passed to allocate an amount of no more than 400 million yen (75,000 shares) separate from other compensation, etc., for FY2022 minus the amount requivalent to the forfeited stock acquisition rights.

### **Cross-Shareholdings**

### **Basic Approach**

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.

### State of holdings and reduction

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 FY2018. By the end of March 2023, we had reduced our cross-shareholdings, bringing the total amount on the balance sheet to 107.8 billion yen and the ratio of cross-shareholdings to consolidated net assets to 14.4%. 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.





### **Internal Control System**

# Developing and operating an 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**

# Developing and operating an 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.

Audit & Supervisory Board Members are obliged to attend

Audit & Supervisory Board Members are obliged to attend Management Meetings and inspect their minutes, as these meetings are also subject to auditing.

### Information Disclosure

### Conducting appropriate and timely 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 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 FY2022, due to the impact of COVID-19, we continued to use the Internet and held approximately 220 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**

See the following for details.

Web Risk Management

https://sustainability.ono-pharma.com/en/themes/82

**Enterprise Risk Management (ERM)** 

### **Aiming For Overall Optimization**

We have conducted Enterprise Risk Management (ERM) since 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, as managing department for risk management, the Legal Department established risk management regulations to promote ERM.

### **Basic Approach**

- 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 expected to

- 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.

### **Promotion System**

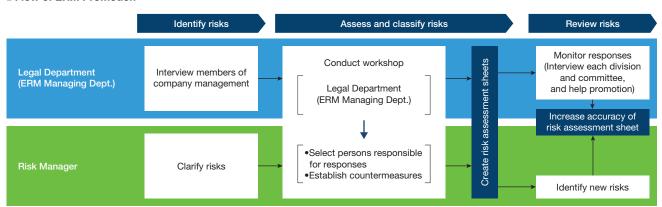
### **Basic Approach**

- 1. With the President and Representative Director as the chief risk management officer and the Executive Director, Corporate Strategy & Planning, a member of the Board of Directors and Senior Executive Officer, as the officer in charge of risk management, we view risk management issues as important issues in terms of the management strategy and implement related initiatives, such as building a company-wide management system.
- Each Division Head uses the division's Risk Management Promotion Meeting to supervise the division's risk management.
- 3. Office Managers conduct daily risk management.
- The Legal Department periodically monitors the risk management status of each division from the viewpoint of ERM.

### Risk Management System



### **■ Flow of ERM Promotion**



### **Risk Management**

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. Furthermore, we are reinforcing the company-wide risk management system by sharing information on risks discussed at each division's Risk Management Promotion Meeting and the state of managing those risks with the Business Audit Department.

### **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.

### **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, the managing department of the Risk Management Committee, also participates in this working group, and progress is reported to the Company-Wide Risk Management Committee to ensure coordination with ERM. (See p. 73)

### **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 to management and all employees to raise their awareness and sensitivity toward risks every year.

### **Expanding Globally**

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. Since FY2022, we have promoted efforts to reinforce the Group management system by checking the state of management of risks identified by subsidiaries.

**Business Continuity Plan (BCP)** 

# Working to Increase Business Continuity Capabilities

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. In addition, in preparation for a massive disaster, we have divided response functions between the Osaka Headquarters and the Tokyo Building, creating a dual-base system.

The BCM Committee is working to increase the effectiveness of the business continuity response by developing a business continuity plan to respond to all hazards in the medium- and long-term and conducting training in partnership with divisions. With an eye toward conducting our own sales in the U.S. and Europe, we are also moving forward with formulating a global crisis response and business continuity plan, which includes overseas subsidiaries.

Web BCP System

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

### **Information Security**

### **Establishing Specialized Bodies**

In addition to setting a global information security policy, strictly managing information assets, including data related to such activities as R&D and the personal information of stakeholders inside and outside the Company, ONO appropriately manages that information. Taking into consideration cyberattacks and the greater security threats throughout the world in recent years, we are striving to further strengthen cybersecurity based on a global standard framework.

