Top Message

Gyo Sagara

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President, Representative Director, and CEO

Aiming to Be a Global Specialty Pharma, We Further Accelerate Growth Strategies and Increase Our Corporate Value

FY2020 Review

Despite the COVID-19 pandemic, we have achieved increased revenue and profits and enhanced our R&D capabilities to pursue further growth.

During FY2020, the world experienced unprecedented challenges from the novel coronavirus infectious disease (COVID-19). Despite the negative impact of COVID-19 on our corporate activities, we have achieved increased revenue and profits for three consecutive years, posting record-high sales revenue of over 300 billion yen. As a pharmaceutical company specializing in new drug development, our research and development (R&D) activities over the past 5 and 10 years have contributed to our current business performance. In other words, our sound business growth is a testament to our continued efforts in the past. In addition, departments in charge of sales, post-marketing surveillance, etc. have also exerted relentless efforts to navigate through the adversity of COVID-19. I am genuinely proud of achieving the milestone sales revenue of 300 billion yen even in such adverse circumstances.

Meanwhile, our R&D performance is highlighted by the acquisition of regulatory approval for 11 new drugs in Japan in 2020, the largest number of new drugs in one year. While being a medium-sized company, these significant results have been achieved because we have been promoting open innovation more vigorously than our competitors. To cite an example, we are currently undertaking approximately 200 joint research projects at home and abroad. Such solid research foundation and our constant pursuit of innovation give us a competitive advantage over larger-sized pharmaceutical companies.

In our response to the COVID-19 pandemic, we actively accelerated digitization and learned its utility and limitation. While introducing online meetings early to improve business efficiency, we realized the importance and appropriateness of face-to-face meetings where people get together to freely exchange and realize ideas. It was unfortunate that since lecture meetings also went online, opportunities for participants to exchange information at a banquet after a seminar were no longer available. We will take advantage of what we have experienced and learned during the pandemic in our activities post-COVID-19.

Industry Environment and Medium- to Long-term Challenges

R&D and overseas expansion hold the key to our growth in the next 5 and 10 years.

The business environment surrounding pharmaceutical companies has become increasingly tough. Reduction of social security to cope with the aging population and the dropping birthrate as well as the weakening financial base has negatively impacted drug prices. On the other hand, development competition among pharmaceutical companies has reduced the areas with unmet medical needs with success rates of drug discovery still remaining low.

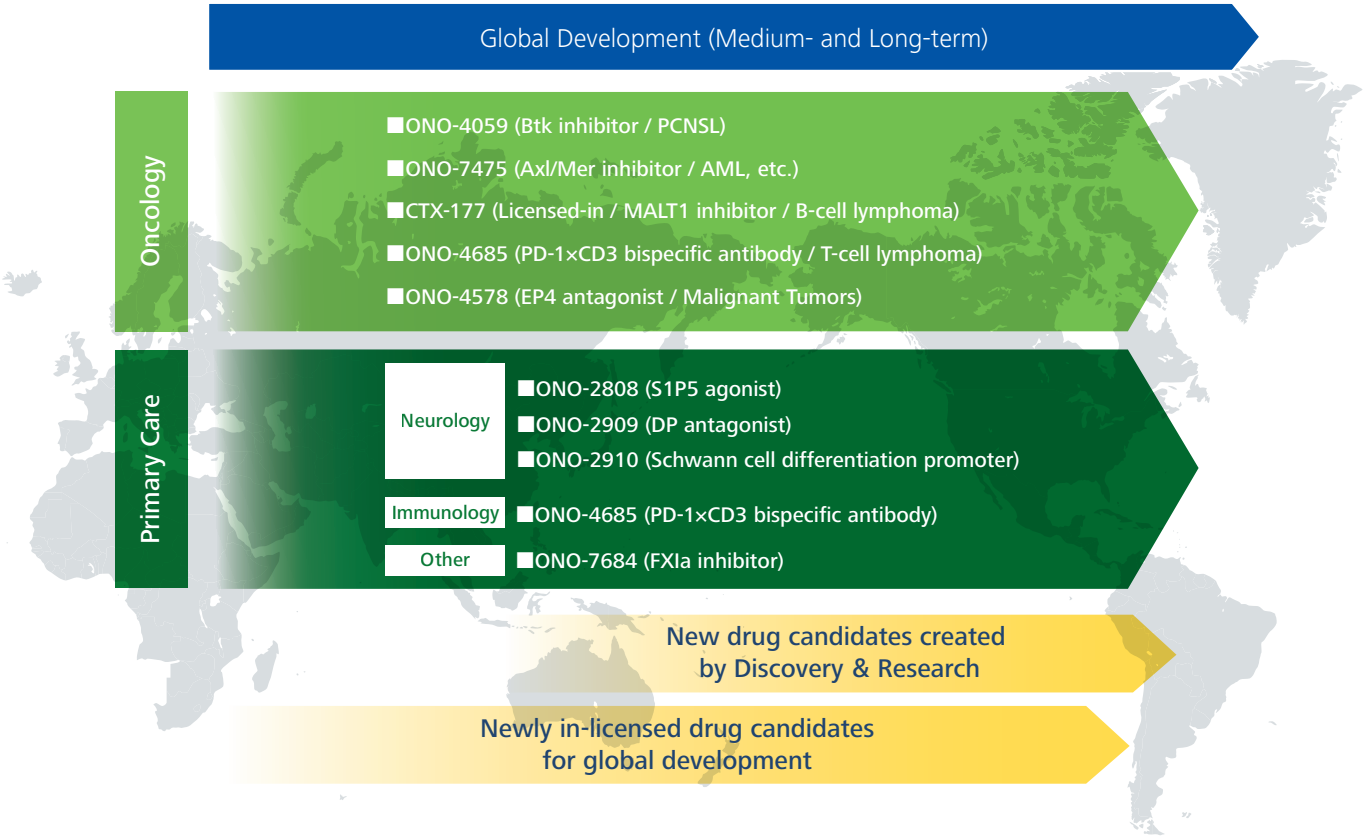
In these circumstances, we will face the patent cliff for our biggest growth driver, the anticancer drug OPDIVO for I.V. Infusion, 5 and 10 years later. The royalty revenue associated with PD-1 and PD-L1 patents will start to decrease in 2024 and terminate at the end of 2026. OPDIVO will reach patent expiration in Japan and abroad in 2031 and 2028, respectively. In order to overcome the patent cliff, we have been placing top priorities on the creation of new drugs and overseas expansion.

