Game-changing R&D

Based on our unique drug discovery “Compound-Orient” approach, we have identified the therapeutic areas with high medical needs as our priority areas of research to develop new drugs that will provide new treatment options with innovation to the frontline of healthcare. For this, we will strengthen and enhance research and drug discovery alliance with world-leading universities, research institutes, and biopharmaceutical companies in specific research areas. We will also drive forward activities in areas with great medical needs, by in-licensing innovative compounds and acquiring novel technologies.

Our Mission in Research and Development

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

Open innovation

ONO’s new drug discovery seeds

In-licensing promising new drug candidate compounds from around the world

Discovering compounds with unique pharmacological action

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Disease Expertise Enhancement

Focusing on the four therapeutic areas with high unmet medical needs as priority areas of research

Oncology | **Immunology** | **Neurology** | **Specialty**

ONO’s unique drug discovery “Compound-Orient” approach

Finding diseases against which the properties of compounds are most potentially effective

Creating unique and innovative new drugs

Drug Discovery Strategy

Based on the drug discovery "Compound-Orient" approach focusing on characteristic bioactive lipids and unique drug targets to generate innovative new drug candidate compounds, we enhance knowledge and expertise of diseases in each of the oncology, immunology, neurology, and specialty research domains with high medical needs by focusing our resources on these domains as priority areas. To reinforce our competitiveness in drug discovery in each domain, we performed structural reform in April 2019 by adding the Research Centers of Immunology, Neurology, and Specialty Products to the already-existing Oncology Research Center. Each organization accumulates knowledge and expertise of diseases in each of the priority areas to properly understand medical needs, working toward developing breakthrough pharmaceutical products with medical impacts.

While we vigorously promote open innovation globally to adopt world-leading technologies, information, and networks, we not only pursue small molecule drug discovery on which we have focused, but also tackle the challenge of providing new treatment options with innovation to the healthcare frontline by using modalities including antibodies, nucleic acids, cells and viruses.

A Research Capability Combining Knowledge with Technology

The development of innovative new drugs is driven by the spirit of challenge and the motivation of individual scientists and their ability to think creatively responding to change. We set high and achievable targets with clear outcomes, in order to enhance motivation and creative thinking among our researchers. ONO's research organization is based on project teams where members converge from different fields, bringing cutting-edge expertise from contrasting backgrounds. The interaction within the teams stimulates and mutually enhances our research achievements. Each project team actively promotes open innovation with the aim of discovering innovative drugs with top-class researchers all over the world.

We conduct drug discovery research through coordination of the efforts of three laboratories, the Minase Research Institute, the Fukui Research Institute and the Tsukuba Research Institute, and work to strengthen our research capability to further accelerate, and raise success rates of, drug discovery. In April 2019, a Translational Research Laboratory was newly established in the Research Project Management to bridge between basic and clinical research for the promotion of research.

In the Minase Research Institute's research building No. 3, our center for invention and medicinal chemistry, integration of our compound synthesis and analysis functions has further matured, and thereby driving R&D forward by building capability with consistency in chemistry research, from exploration of breakthrough drug seeds through to clinical researches. This has led to strengthening combination of knowledge and technology among researchers and among teams.

A Drug Discovery System in Each of the Four Priority Areas

Oncology	**Research Center of Oncology**	As a pioneer in cancer immunotherapy, the Center works toward discovering innovative drugs for cancer patients with our experience, and technology and knowhow, nurtured through R&D of the immune checkpoint inhibitor OPDIVO. The Center are pursuing the original and unique drug seeds and new drug modalities not only through the "Open innovation" with academia and biotech companies in the world with cutting edge technologies and but also promoting translational research.
Immunology	**Research Center of Immunology**	Based on the long-year experience of immunology research which has helped create OPDIVO, the Center, the successor to the Research Center of Immunology established in April 2016, strives to keep research capabilities with a primary focus on biopharmaceutical development in immunology, working toward drug discovery in both areas of cancer immunotherapy and autoimmune therapy. The Center is operated in accordance with the policy of advancing unique research with strong awareness of serendipity and insight not to miss it.
Neurology	**Research Center of Neurology**	The Center focuses on not only neurons as major components of the nervous system, but also glial cells which maintain and support the environments necessary for survival and multiple functions of neurons. Through our intensive analysis of patient-derived tissues and iPS cells, the Center is dedicated to discovering innovative drugs to provide disease-modifying therapies, as well as symptomatic treatments, to patients with neurodegenerative diseases, which are becoming serious problems in the aging society, and those with mental disorders or chronic pain, which are still largely detrimental to society.
Specialty	**Research Center of Specialty Products**	The Center works toward discovery of clinically valuable pharmaceutical products for diseases for which treatment is high in unmet needs, free from the disease field. For this, it is important that the Center accurately determine real healthcare needs of patients, healthcare providers and society in general and come up with drug discoveries with the understanding of pathogenesis. Also based on ONO's unique compound-orient approach, the Center proceeds with drug discovery.

Strengthening competitiveness in drug discovery by accumulating and using knowledge and expertise of diseases in each domain.

Four Growth Strategies

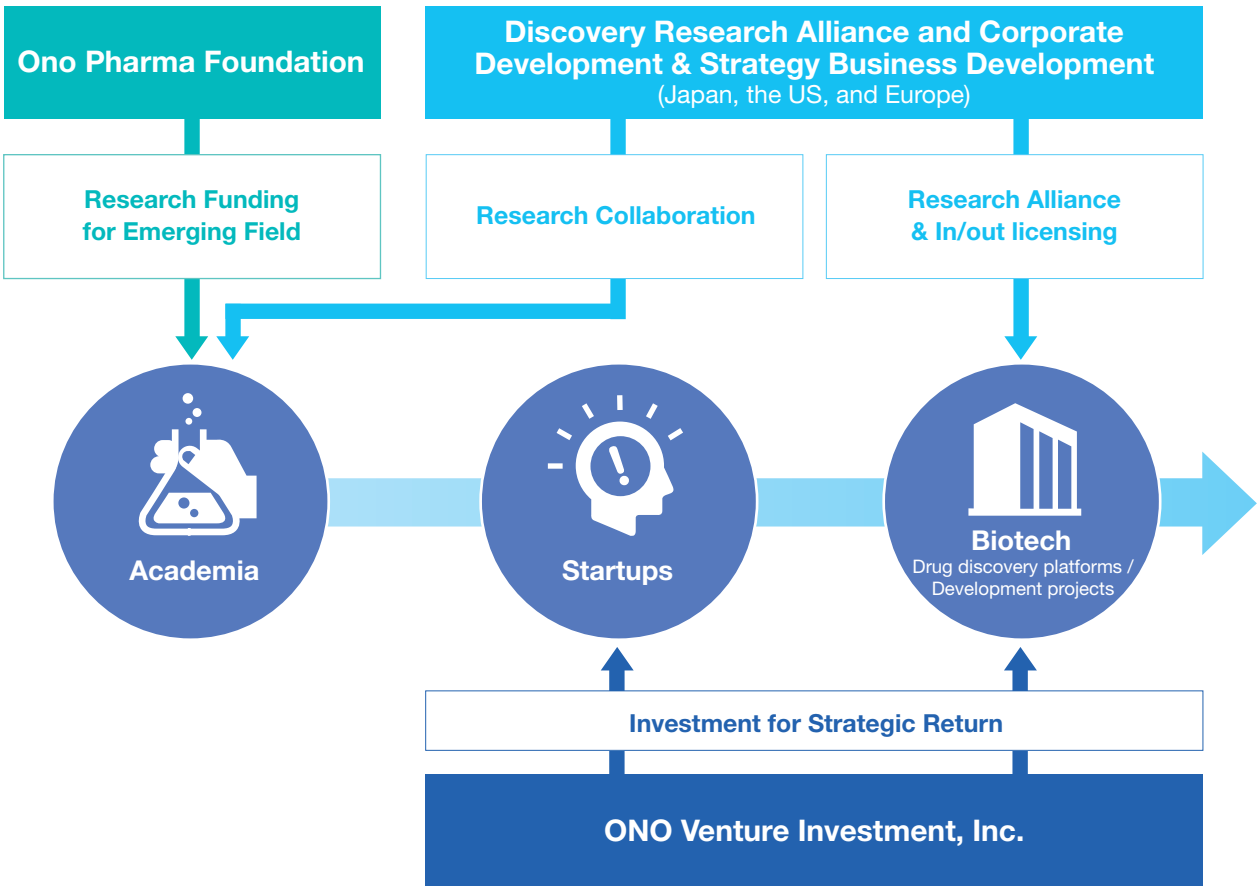
Open Innovation

ONO has discovered new drug discovery seeds and developed breakthrough new drugs initiated through collaboration with research institutes including universities since before the words “open innovation” started to become widely used. With Discovery Research Alliance and Corporate Development & Strategy Business Development taking the lead, we continue to pursue drug discovery collaborations and vigorous compound licensing activities with world top-class researchers and biopharmaceutical companies mainly in the priority areas of research. We also pursue collaboration activities with speed to collect cutting-edge scientific information and proceed with drug discovery based thereon ahead of the competition as fast as possible. We post employees with extensive experience in discovery research to our overseas subsidiaries in the US and UK, and they visit world top-class researchers and biopharmaceutical companies in the US and Europe to launch alliances.

Through the Ono Pharma Foundation, which was established in 2017, we provide grants for research activities in academia with an eye toward the future. We select research grant winners every year and subsidize attractive basic research projects that may bring about innovations in the future. This has led even to grant winners developing a social network in the field of frontier sciences.

To strengthen and accelerate these activities to realize a more strategically wide range of open innovation, we established a subsidiary in the US named Ono Venture Investment, Inc. This company manages Ono Venture Investment Fund I, L.P. (established in July 2020), a venture capital fund in the US, and make investments focused on early stage biopharma startups for the purpose of strategic investment in drug targets and cutting-edge technologies to discover innovative drugs. By adding to open innovation the new framework of capital alliances with and investments in biopharmaceutical companies, we strive to be more competitive in drug discovery and R&D.

Overview: Open Innovation



Development Policy

We are committed to promoting clinical development with speed to deliver new drugs that meet medical needs as soon as possible, for the benefit of people suffering from disease throughout the world.

Our development pipeline currently includes OPDIVO, as well as new drug candidate compounds including antibody drugs, which we are working to develop to achieve expedited market launch. Among others, we work toward clinical development in the oncology domain, in which unmet medical needs are high, positioning it as an important strategic area.

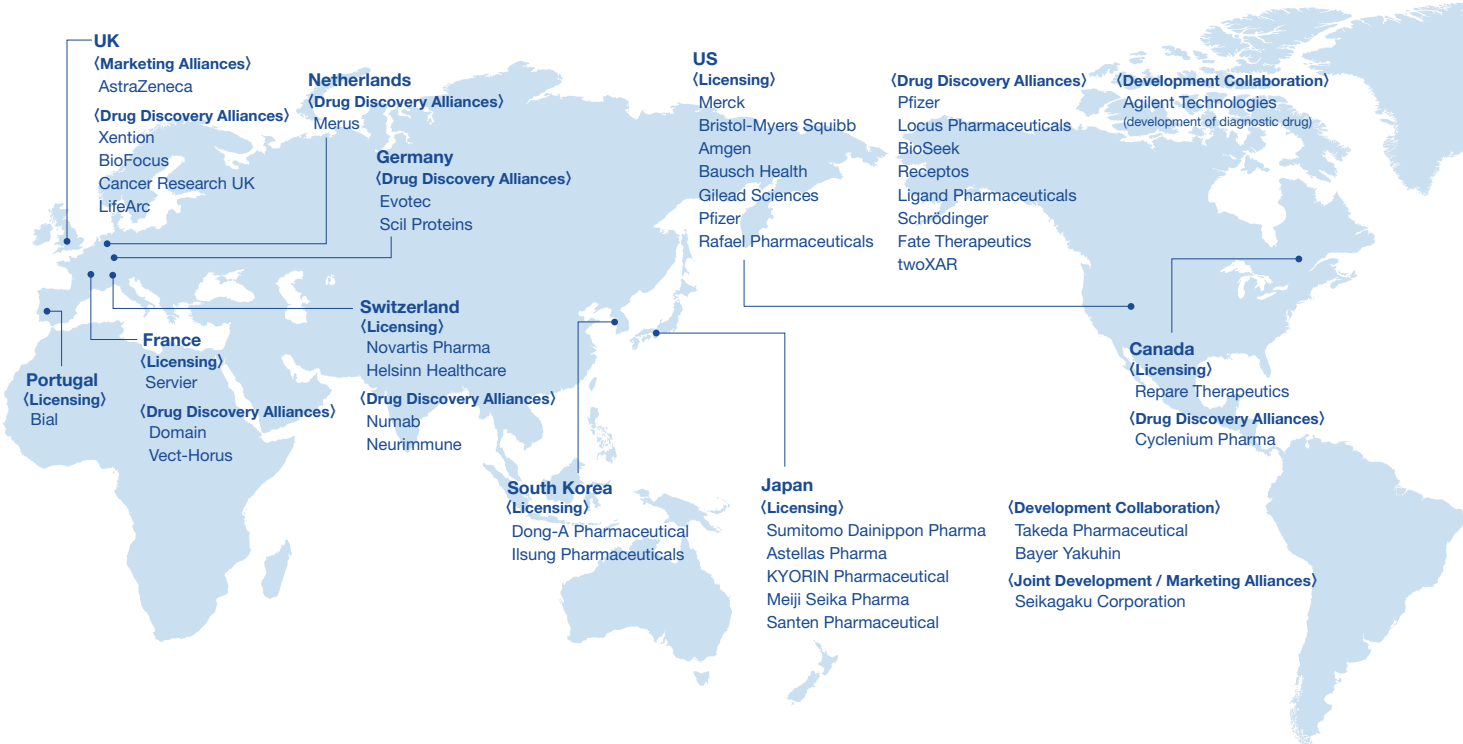
In April 2019, we transferred the functions of the Global Clinical Development Division from Japan to our US subsidiary ONO PHARMA USA, INC. We will pursue organizational improvements that enable us to conduct clinical trials in the US and Europe and apply for approval with the regulators.

Vigorous Activities for Licensing Initiatives

We continue to forge ahead with licensing activities to take in new drug candidates with the aim of introducing compounds attractive for diseases with high therapeutic need, and compounds that have high value in terms of corporate strategy and efficiency, while taking into consideration the development pipeline and existing products. Our aim is to expand the development pipeline to provide a continuous stream of new market launches. In the oncology domain, we take advantage of our strength with OPDIVO in acquiring product candidate compounds in a wide range of areas such as molecular target drugs including antitumor drugs and cell therapies.

Meanwhile, we are working in anticipation of our own overseas marketing in the US and Europe. We also have departments in charge of licensing activities keenly out-licensing discovered compounds to our partners upon examining optimum measures to deliver our new in-house developed drugs to patients worldwide as quickly as possible, in light of proposed indication and market size.

Our Partners inside and outside Japan (As of July 24, 2020)



〈Main Achievements in FY2019〉

June 2019	ONO entered into exclusive license agreement with Rafael Pharmaceuticals on the cancer metabolism inhibitor ONO-7912 (CPI-613) / Devimistat and other related compounds
July 2019	ONO and Forty Seven signed a license agreement related to the anti-CD47 antibody ONO-7913 / Magrolimab
March 2020	ONO entered into a new research and option agreement with Numab

Maximizing Product Value

We actively pursue R&D activities to achieve expedited market launch and additional indication approval. We also develop a strategy formation that constantly ensures competitive advantage by adjusting with agility to environmental changes in each stage of the product life cycle, thereby to achieve peak sales in the shortest period from launch and to maximize the potential of every product we offer.

Development Activities

- Maximizing OPDIVO's product value

(Adding indicated tumors, adding treatment lines, developing combination therapies, searching for biomarkers)

Achieving Expedited Market Launch and Additional Indication Approval

Marketing Activities

- Developing a strategy formation that constantly ensures competitive advantage
- Understanding potential medical needs toward development of narrative-based medicine (NBM)

Achieving Peak Sales in the Shortest Period from Launch

Information Dissemination & Collection Activities

- Using a sales force automation (SFA) system and AI to bring efficiency to MR activities
- Prompt and appropriate provision of medical and scientific information
- Strengthening community-based activities

Enhancing Product Value and Contributing to the Frontline of Healthcare

Stable Supply of High-Quality Drugs and Drug Reliability Assurance

- Having a quality assurance system in place that is compliant with global regulations
- Upgrading of risk management systems at manufacturing centers
- Strengthening production systems
- Initiatives for proper use of pharmaceuticals

Etc.

Maximizing OPDIVO's Product Value

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

Adding indicated tumors	We are working on development to obtain additional approval for more than 20 indications for cancers, including the 9 cancers for which the drug has already been approved for in Japan.
Adding treatment lines	We move ahead with clinical trials to enable OPDIVO's use at earlier stages from third- to second- to first-line drug treatment.
Developing combination therapies	Searching for combinations of boosting its therapeutic effects by combining OPDIVO with other drugs or treatments.
Searching for biomarkers	We advance the search for optimal biomarkers that will predict patients who are more likely to be expected to exhibit the therapeutic effects of OPDIVO.

Marketing Activities to Enhance Product Value

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

Developing a More Efficient Sales System

Our information-sharing framework enables our MRs to share across the company the valuable information they gather from the frontline of healthcare. We also continually pursue brining efficiency to MR activities by using the FAQ system and AI. In the primary care domain, we work with a medical case zone-based marketing system that allow for closer community-based area activities, as well as team management encouraging inter-domain communication. In the oncology domain, we divide MRs into two teams—one with focus on lung and renal cell cancers and the other with focus on gastrointestinal and hematologic cancers to strengthen their expertise and improve the quality and quantity of information that they will provide to healthcare professionals.

Prompt and Appropriate Provision of Medical and Scientific Information

One role of drug manufacturers is to relay up-to-date information as quickly as possible about daily advances in healthcare to the frontline of healthcare and to provide opportunities for information exchange. We actively provide information by organizing symposiums and seminars in conjunction with academic conferences held in Japan and through workshops and lectures in regional areas. In addition, we put effort into disseminating up-to-date drug information through operating several websites for medical professionals. In FY2019, we continued to hold web-based seminars and product presentations in line with various needs, including more than 130 live webinars, to relay up-to-date drug information to the frontline of healthcare.
Our Medical Affairs Department works to attain a high level of expertise and academic knowledge in oncology and primary care domains to assess and collect medical and scientific needs of healthcare professionals through meeting with experts or attending at advisory board meetings. In response to request from healthcare professionals, we provide such evidence-based medical and scientific information with transparency to contribute to the healthcare frontline.

Enhancing Product Value Through Drug Reliability Assurance Activities

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

Initiatives to Ensure Stable Supply of High-Quality Drugs

Stable supply of high-quality drugs is essential to maximizing product value. We ensure that all drugs are produced, whether in-house or through outsourcing, under appropriate quality assurance system. We take various measures to stably supply high-quality drugs, including strengthening the quality system in accordance with ICH Q10 Pharmaceutical Quality System, and upgrading of risk management systems at our manufacturing centers.
In addition to strengthening our production capabilities aimed at future business expansion, a new plant has been constructed in Yamaguchi Prefecture to mitigate the risk of major disaster from the business continuity perspective. The new plant is now in operation, starting in the spring of 2020.

Globalizing Business

To supply the world with new drugs, we are reinforcing overseas business expansion in anticipation of our own overseas marketing of specialty products for which marketing activities can be carried out with small staff. In South Korea and Taiwan, we have already set up wholly owned subsidiaries and have started selling products. We are also working to improve and strengthen our development and other systems, with a view to future marketing through our own sales organizations in US and Europe.