At the same time, we newly established a Cybersecurity Section as a specialized body and are moving forward with expert team–based risk management and security measures. We are also raising awareness of cybersecurity throughout the Company by conducting employee education and regular security audits.

Web Information Security Management https://sustainability.ono-pharma.com/en/themes/82#918

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# **Financial Review**

### **Financial Results for FY2022**

An overview of our business performance in FY2022 is presented below.

(Billions of yen)

	FY2018	FY2019	FY2020	FY2021	FY2022	% change FY2021/FY2022
Revenue	288.6	292.4	309.3	361.4	447.2	+23.8%
Operating profit	62.0	77.5	98.3	103.2	142.0	+37.6%
Profit for the year (attributable to owners of the Company)	51.5	59.7	75.4	80.5	112.7	+40.0%

### Revenue

Revenue totaled ¥447.2 billion, which was an increase of ¥85.8 billion (23.8%) 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 treatments for gastric cancer, esophageal cancer, etc., resulting in sales of ¥142.3 billion, an increase of ¥29.9 billion (26.6%) year on year.

### Other Main Product

With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heat failure and chronic kidney disease were ¥56.5 billion (54.3% increase year on year). Sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥24.8 billion (8.1% increase year on year). Sales of Glactiv Tablets for type-2 diabetes were ¥22.5 billion (8.3% decrease year on year). Sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥8.7 billion (4.0% increase year on year). Sales of Velexbru Tablets for malignant tumors were ¥8.5 billion (36.2% increase year on year). Sales of Parsabiv Intravenous Injection for dialysis for secondary hyperparathyroidism on hemodialysis were ¥8.4 billion (5.3% decrease year on year). Sales of Ongentys Tablets for Parkinson's disease were ¥5.0 billion (72.9% increase year on year).

### **Long-term Listed Products**

Revision of the National Health Insurance (NHI) drug price reduction, etc., resulted in sales of Opalmon Tablets for peripheral circulatory disorder of ¥4.4 billion (7.6% decrease year on year) and sales of Onon Capsules for bronchial asthma and allergic rhinitis of ¥2.5 billion (30.7% decrease year on year).

### **Royalty and Others**

Royalty and others increased by ¥36.7 billion (31.8%) year on year to ¥152.1 billion.

(Billions of yen)

	FY2021	FY2022	% change FY2021/FY2022
Revenue of goods and products	246.0	295.0	+20.0%
Royalty and others	115.4	152.1	+31.8%

### **Profit and Loss**

Operating profit was ¥142.0 billion, an increase of ¥38.8 billion (37.6%) year on year.

Profit attributable to owners of the Company increased by \$32.2 billion (40.0%) year on year to \$112.7 billion in association with the increase of the profit before tax.

### Cost of Sales

Cost of sales increased by  $\pm 16.6$  billion (17.7%) year on year to  $\pm 110.1$  billion mainly due to an increase in revenue of goods and products.

### **Research and Development Costs**

Research and development costs increased by ¥19.5 billion (25.7%) year on year to ¥95.3 billion, mainly due to increase in research costs, costs for drug discovery collaboration, and development costs for clinical trials.

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

Selling, general, and administrative expenses (except for research and development costs) increased by ¥12.4 billion (16.1%) year on year to ¥89.5 billion mainly due to increase in co-promotion fees associated with expanding sales of Forxiga Tablets and investments in information infrastructure related to IT and digital technologies.

### **Other Expenses**

Other expenses recorded in the fiscal year ended March 31, 2023 were ¥11.1 billion mainly due to a lump-sum payment associated with the settlement of litigation on patents with Dana-Farber Cancer Institute, Inc., and a contribution to Ono Pharma Oncology, Immunology, Neurology Research Foundation, which was established in January 2023. However, other expenses decreased ¥1.6 billion (12.9%) year on year mainly due to the absence of expenses associated with the litigation on patents relating to the PD-1 antibody recorded in the fiscal year ended March 31, 2022.

	FY2021	FY2022	% change FY2021/FY2022
Cost of sales	93.5	110.1	+17.7%
Research and development costs	75.9	95.3	+25.7%
Selling, general, and administrative expenses	77.1	89.5	+16.1%

### **Cash Flows**

Cash and cash equivalents at the end of the fiscal year totaled ¥96.1 billion, which was an increase of ¥27.0 billion from ¥69.1 billion at the end of the previous fiscal year, mainly due to ¥159.6 billion provided by operating activities, ¥100.3 billion used in investing activities, and ¥32.5 billion used in financing activities.

### **Cash Flows from Operating Activities**

Net cash provided by operating activities was ¥159.6 billion, as a result of profit before tax of ¥143.5 billion, and depreciation and amortization of ¥17.5 billion.

### **Cash Flows from Investing Activities**

Net cash used in investing activities was ¥100.3 billion, as a result of payments into time deposits of ¥138.2 billion, etc., while there were proceeds from withdrawal of time deposits of ¥48.0 billion, etc.

### **Cash Flows from Financing Activities**

Net cash used in financing activities was ¥32.5 billion, as a result of dividends paid of ¥29.7 billion, etc.

(Billions of yen)

	FY2021	FY2022
Cash flows from operating activities	61.8	159.6
Cash flows from investing activities	6.0	-100.3
Cash flows from financing activities	-60.2	-32.5
Impact of exchange rate changes related to cash and cash equivalents	0.4	0.2
Cash and cash equivalents at the end of the fiscal year	69.1	96.1

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

Plant and equipment investment during the fiscal year totaled ¥7.7 billion. This included investment in enhancing and maintaining research facilities (¥4.1 billion), business facilities (¥2.2 billion), and manufacturing facilities (¥1.4 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 ¥310.0 billion, an increase of ¥15.0 billion (5.1%) year on year. Among new main products, sales of Opdivo Intravenous Infusion are expected to be ¥155.0 billion, an increase of ¥12.7 billion (8.9%) year on year, due to its expanded use in treatments for gastric cancer, esophageal cancer, and urothelial carcinoma, despite the intensifying competitive environment. In other new main products, sales of Forxiga Tablets are expected to increase by ¥8.5 billion (15.0%) year on year to ¥65.0 billion, as well as anticipating higher sales of Velexbru Tablets and Ongentys Tablets.

Furthermore, royalty and others are expected to increase by ¥12.9 billion (8.5%) year on year to ¥165.0 billion, anticipating that royalty revenue would grow continuously.

Revenue is therefore expected to be ¥475.0 billion, an increase of ¥27.8 billion (6.2%) year on year.

### **Profit and Loss**

Cost of sales is expected to be ¥113.0 billion, an increase of ¥2.9 billion (2.7%) year on year, due to an increase in revenue of goods and products.

Research and development costs are expected to be ¥109.0 billion, an increase of ¥13.7 billion (14.3%) 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, and global development study. Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥96.0 billion, an increase of ¥6.5 billion (7.3%) year on year, due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets, active investments in information infrastructure related to IT and digital technologies, and active investment to strengthen global businesses including the USA.

Other expenses are expected to decrease by ¥6.6 billion (59.3%) year on year to ¥4.5 billion, mainly due to the absence of a lump-sum payment associated with the settlement of litigation on patents with Dana-Farber Cancer Institute, Inc., recorded in the fiscal year ended March 31, 2023.

Therefore, operating profit is expected to be ¥153.0 billion, an increase of ¥11.0 billion (7.8%) year on year, and profit attributable to owners of the Company is expected to be ¥115.0 billion, an increase of ¥2.3 billion (2.0%) year on year.

		, , ,
	FY2023 (forecast)	% change FY2022/FY2023
Revenue	475.0	+6.2%
Revenue of goods and products	310.0	+5.1%
Royalty and others	165.0	+8.5%
Operating profit	153.0	+7.8%
Profit for the year (attributable to owners of the Company)	115.0	+2.0%

# **Consolidated Financial Summary**

IFRS	2015.3	2016.3	2017.3	
Operating Results				
Revenue	135,775	160,284	244,797	
Cost of sales	35,136	41,524	65,524	
Selling, general, and administrative expenses	42,222	43,979	62,049	
Research and development costs	41,346	43,369	57,506	
Operating profit	14,794	30,507	72,284	
Profit for the year (attributable to owners of the parent company)	12,976	24,979	55,793	
Financial position, cash flows, etc.				
Total assets	524,588	540,450	617,461	
Total equity	475,213	476,255	524,211	
Cash flows from operating activities	31,579	12,842	74,450	
Cash flows from investing activities	(12,756)	13,037	(17,989)	
Cash flows from financing activities	(19,603)	(19,465)	(20,552)	
Investment in plant and equipment	16,031	15,771	9,532	
Depreciation and amortization	6,100	6,534	7,821	
Amount Per Share <sup>⁺1</sup>				
Basic earnings (Yen)	24.48	47.13	105.27	
Equity attributable to owners of the parent company (Yen)	887.81	889.38	979.42	
Cash dividends (Yen)	180.00	180.00	40.00	
Other Indicators				
Operating income to revenue ratio (%)	10.9	19.0	29.5	
R&D cost-to-revenue ratio (%)	30.5	27.1	23.5	
Equity ratio (%)	89.7	87.2	84.1	
ROA (%) <sup>'2</sup>	3.6	6.2	12.9	
ROE (%) <sup>'3</sup>	2.8	5.3	11.3	
Payout ratio (%)	147.1	76.4	38.0	
Number of employees	2,913	3,116	3,290	

<sup>\*1</sup> 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, 2015. Also, "Cash dividends" for the fiscal year ended March 31, 2015 to the fiscal year ended March 31, 2016 indicate the amounts before conducting the stock split.

2 ROA = Profit before tax / Total assests (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)

(Millions of yen)						
2023.3	2022.3	2021.3	2020.3	2019.3	2018.3	
447.407	001.001	200.004	000 400	000.004	001.000	
447,187	361,361	309,284	292,420	288,634	261,836	
110,062	93,511	85,573	79,063	83,829	65,391	
89,486	77,057	69,230	67,679	70,033	68,055	
95,344	75,879	62,384	66,497	70,008	68,821	
141,963	103,195	98,330	77,491	62,010	60,684	
112,723	80,519	75,425	59,704	51,539	50,284	
882,437	739,203	745,428	673,444	655,056	609,226	
747,812	661,674	639,743	568,022	562,736	529,619	
159,610	61,829	73,977	74,157	66,774	15,727	
(100,259)	6,038	(57,586)	(10,234)	(49,763)	(34,189)	
(32,484)	(60,237)	(24,754)	(54,721)	(22,279)	(62,549)	
7,725	9,336	9,100	9,520	21,351	18,593	
17,451	17,721	15,820	14,214	10,621	9,213	
230.85	162.19	151.11	118.47	100.25	97.00	
1,519.19	1,343.40	1,270.45	1,126.95	1,084.08	1,019.97	
70.00	56.00	50.00	45.00	45.00	45.00	
31.7	28.6	31.8	26.5	21.5	23.2	
21.3	21.0	20.2	22.7	24.3	26.3	
84.1	88.7	85.1	83.5	85.1	86.1	
17.7	14.1	14.2	12.0	10.3	10.4	
16.1	12.5	12.6	10.7	9.5	9.6	
30.3	34.5	33.1	38.0	44.9	46.4	
3,761	3,687	3,607	3,560	3,555	3,480	

# **Details of Revenue**

(Billions of yen)

	2019.3	2020.3	2021.3	2022.3	2023.3	<b>2024.3</b> (Forecast)
Revenue of Major Products						
OPDIVO Intravenous Infusion	90.6	87.3	98.8	112.4	142.3	155.0
FORXIGA Tablets	14.5	18.1	22.4	36.7	56.5	65.0
ORENCIA for Subcutaneous Injection	17.4	19.8	21.9	22.9	24.8	25.5
GLACTIV Tablets	26.9	26.1	25.5	24.5	22.5	21.0
KYPROLIS for Intravenous Infusion	4.9	6.0	7.1	8.4	8.7	8.5
PARSABIV Intravenous Injection	5.7	7.1	8.1	8.9	8.4	8.0
VELEXBRU Tablets	_	_	2.1	6.3	8.5	9.5
ONGENTYS Tablets	_	_	0.3	2.9	5.0	6.5
ONOACT for Intravenous Infusion	4.6	4.9	4.7	4.9	4.5	4.5
OPALMON Tablets	10.4	8.3	5.5	4.7	4.4	3.5
BRAFTOVI Capsules	*	*	1.1	2.7	3.2	4.0
MEKTOVI Tablets	*	*	1.0	2.2	2.5	3.0
ONON Capsules	4.4	3.5	2.9	3.6	2.5	*

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

### **Breakdown of Revenue**

Revenue of goods and products	208.9	205.6	214.5	246.0	295.0	310.0
Royalty and others	79.7	86.8	94.7	115.4	152.1	165.0
OPDIVO Intravenous Infusion	58.5	61.6	59.8	69.9	89.6	*
Keytruda® (Merck)	12.8	19.3	24.3	30.8	45.2	*
Other	8.4	5.9	10.6	14.7	17.4	*

<sup>\*</sup> Not disclosed.

### **Revenue by Region**

Japan	207.4	202.9	212.9	242.0	288.2
Americas	72.9	82.0	86.3	106.9	142.8
Asia	7.4	7.5	7.4	8.9	11.6
Europe	1.0	0.1	2.7	3.6	4.6

# **Consolidated Financial Statement**

### **Consolidated Statement of Financial Position**

	sition	
	2022.3	2023.3
ssets		
Current assets:		
Cash and cash equivalents	69,112	96,135
Trade and other receivables	99,788	114,396
Marketable securities	60	20
Other financial assets	47,797	68,134
Inventories	41,817	44,814
Other current assets	22,692	21,602
Total current assets	281,266	345,101
Non-current assets:		
Property, plant, and equipment	112,131	108,420
Intangible assets	64,734	69,134
Investment securities	125,046	123,308
Investments in associates	108	115
Other financial assets	127,302	197,441
Deferred tax assets	25,074	35,604
Retirement benefit assets	377	2 244
Other non-current assets	3,165	3,314
Total non-current assets	457,937	537,336
Total assets	739,203	882,437
abilities and Equity  Current liabilities:  Trade and other payables	49.689	66.794
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable	49,689 2,301 716 1,526	66,794 2,490 661 34,575
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities	2,301 716 1,526 11,694	2,490 661 34,575 18,409
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities	2,301 716 1,526	2,490 661 34,575
Current liabilities:  Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities  Total current liabilities  Non-current liabilities:	2,301 716 1,526 11,694 65,926	2,490 661 34,575 18,409 122,929
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities	2,301 716 1,526 11,694 65,926	2,490 661 34,575 18,409 122,929
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities Other financial liabilities	2,301 716 1,526 11,694 65,926	2,490 661 34,575 18,409 122,929 6,678 0
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities Other financial liabilities Retirement benefit liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322	2,490 661 34,575 18,409 122,929 6,678 0 3,350
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities Other financial liabilities Retirement benefit liabilities Deferred tax liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322 1,009	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities Other financial liabilities Retirement benefit liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322	2,490 661 34,575 18,409 122,929 6,678 0 3,350
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities Other financial liabilities Retirement benefit liabilities Deferred tax liabilities Other non-current liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322 1,009 771	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities Other financial liabilities Retirement benefit liabilities Deferred tax liabilities Other non-current liabilities Total non-current liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322 1,009 771	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695
Current liabilities: Trade and other payables Lease liabilities Other financial liabilities Income taxes payable Other current liabilities Total current liabilities  Non-current liabilities: Lease liabilities Other financial liabilities Retirement benefit liabilities Deferred tax liabilities Other non-current liabilities Total non-current liabilities Total liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322 1,009 771	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695
Current liabilities:     Trade and other payables     Lease liabilities     Other financial liabilities     Income taxes payable     Other current liabilities     Total current liabilities  Non-current liabilities:     Lease liabilities     Other financial liabilities     Retirement benefit liabilities     Deferred tax liabilities     Other non-current liabilities     Total non-current liabilities  Total liabilities  Total liabilities  Equity:	2,301 716 1,526 11,694 65,926 6,501 0 3,322 1,009 771 11,603 77,529	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695 134,625
Current liabilities:     Trade and other payables     Lease liabilities     Other financial liabilities     Income taxes payable     Other current liabilities  Total current liabilities:  Non-current liabilities:  Lease liabilities Other financial liabilities Retirement benefit liabilities Retirement benefit liabilities Other non-current liabilities  Total non-current liabilities  Total liabilities  Total ron-current liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322 1,009 771 11,603 77,529 17,358 17,241 (74,683)	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695 134,625
Current liabilities:     Trade and other payables     Lease liabilities     Other financial liabilities     Income taxes payable     Other current liabilities  Total current liabilities:  Non-current liabilities:  Lease liabilities Other financial liabilities Retirement benefit liabilities Retirement benefit liabilities Other non-current liabilities  Total non-current liabilities  Total liabilities  Total reserves Treasury shares Other components of equity	2,301 716 1,526 11,694 65,926  6,501 0 3,322 1,009 771 11,603 77,529  17,358 17,241 (74,683) 51,236	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695 134,625 17,358 17,080 (54,161) 51,701
Current liabilities:     Trade and other payables     Lease liabilities     Other financial liabilities     Income taxes payable     Other current liabilities  Total current liabilities:  Non-current liabilities:  Lease liabilities Other financial liabilities Retirement benefit liabilities Retirement benefit liabilities Other non-current liabilities  Total non-current liabilities  Total liabilities  Total ron-current liabilities	2,301 716 1,526 11,694 65,926 6,501 0 3,322 1,009 771 11,603 77,529 17,358 17,241 (74,683)	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695 134,625
Current liabilities:     Trade and other payables     Lease liabilities     Other financial liabilities     Income taxes payable     Other current liabilities  Total current liabilities:  Non-current liabilities:  Lease liabilities Other financial liabilities Retirement benefit liabilities Retirement benefit liabilities Other non-current liabilities  Total non-current liabilities  Total liabilities  Total reserves Treasury shares Other components of equity	2,301 716 1,526 11,694 65,926  6,501 0 3,322 1,009 771 11,603 77,529  17,358 17,241 (74,683) 51,236	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695 134,625 17,358 17,080 (54,161) 51,701
Current liabilities:     Trade and other payables     Lease liabilities     Other financial liabilities     Income taxes payable     Other current liabilities  Total current liabilities:  Non-current liabilities: Lease liabilities Other financial liabilities Petirement benefit liabilities Retirement benefit liabilities Other non-current liabilities Total non-current liabilities  Total liabilities  Total reserves Treasury shares Other components of equity Retained earnings	2,301 716 1,526 11,694 65,926  6,501 0 3,322 1,009 771 11,603 77,529  17,358 17,241 (74,683) 51,236 644,754	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695 134,625 17,358 17,080 (54,161) 51,701 709,890
Current liabilities:     Trade and other payables     Lease liabilities     Other financial liabilities     Income taxes payable     Other current liabilities  Total current liabilities:  Non-current liabilities:  Lease liabilities Other financial liabilities Retirement benefit liabilities Retirement benefit liabilities Other non-current liabilities  Total non-current liabilities  Total liabilities  Total roan-current liabilities  Total roan-current liabilities  Total liabilities  Equity: Share capital Capital reserves Treasury shares Other components of equity Retained earnings  Equity attributable to owners of the parent company	2,301 716 1,526 11,694 65,926  6,501 0 3,322 1,009 771 11,603 77,529  17,358 17,241 (74,683) 51,236 644,754 655,906	2,490 661 34,575 18,409 122,929 6,678 0 3,350 983 684 11,695 134,625 17,358 17,080 (54,161) 51,701 709,890 741,869

### **Consolidated Statement of Income**

(Millions of yen)

	2022.3	2023.3
Revenue	361,361	447,187
Cost of sales	(93,511)	(110,062)
Gross profit	267,850	337,124
Selling, general, and administrative expenses	(77,057)	(89,486)
Research and development costs	(75,879)	(95,344)
Other income	980	734
Other expenses	(12,698)	(11,065)
Operating profit	103,195	141,963
Finance income	2,710	2,478
Finance costs	(874)	(913)
Share of profit (loss) from investments in associates	(6)	4
Profit before tax	105,025	143,532
Income tax expense	(24,340)	(30,619)
Profit for the year	80,684	112,913
Profit for the year attributable to:		
Owners of the parent company	80,519	112,723
Non-controlling interests	166	190
Profit for the year	80,684	112,913
Earnings per share:		(Yen
Basic earnings per share	162.19	230.85
Diluted earnings per share	162.16	230.79

# **Consolidated Statement of Comprehensive Income**

	2022.3	2023.3
Profit for the year	80,684	112,913
Other comprehensive income (loss):		
Items that will not be reclassied to prot or loss:		
Net gain (loss) on financial assets measured at fair value through other		
comprehensive income	(2,094)	2,518
Remeasurement of defined benefit plans	199	(114)
Share of net gain (loss) on financial assets measured at fair value through		
other comprehensive income of investments in associates	2	2
Total of items that will not be reclassified to profit or loss	(1,893)	2,406
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	814	472
Total of items that may be reclassified subsequently to profit or loss	814	472
Total other comprehensive income (loss)	(1,079)	2,878
Total comprehensive income (loss) for the year	79,606	115,791
Comprehensive income (loss) for the year attributable to:		
Owners of the parent company	79,444	115,608
Non-controlling interests	161	182
Total comprehensive income (loss) for the year	79,606	115,791

Value Creation

### **Consolidated Statement of Changes in Equity**

	E	quity attribut	able to own	ers of the par	ent compa	ny		
_	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company		Total equity
Balance at April 1, 2021	17,358	17,231	(44,705)	62,299	581,950	634,133	5,610	639,743
Profit for the year Other comprehensive					80,519	80,519	166	80,684
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 Disposition of treasury shares Cash dividends		(31)	(30,009) 31		(27,703)	(30,009) 0 (27,703)	(4)	(30,009) 0 (27,707)
Share-based payments Transfer from other components of equity		41			(=:,:::)	41	( ' )	41
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
Profit for the year Other comprehensive				0.000	112,723		190	112,913
income (loss)				2,886		2,886	(8)	2,878
Total comprehensive income (loss) for the year	_	_	_	2,886	112,723	115,608	182	115,791
Purchase of treasury shares Retirement of treasury shares Disposition of treasury shares Cash dividends		(20,356) (168)	(2) 20,356 168	)	(29,786)	(2) — — — (29,786)	(6)	(2) - - (29,792)
Share-based payments Transfer to capital surplus		142			(29,780)	142	(0)	142
from retained earnings Transfer from other components of equity		20,221			(20,221)	_		_
to retained earnings				(2,421)	2,421	_		_
Total transactions with the owners	_	(161)	20,522	(2,421)	(47,586)	(29,646)	(6)	(29,653)
Balance at March 31, 2023	17,358	17,080	(54,161)	51,701	709,890	741,869	5,944	747,812
balance at March 31, 2023	17,358	17,000	(54, 161)	51,701	709,890	741,809	5,944	74

## **Consolidated Statement of Cash Flows**

	2022.3	2023.3
Cash flows from operating activities		
Profit before tax	105,025	143,532
Depreciation and amortization	17,721	17,451
Impairment losses	3,404	1,498
Interest and dividend income	(2,349)	(2,402)
Interest and dividend income	70	74
(Increase) decrease in inventories	(2,464)	(2,945)
(Increase) decrease in free notes  (Increase) decrease in trade and other receivables	(15,283)	(14,513)
Increase (decrease) in trade and other payables	8,177	13,090
Increase (decrease) in trade and other payables Increase (decrease) in provisions	(20,721)	13,090
, , ,	(20,721)	214
Increase (decrease) in retirement benefit liabilities	130	27
(Increase) decrease in retirement benefit assets	(1,000)	<del></del> -
Increase (decrease) in accrued consumption tax		5,564
Other	1,069	2,347
Subtotal	93,835	163,935
Interest received	40	53
Dividends received	2,317	2,334
Interest paid	(70)	(74)
Income taxes paid	(34,293)	(6,637)
Net cash provided by (used in) operating activities	61,829	159,610
Cash flows from investing activities Purchases of property, plant, and equipment	(5,497)	(5,340)
Proceeds from sales of property, plant, and equipment	14	6
Purchases of intangible assets	(6,780)	(9,157)
Purchases of investments	(1,127)	(2,432)
Proceeds from sales and redemption of investments	22,782	7,864
Payments into time deposits	(57,486)	(138,159)
Proceeds from withdrawal of time deposits	55,800	47,996
Other	(1,667)	(1,037)
Net cash provided by (used in) investing activities	6,038	(100,259)
Cash flows from financing activities		
Dividends paid	(27,666)	(29,742)
Dividends paid to non-controlling interests	(4)	(6)
Repayments of lease liabilities	(2,560)	(2,733)
Purchases of treasury shares	(30,007)	(1)
Net cash provided by (used in) financing activities	(60,237)	(32,484)
Net increase (decrease) in cash and cash equivalents	7,631	26,868
Cash and cash equivalents at the beginning of the year	61,045	69,112
Effects of exchange rate changes on cash and cash equivalents	436	155
Cash and cash equivalents at the end of the year	69,112	96,135

# Corporate Information / Stock Information

### Profile (as of March 31, 2023)

Company Name ONO PHARMACEUTICAL CO., LTD.

Founded 1717

Date of Incorporation 1947

Paid-in Capital 17,358 million yen

Number of Employees 3,761 (Consolidated) 3,381 (Non-consolidated)

Total Number of 1,500,000,000

**Number of Shares** 517,425,200

**Issued and Outstanding** (Including 29,025,954 shares of treasury stock)

Number of Shareholders 61,926

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)	63,932	13.09
STATE STREET BANK AND TRUST COMPANY 505001	23,407	4.79
Custody Bank of Japan, Ltd. (Trust account)	22,876	4.68
Meiji Yasuda Life Insurance Company	18,594	3.80
Ono Scholarship Foundation	16,428	3.36
KAKUMEISOU Co., LTD	16,153	3.30
STATE STREET BANK WEST CLIENT - TREATY 505234	8,924	1.82
MUFG Bank, Ltd.	8,640	1.76
Aioi Nissay Dowa Insurance Co., Ltd.	7,779	1.59
SSBTC CLIENT OMNIBUS ACCOUNT	6,658	1.36

Note: 1. The Company is excluded from the principal shareholders listed in the table above,

although the Company holds 29,025,954 shares of treasury stock.

2. The shareholding percentage is calculated by deducting treasury stock (29,025,954 shares).

### Major Offices (as of March 31, 2023)

**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 Sapporo, Sendai, Tokyo, Yokohama, Nagoya, in Japan 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
Ono Pharma UD Co., Ltd.

michiteku Co., Ltd.

Overseas Subsidiaries ONO PHARMA USA, INC., Cambridge, USA
ONO PHARMA UK LTD. London, UK

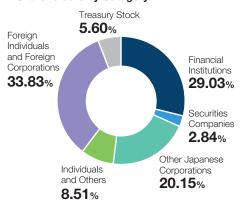
ONO PHARMA KOREA CO., LTD., Seoul, South Korea
ONO PHARMA TAIWAN CO., LTD., Taipei, Taiwan

Ono Venture Investment, Inc., California, USA Ono Venture Investment Fund I, L.P., California, USA

**Related Party** 

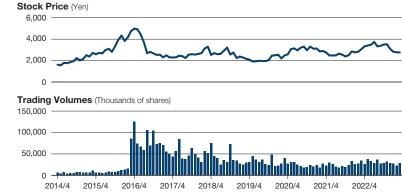
Namicos Corporation

### **■** 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.