Specifically, we aim to address the patent cliff expected in 2026 and 2031 by overseas expansion and launch of products developed in-house and further growth overseas, respectively. It is vital for us to have promising new drug candidates to prepare for their launch 10 years later. Hence we have to work extremely hard for the coming couple of years to achieve our target.

Designating the oncology, immunology, neurology, and specialty domains with high medical needs as priority areas, we have been focusing our management resources on these domains. Specifically, in addition to ONO-4578 (EP4 antagonist) for the treatment of malignant tumors and ONO-4685 (PD-1×CD3 bispecific antibody) for the treatment of autoimmune disease, compounds developed in-house have successfully entered the clinical stage including ONO-2910 (Schwann cell differentiation promoter) for the treatment of peripheral neuropathy, ONO-2909 (DP1 antagonist) for the treatment of narcolepsy, and ONO-2808 (S1P5 receptor agonist) for the treatment of neurodegenerative disease. We also actively promote open innovation as well as using modalities including antibodies, nucleic acids, cells and viruses in addition to pursuing small molecule drug discovery in order to provide innovative treatment options.

Regarding overseas expansion, in the US, we have initiated a phase II clinical trial of BTK inhibitor VELEXBRU Tablets (ONO-4059), which has already been launched in Japan for the treatment of primary central nervous system lymphoma (PCNSL) and Waldenstrom macroglobulinemia (WM)/lymphoplasmacytic lymphoma (LPL). We also expect to commence clinical trials of multiple compounds this year. The scale of the US market is five times larger than that of the Japanese market. That is, if we can launch a product with domestic sales of 20 billion yen in the US, sales of about 100 billion yen can be expected. Such huge sales will help us not only compensate for the negative impact of the patent cliff but also realize further growth.

▶Continuous pipeline and overseas expansions



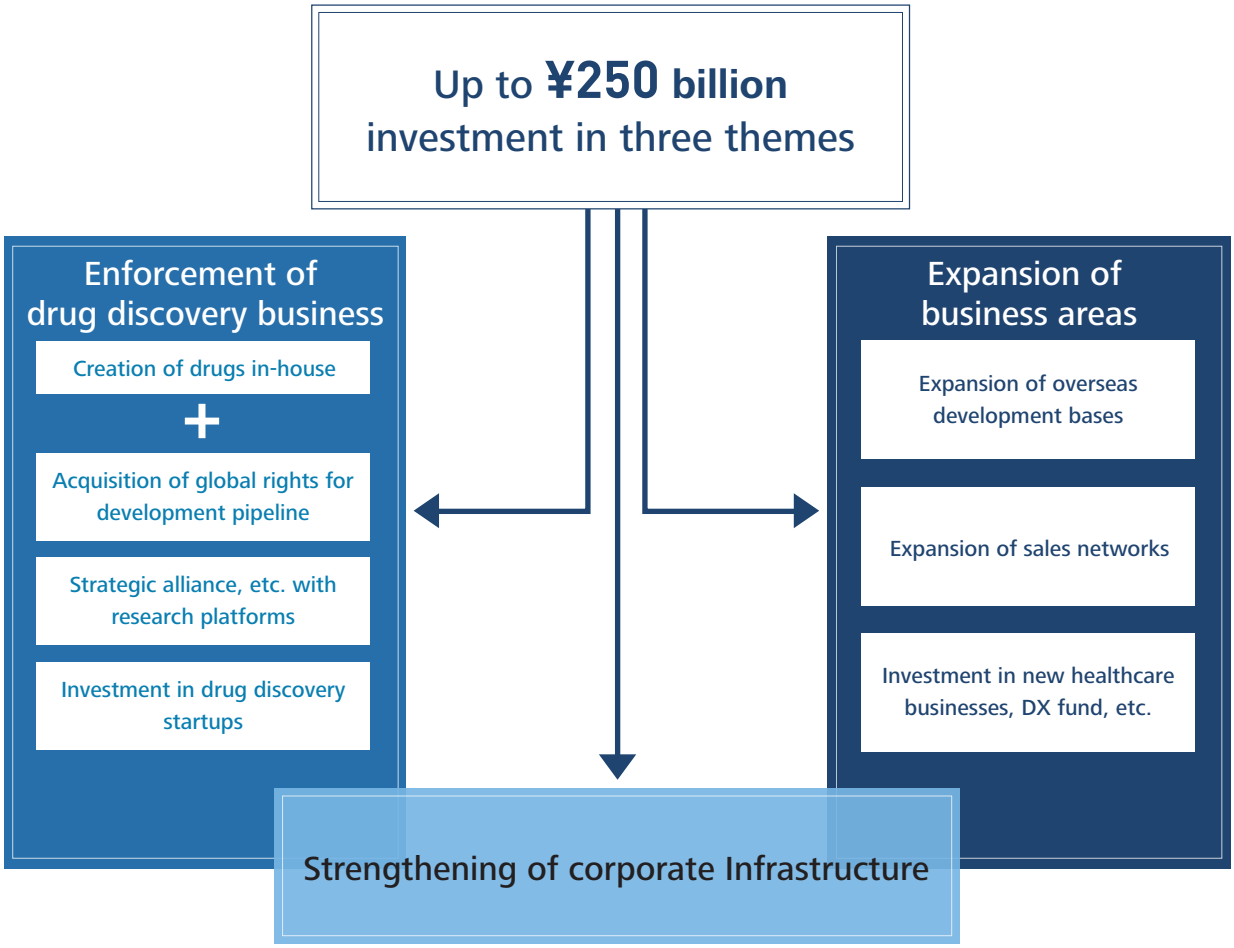
Strategic Investment to Promote Sustainable Growth

Investment policy to promote four growth strategies

In order to attain sustainable growth of our company, we have to acquire resources for growth by maximizing product value and to make investment for future growth. As described in our growth strategies and investment policy that were presented at the time of the announcement of financial results in May 2021, we will invest 200 to 250 billion yen over the next 5 years with cash generated by reduction of cross-shareholdings (100 billion yen) and cash on hand in the enforcement of the drug discovery business, expansion of business areas, and strengthening of corporate infrastructure.

Especially, placing our focus on the enforcement of the drug discovery business, we will invest at the largest scale ever into significantly strengthening our R&D capabilities. Our annual R&D cost will be increased from the current level of 70 to 100 billion yen. Separately, 150 to 200 billion yen will be invested over the next 5 years into the acquisition of global rights for proof of concept (POC)-established pipelines, strategic alliance and incorporation with research platforms, investment in drug discovery startups, etc.

For the expansion of business areas, we will invest in expanding overseas development bases and sales networks, new healthcare businesses, DX fund, etc. In our history of over 300 years as an R&D-based pharmaceutical company specializing in prescription drug development, we went through hardship when development of compounds in-house was terminated one after another. As previously mentioned, with the business environment becoming increasingly challenging, there is a risk that success/failure of R&D could directly impact our business results. One of the aims of entering new business areas is to mitigate such risk. As the first step of our endeavor, focusing on the healthcare business in which we can take advantage of the fruits of our research on prostaglandins and lipids, Ono Pharma Healthcare Co., Ltd. (a wholly-owned subsidiary of ONO), whose main business is health foods and foods with function claims in the healthcare field, was established in February 2021. Over the next 5 years, we will invest 30 to 50 billion yen in expanding business areas as well as strengthening corporate infrastructure focusing on digital infrastructure development.



Progress of Four Growth Strategies

Growth Strategy 1 Maximizing Product Value

Pursuing maximization of value of main products with high potential, centering on OPDIVO

We pursue maximization of OPDIVO's product value, with focus on the gastrointestinal cancers including gastric and esophageal cancers. There is a relatively large number of gastrointestinal cancer patients in Japan, South Korea, and Taiwan where we have marketing license for OPTIVO. While the number of gastric cancer patients is about one-tenth the number of lung cancer patients in Europe and the US, the numbers of these patients are roughly the same in East Asia. Hence it is important to expand OPDIVO use in order to increase treatment options for patients in this region. Meanwhile, the market holds a great potential; if OPDIVO is used in the first-line treatment for all domestic gastric cancer cases, the sales will reach about 110 billion yen. If it is used as relapse prophylaxis after surgery in all patients with high risk of relapse, the sales will be approximately 70 billion yen. Although OPDIVO will not be used for all patients in reality, we can further enhance the value of OPDIVO. To this end, we have been pursuing addition of indicated tumors and treatment lines, and development of combination therapies since the effect of OPDIVO as monotherapy is relatively limited.

With regard to our products other than OPDIVO, approximately 80% of the products will be replaced with their generic equivalents soon after patent expiration. Hence, in order to recoup R&D costs in a relatively short period of time, it is essential to achieve peak sales in the shortest period from launch. To this end, with the Medical Affairs Department playing the central role, we exert our utmost efforts to ensure the best preparation for product launch including pre-launch discussion with physicians on a science basis. One of our products with strong sales potential is FORXIGA Tablets for the treatment of diabetes. We received approval of the drug for the additional indication of chronic cardiac failure in November 2020. The approval for another additional indication of chronic kidney disease is also expected to be obtained in 2021. Our other promising products include ORENCIA for S.C. Injection for the treatment of rheumatoid arthritis, BRAFTOVI Capsules and MEKTOVI Tablets for the treatment of malignant tumors, ONGENTYS Tablets for the treatment of Parkinson's disease (launched in August 2020), ADLUMIZ Tablets for the treatment of cancer cachexia (launched in April 2021), and JOYCLU Intra-articular Injection for the treatment of joint function improvement (launched in May 2021). We will deliver the full potential of our products in order to acquire resources for further growth.

Growth Strategy 2 Enhancing R&D Capabilities

Expanding the development pipeline by enhancing open innovation and licensing activities, etc.

We place our focus on open innovation as well as licensing activities that we have been pursuing for years to enhance our R&D capabilities, showing successful results.

As a means of enhancing open innovation, we entered sponsorship agreements in February 2021 with LabCentral and MBC BioLabs, both of which are private, non-profit organizations in the US supporting the development of biotech startup companies. Thanks to the sponsorship, we can early access the most updated information of the companies supported by these organizations. Meanwhile, in March 2021, we joined the University of California Drug Discovery Consortium (UC DDC), which has allowed us to approach early-stage research themes originating from any of the seven US DDC campuses and to let our researchers attend symposiums, etc. hosted by US DDC. These are only a few of the various activities that we carry out. As previously described, approximately 200 joint research projects are currently underway in Japan and overseas. With our researchers participating in particularly promising joint research projects, we expect that their expertise and skills will be significantly improved.

We also actively seek opportunities for M&A of startups that possess attractive drug discovery platforms and compounds in order to strengthen our R&D capabilities.

With regard to our licensing activities, we entered into license agreements with SK Biopharmaceuticals Co., Ltd. (South Korea) for an antiepileptic drug in October 2020 and with Chordia Therapeutics Inc. (Japan) for an anti-hematologic cancer drug in December 2020. In February 2021, we also signed a license agreement with Ribon Therapeutics, Inc. (US) for an anticancer agent, thereby licensing in a new drug candidate compound. Under the terms of agreement with Chordia Therapeutics Inc., we have obtained exclusive global rights to develop, manufacture and commercialize CTX-177, a mucosa-associated lymphoid tissue lymphoma translocation protein 1 (MALT1) inhibitor, and related compounds. Although licensed-in drugs have previously been for domestic sales only, we are seeking acquisition of global rights to pursue expansion of our business operations overseas including the US.

Growth Strategy 3 Globalizing Business

Expanding our business in the US and making progress on the road to become a Global Specialty Pharma

For overseas expansion that holds the key to our future growth, we have been proceeding with developing our own sales organizations in the US. Meanwhile, in April 2019, we transferred the functions of the Global Clinical Development Division from Japan to our US subsidiary in order to conduct clinical trials and approval application work in the US and Europe.

In April 2021, we relocated the office of our US subsidiary from New Jersey to Cambridge, Massachusetts to pursue organizational enhancement. Cambridge is the home of world-leading universities/research institutions including Massachusetts Institute of Technology (MIT) and Harvard University as well as a number of the world's leading pharmaceutical companies and biopharma startups. Moreover, in geographical terms, there are more opportunities to attract top-tier talent in Cambridge than in New Jersey. The new office comprised of about 10 Japanese and 20 local staff came into operation, commencing a phase II study of BTK inhibitor VELEXBRU Tablets. While strengthening our development capabilities in the US, we will establish our own sales organization with hundreds of staff members over the next two to three years by setting up Marketing, Sales, