

Top Message

**Discovering Innovative Drugs to Accomplish Our
Social Mission, We Steadily Pursue Growth
Strategies to Increase Our Corporate Value**



G. Sagara

Gyo Sagara

President, Representative Director, and CEO

Corporate and Management Philosophies

We will continue being challengers to overcome the fight against disease.

“Dedicated to Man’s Fight against Disease and Pain.” This is ONO PHARMACEUTICAL’s corporate philosophy. This spirit of enterprise, which we have continuously upheld since our foundation in 1717, is engraved on the stone monument at the Minase Research Institute, built in 1968. With more than 300 years passing since ONO’s foundation, human society and life have changed considerably but people’s desire to stay healthy and our mission of delivering innovative drugs to patients around the world have been and will be unchanged. Our corporate philosophy represents our enthusiasm condensedly and serves as a basis on which all employees work.

In 2014, when we started to take fully-fledged steps to become a Global Specialty Pharma by competing in the global arena, our

corporate philosophy took concrete forms and there grew a trend to reflect it on each employee’s behavior. Our workforce diversifying through overseas expansion, we faced the need to provide signposts for employees to work toward common goals. In response to this tendency, we incorporated Our Vision “Be Passionate Challengers” and Values in a mission statement in 2014. We have since been working to hold workshops regularly for all employees to deepen understanding of Our Vision and Values, so that, if demotivated, they can go back to the mission statement to make appropriate decisions. I myself call it to mind from time to time to drive myself to pursue my mission as president.

Influence of Novel Coronavirus Infectious Disease (COVID-19)

Even in unprecedented circumstances, we continue business activities to accomplish our social mission as a life science company.

Looking at the situation that society is in now, “Man’s Fight against Disease and Pain” is going on worldwide due to the novel coronavirus infectious disease (COVID-19). We would like to express our heartfelt sympathy to all those who have been affected by the pandemic. We would also like to wish them a speedy recovery.

Even under these circumstances, the primary social mission for us to accomplish as a life science company is to ensure the stable supply of drugs. Fortunately, our sources of raw materials are mainly located in regions without explosive outbreak of virus, and we have confirmed that there is no problem with the procurement of materials in the year ahead. In addition, drug production also continues in full operation at two plants in Japan (Fujiyama Plant and Yamaguchi Plant). Our plants are in less densely populated areas and employees drive to work there, facing lower risk of infection. We ensure that infection prevention measures are in place within the plants to secure stable supply while keeping employees safe and healthy.

Meanwhile, research and development (R&D) projects that can be easily resumed have been suspended and employees engaged in them have shifted to telework to prevent the spread of infection. Since it takes 10 years or more to complete drug R&D projects due to their nature, we expect that we can make up for months of delay by gradually returning to normal operations, depending on the status of control of the infection. We are also hoping to contribute to R&D of anti-COVID-19

drugs. In June 2020, we started clinical trials with FOIPAN (generic name: camostat mesilate), an oral protease inhibitor we manufacture and market for the treatment of chronic pancreatitis and other conditions, because several basic research papers suggest that the drug may be effective against the COVID-19 infection. In addition, we are providing clinical research products at the request of medical and research institutions inside and outside Japan, to work for development as a company that owns drugs with potential to treat coronavirus.

Regarding information dissemination activities to healthcare professionals, we have temporarily refrained entirely from visiting medical institutions. In the meantime, we have reaped a harvest of findings about the benefits and limitations of digital technology with widespread of remote meeting and teleconferencing. Taking advantage of this experience in addition to two years of development and use of AI-based MR support tools, we will further promote use of digital technology in information dissemination activities.

In this connection, the earnings forecast for FY2020 expects a slight decrease in revenue due to the negative impact of refrained activities and decreased hospital visits if we have to continue to refrain from visiting medical institutions. With decreased business activities leading to reduced spending, however, the impact on operating profit is estimated to be insignificant. If it becomes necessary to revise the earnings forecast, we will disclose it promptly.

Business Environment Awareness and Medium- and Long-Term Challenges

In an increasingly difficult management environment, we understand it is important to further expand the development pipeline and promote overseas expansion.

The environment surrounding the pharmaceutical industry remains tough. In developed countries, healthcare cost reduction measures including NHI drug price reduction are inevitably further promoted with populations aging and birthrates dropping, as well as with social security spending cuts due to weak financial conditions. In addition, more fierce development competition between pharmaceutical companies have shifted targets with unmet medical needs for drug discovery and development to more complicated diseases. As a result, drug discovery has become increasingly more difficult, and prolonged development periods and increased R&D costs have become challenges that pharmaceutical companies commonly have to address.

As a longer-term challenge to address, we also have to protect ourselves against patent-cliff risks associated with patent expiration of our biggest growth driver OPDIVO. Currently, the anticancer drug makes up more than 50% of the ONO PHARMACEUTICAL GROUP's revenue. However, until 2031, when OPDIVO reaches patent expiration, we must discover new drugs that will subsequently drive growth. As it is unlikely to discover only one new drug as highly profitable as OPDIVO, we assume that it is necessary to continually develop new drugs. Another medium- and long-term challenge we are aware of is to reinforce overseas business expansion. The domestic

prescription medicine market size is currently valued at 10 trillion yen but the market is not expected to expand in the future with the population aging and birthrate dropping as well as with the financial base weakening. The importance of overseas markets is therefore increasing for us. We aim to establish itself as a Global Specialty Pharma with original and innovative new drugs in competing in the global arena. In South Korea and Taiwan, we have already started selling our products. We are also proceeding with developing our own sales organizations in the US and Europe, striving to expand revenue sources into overseas markets.



Business Models

We strongly promote open innovation based on our unique drug discovery “Compound-Orient” approach.

ONO PHARMACEUTICAL is made unique among many pharmaceutical companies in the world by its own drug discovery approach called “Compound-Orient.” Since successful total chemical synthesis of bioactive lipid prostaglandins (PGs) in 1968, we have successfully launched many PG-related products on the market. The Compound-Orient is a drug discovery approach focusing on unique bioactivity and unique target compounds to find diseases against which drug candidates are most potentially effective. It has the potential to lead to discovering original and innovative new drugs that only ONO can create. Thanks to this drug discovery approach, we have successfully discovered a cancer immunotherapy drug with innovative mechanism of action, with focus on the potential of PD-1 of which physiological function was long unknown. However, the approach is highly risky and it is difficult to keep on discovering innovative drugs in-house alone with innovation in medical technology progressing so rapidly.

We therefore concentrate on open innovation. We have worked on R&D in collaboration with research institutes including

universities for 60 years since before the words “open innovation” started to become widely used. Currently, we continue to vigorously pursue collaborations in various forms: research collaborations with world top-class researchers, drug discovery alliances with biopharmaceutical companies with advanced technologies, in-licensing of new drug candidate compounds of high value in corporate strategy and efficiency, provision of research grants to academia through Ono Pharma Foundation.

In addition, we established Ono Venture Investment Fund I, L.P. (July 2020), a venture capital fund that invests in early stage biopharma startups, and the subsidiary Ono Venture Investment, Inc. (May 2020), which manages that fund, in the US for the purpose of in-licensing of or forming partnerships for drug targets and cutting-edge technologies. Using good judgement cultivated through more than 60 years of experience in open innovation, we will also enter into capital tie-ups with promising biopharmaceutical companies to further enhance our competitiveness in drug discovery and R&D.

Growth Strategies

We pursue four growth strategies to achieve sustained growth.

To become a Global Specialty Pharma, we pursue four growth strategies: “Maximizing Product Value,” “Game-changing R&D,” “Globalizing Business,” and “Strengthening Corporate Infrastructure” (see pp. 29-38).

The strategies have made progress in the past year. For Maximizing Product Value, we received approval of OPDIVO for two additional indications in February 2020, resulting in 9 cancer indications. In particular, one additional indication is esophageal cancer, which makes the drug the first immune checkpoint inhibitor in the world to be approved for the disease. We also received approval of ORENCIA for S.C. Injection and ORENCIA for I.V. Infusion to include the description of prevention of structural damage of joints in current indication of rheumatoid arthritis. In addition, we received supplemental approval of KYPROLIS for Intravenous Injection for additional dosage and administration for treatment of relapsed or refractory multiple myeloma. This approval allows the drug to be administered once-weekly leading to superior convenience, in addition to

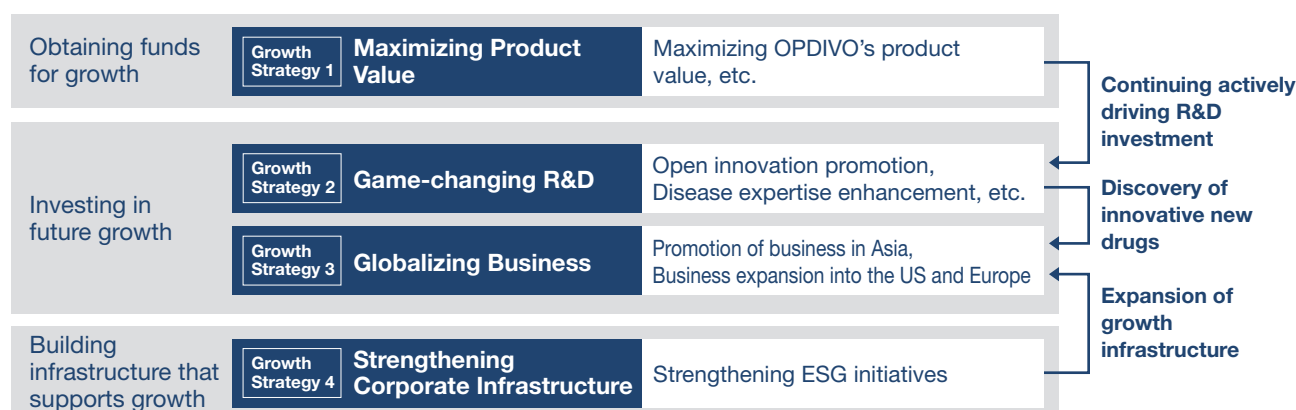
conventional twice-weekly administration.

For Game-changing R&D, we have identified the oncology, immunology, neurology, and specialty domains with high medical needs as our priority areas of research, focusing management resources into these areas to enhance disease expertise in each. As described above, we have established a corporate venture capital in the US, which is expected to lead to further strengthening of our open innovation and earlier acquisition of new technologies.

For Globalizing Business, we transferred the functions of the Global Clinical Development Division from Japan to our US subsidiary in April 2019. We have completed organizational improvements that enable us to conduct clinical trials and approval application work in the US and Europe.

For Strengthening Corporate Infrastructure, we put enterprise risk management (ERM) in place in FY2019, establishing an entire risk management system, under which we identify risks and decide how to respond to them (see pp. 53-54 and 63-64).

● Four Growth Strategies towards Accomplishing Growth Scenario



Strategic Investments for Growth

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

Strategic investments are essential to building piles of future growth. We believe it important to focus our finite management resources on drug discovery and development as an R&D-based pharmaceutical company specializing in new drug development. Our focus of investment is on creating new innovations and developing human resources.

We have pursued quality, not scale, in drug discovery. However, we need a certain scale to secure quality so that we can

compete and survive in the fiercely competitive global marketplace in the future. Currently, developing a new drug in Japan costs about 20 billion yen but it takes 10 times that amount, or about 200 billion yen, to develop globally. Even if we created an excellent new drug candidate compound, we would have no other choice but to earn royalties from licensing out it, without enough funding and know-how to conduct clinical trials globally. Given these circumstances, we aim to increase its

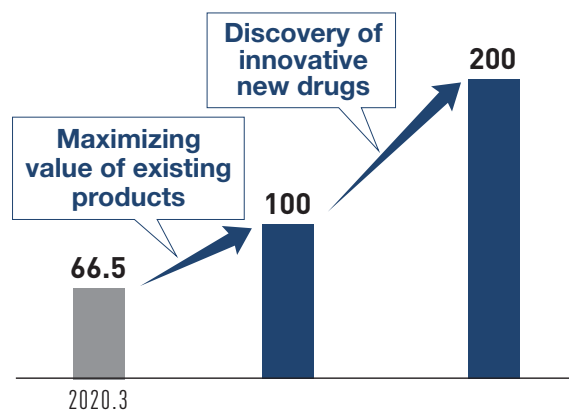
● R&D Investment Policy

Focusing limited management resources into drug discovery and development

Creating new innovations

Developing human resources

R&D investment objective (billions of yen)



annual R&D expenditure from the current 70 billion yen, to 100 billion yen initially, and eventually to 200 billion yen, the highest level in Japan. In order to invest that much in R&D, of course, we need to increase sales. However, we expect it is possible to increase the R&D expenditure to 100 billion yen by maximizing the value of existing products, especially OPDIVO.

Regarding human resources, we put considerable effort on the development and acquisition of global human resources. We have started with posting young employees of the research

department to joint research and drug discovery alliance partners in Europe and the US. Currently, we are trying out similar programs in the development, clinical trials and marketing departments. We have also acquired many talents through mid-career professional recruitment. Considering that highly qualified workers are more mobile, we focus particularly on developing our younger employees. We strive to create an attractive work environment that can retain them as long as possible.

Toward Increasing Corporate Value

We believe it important to provide value through business activities to continue being a company that is valued and needed by society.

I would like to clarify again what values ONO aims to offer as a member of society.

We believe that our corporate value lies in continuously creating drugs that can cure diseases that have been incurable so far. And our mission is to consequently bring health and smiles to people. The negative aspects of pharmaceuticals, such as drug cost increase that is putting pressure on health insurance finances, have often gotten much attention. However, creation of good medicines might help increase people's healthy life expectancy and the number of people who can work well into older age, leading to the productivity of the country and in turn the increased tax revenue to reduce the financial burden of social security.

In addition to offering value through our core business as a pharmaceutical company, we believe it also important to carefully listen to diverse stakeholders and contribute to solving issues facing society and creating sustainable society. For this,

we continue to strengthen our environmental, social and governance (ESG) initiatives. In FY2018, considering changes in the external environment and the demands of society, we defined important corporate social responsibility (CSR) issues (materiality) to be addressed. We also analyzed how the materiality is related to the sustainable development goals (SDGs), and chose SDGs that we should particularly contribute to achieving.

To pursue the initiatives, we have clarified vision. We have also set specific goals and extracted issues through information collection and analysis to collaborate internally and externally. In addition, we have focused on enhancing external ESG evaluations and our activities to date have been steadily bearing fruit. Through these activities, we will continue being "a company that is valued and needed by society." I believe this is nothing but enhancing ONO's corporate value.

ESG Initiatives

We strengthen environmental, social and governance initiatives.

In relation to activities to address most pressing environmental challenges facing the world, we established a medium- and long-term environmental vision called “ECO VISION 2050” in June 2019, in which we set a goal of becoming an environmental leading company in the pharmaceutical industry by 2050. We have defined three important items as “Realization of a decarbonized society,” “Realization of a water recycling society,” and “Realization of a resource recycling society,” and have set up specific medium- and long-term targets for each, starting activities to achieve them. In particular, regarding realization of a decarbonized society, we have set a high target of reducing greenhouse gas emissions (scopes 1 and 2) by 55% in 2030 compared to FY2017 and to zero in 2050 (see pp. 39-40). This target has been approved by the Science Based Targets initiative (SBTi) as science-based, categorized as the strictest “1.5°C target.” To achieve the target, we have developed a highly feasible roadmap to advance our efforts. We



also expressed our support to the Task Force on Climate-related Financial Disclosures (TCFD) in October 2019 and are committed to proper information disclosure based on the TCFD's recommendations.

Regarding issues facing society, we focus on efforts to improve access to healthcare, in which we are deeply involved as a pharmaceutical company. As part of such efforts, we promote R&D of drugs for pediatric patients, as well as patients with rare diseases and intractable diseases for which medical needs are still unmet. We also participate in the Global Health Innovative Technology Fund (GHIT). As a unique initiative, we implement the ONO Switch Project, which donates to healthcare NPOs and NGOs amounts equivalent to reduction in overtime payment through our reform of working practices (see pp. 51-52). In addition, we work on health management to ensure that our diverse employees can work vigorously to their fullest extent (see pp. 45-46).

Strengthening corporate governance is also a critical issue in earning the confidence of society. Since the implementation of a Corporate Officer system in 2011 to ensure legal compliance as well as management transparency and soundness, we have made effort to enhance our effective governance system to separate management supervision from execution. We have made steady progress in this effort. In 2018, we increased the number of outside directors by one to three, and in June 2020, we appointed its first female external director. We continue to be committed to developing a more effective governance system considering the business environment surrounding our business results and us.

Relationships with Stakeholders

To grow sustainably in the future, we will continue to meet the expectations of all stakeholders.

Companies work with various stakeholders in pursuing business activities. To attain sustained growth toward becoming a Global Specialty Pharma, we have to build and continue strengthening relationships with all stakeholders through business activities respecting their interests and dialogues with them. We therefore adhere to the policy of disclosing necessary information accurately, fairly, impartially, and promptly to all stakeholders. We consider the redistribution of profits to shareholders as a vital management policy. In terms of dividend payout, we will prioritize stable dividend distribution while making appropriate distribution of our profits in line with our business performance. We will flexibly consider and carry out the purchase of treasury shares, as usual, keeping future demand for funds in mind, for the purpose of redistributing more profit to shareholders, raising capital efficiency or tightening the supply-demand balance in the stock market.

The road to become a Global Specialty Pharma is not easy. I believe that passion is the key to achieving this goal. For example, when a biopharmaceutical company with an excellent compound choose a partner to out-license the compound, the company must examine the development, marketing and funding abilities of the partner candidate. However, whether the candidate will agree to enter into alliance depends on the level of passion the company shows. As Our Vision in the mission statement states “Be passionate challengers,” passion drives to overcome difficulties. If the company sets the right goals with passion, people, money, and compounds will come together with the company. With this truth in mind, we at ONO PHARMACEUTICAL will continue being passionate challengers in Man's Fight against Disease and Pain. We highly appreciate your continued and most generous support and cooperation in these endeavors.