Step 1	Globalizing own marketing operations	●Launching own marketing in South Korea and Taiwan ●Building business base in Asia ●Strengthening new drug development framework in US and Europe
Step 2	Expanding own marketing operations into US and Europe	●Expanding sales in Asia ●Launching own marketing in US and European markets
Step 3	Becoming a true global company	●Expanding global development pipeline ●Delivering US/Europe-originated pharmaceutical products to patients around the world

Promotion of Business in Asia

As a beachhead to expand revenue sources into overseas markets, we have been reinforcing overseas business expansion starting in Asia. We established wholly owned subsidiaries, ONO PHARMA KOREA CO., LTD. in South Korea in 2013 and ONO PHARMA TAIWAN CO., LTD. in Taiwan in 2014. The subsidiaries have since launched their own marketing and have demonstrated steady progress.

We have obtained approval for OPDIVO for additional indications not only in Japan but also in the rest of the world. The drug has been approved for 8 and 10 types of cancer in South Korea and in Taiwan respectively (as of June 2020). To significantly contribute to advancement in cancer therapy in South Korea and Taiwan, we also put efforts into safety measures by, e.g., rolling out scientific activities countrywide with Japanese and Western doctors appointed as lecturers to promote proper drug use. In addition, we conduct information dissemination activities not only on a countrywide level but also on a small-scale, locally-focused level to bring a fresh sensitivity to both markets as part of efforts to become the market leader in oncology in Asia.

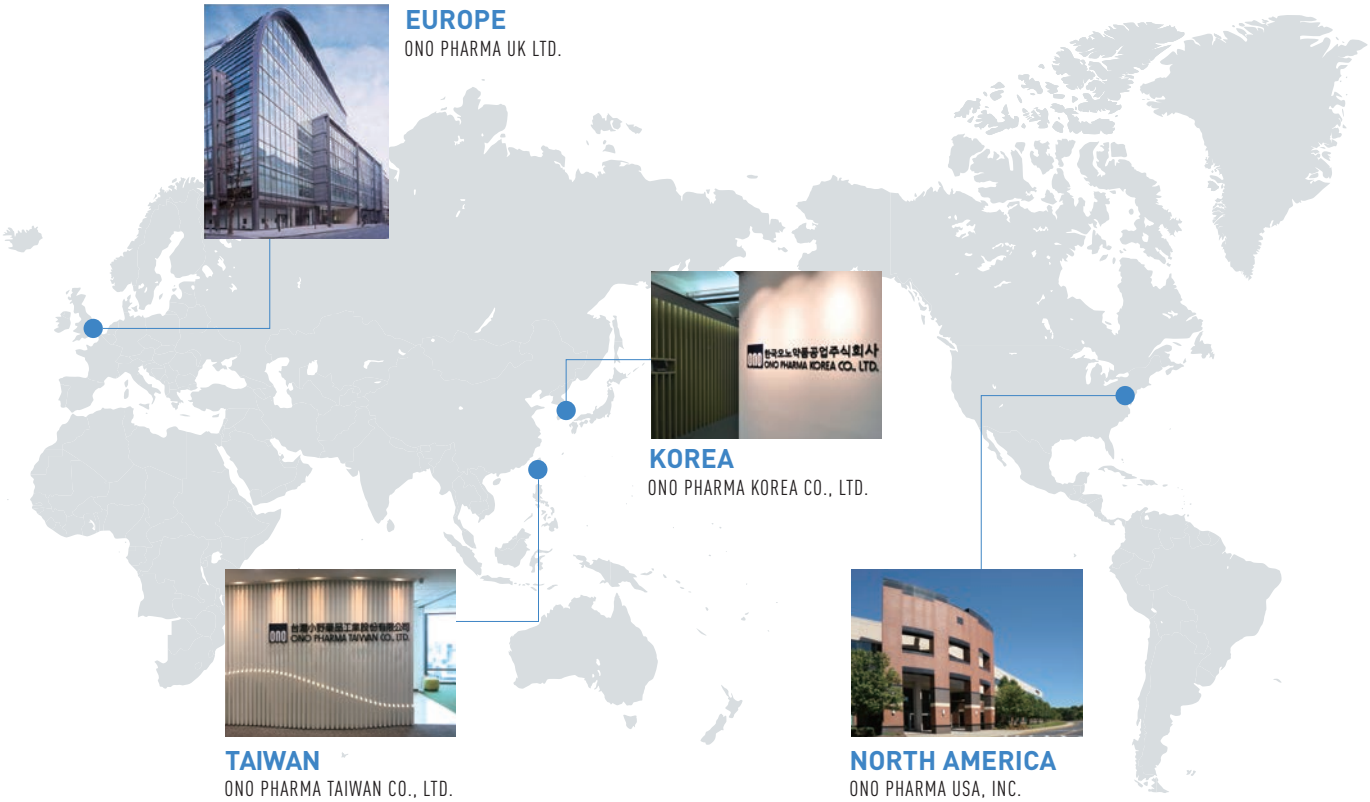
We have also established a division within our Corporate Development & Strategy that is in charge of planning operations in South Korea and Taiwan and expansion into other Asian markets. In close cooperation with the locally incorporated subsidiaries, the division investigates issues and develop overseas business strategies.

Business Expansion into the US and Europe

We have established our own sales organization in South Korea and Taiwan and have pursued out-licensing of new drug candidates developed in-house to deliver them to healthcare settings in other overseas regions. Currently, however, we are in preparatory stages to sell our drugs on our own, also in the US and Europe, the world's largest markets. We are setting up local centers for clinical development and building a structure that ensures that we can perform clinical development and apply for approval by ourselves. In April 2019, we transferred the functions of the Global Clinical Development Division from Japan to our US subsidiary ONO PHARMA USA, INC. We will pursue organizational improvements that enable us to also, in addition to early-stage clinical trials, conduct late-stage clinical trials in the US and Europe and conduct application for approval through consultation with the regulators.

As a first step in business development in the US and Europe, we intend to market in-house developed products in the specialty domain that does not require a large-scale sales organization. We will sell such new drugs with efficacy and safety expected superior to those of the competition, and which can increase our presence there. Among our current pipelines, we consider, as global development pipelines, compounds under development to treat hematologic cancer or neurological disease, so that we can deliver new drugs to patients worldwide.

We continue upgrading our drug development infrastructure in Japan, the rest of Asia, the US, and Europe to strengthen and speed up our global development system.



Strengthening Corporate Infrastructure

ONO continues to strengthen its corporate infrastructure to increase corporate value and realize sustained growth. We are also training personnel who can respond to various environmental changes while leading globalization and increasing diversity and we are strengthening activities for Environment, Society and Governance to fulfill our social responsibilities to all stakeholders.

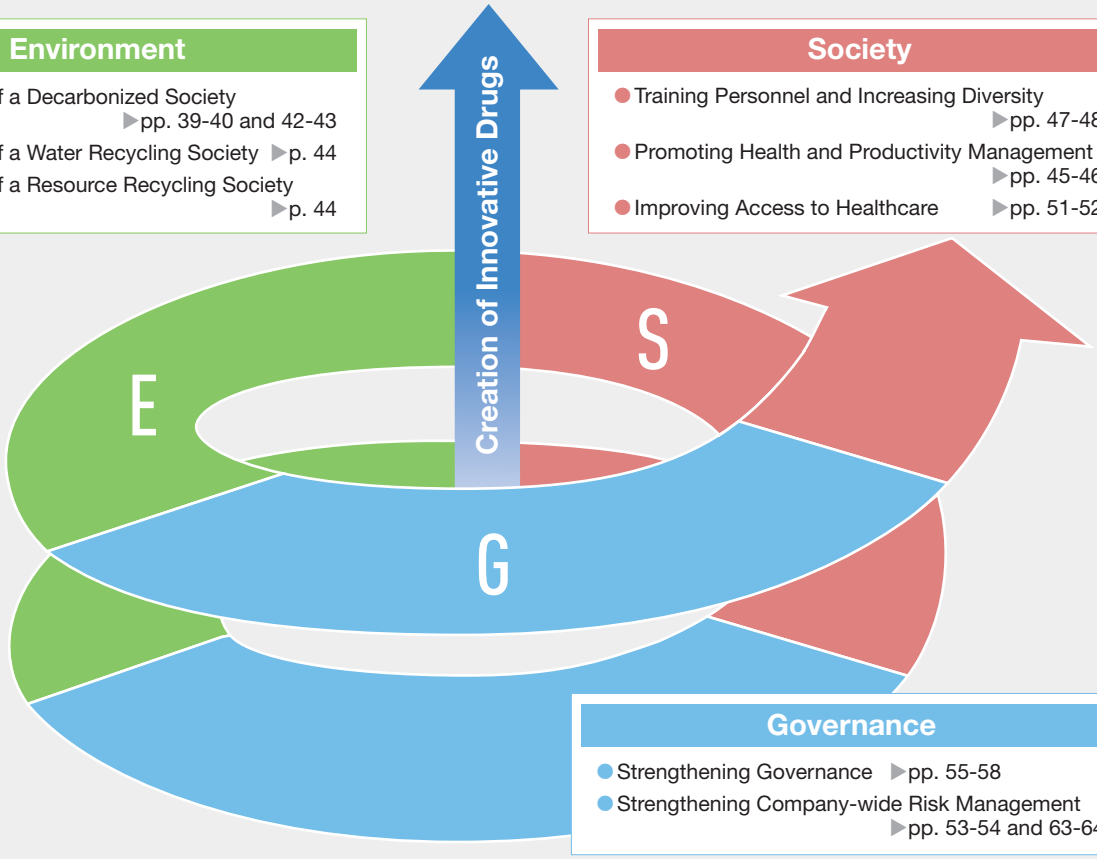
Global Specialty Pharma

Environment

- Realization of a Decarbonized Society ▶pp. 39-40 and 42-43
- Realization of a Water Recycling Society ▶p. 44
- Realization of a Resource Recycling Society ▶p. 44

Society

- Training Personnel and Increasing Diversity ▶pp. 47-48
- Promoting Health and Productivity Management ▶pp. 45-46
- Improving Access to Healthcare ▶pp. 51-52



Governance

- Strengthening Governance ▶pp. 55-58
- Strengthening Company-wide Risk Management ▶pp. 53-54 and 63-64

Strengthening ESG Initiatives

One of major triggers that led ONO to focus on ESG is the release of anticancer drug OPDIVO in 2014. While the concept of ESG has spread around the world, ONO produced an innovative new drug, OPDIVO, that we could deliver to patients globally and it became increasingly important to evolve as a company that could be admired from global standards. Consequently, we established our mission statement, developed a system whereby diverse employees and organizations can engage in business while being aware of the mission statement, created an environment where diverse personnel can enjoy working, and strengthened the training of personnel.

We also consider that it is important to listen to the voices of diverse stakeholders and contribute to resolving social issues and achieving a sustainable society, and we are continuously strengthening activities towards ESG. In FY2018, based on external environmental changes and societal demands, ONO identified priority issues (materiality) for engaging in CSR management and specified SDGs to which ONO should particularly contribute to achieving. We believe we can achieve sustainable growth for ONO and society by steadily performing PDCA of materiality and responding to the expectations of stakeholders.

Use of External Evaluation

Increasing external evaluation is one of our policies for engaging in activities for ESG. From various evaluations, we have narrowed down 8 targets and engaged in activities by establishing goals for each target. As a result, steady progress has been seen as shown in the following table.

External ESG Evaluation

External Evaluation	FY2017	FY2018	FY2019
CDP	Climate Change: A- Water: B	Climate Change: A Water: B	Climate Change: A Water: A-
FTSE	Score: 2.8/5.0	Selected Score: 3.2/5.0	Selected Score: 3.4/5.0
MSCI	Score: BBB	Score: BBB	Selected Score: A
DJSI	Score: 16/100	Score: 19/100	Score: 60/100
Toyo Keizai CSR Ranking	Rank: 254/1413 companies	Rank: 180/1501 companies	Rank: 121/1593 companies
Nikkei Smart Work survey	—	3.5 stars ★★★½☆	4.0 stars ★★★★☆
Nikkei SDGs	—	—	4.5 stars ★★★★½
Survey on Health and Productivity Management	Top 60~70% /1239 companies	White 500	2020 Health & Productivity Stock White 500

History of ONO's Efforts towards ESG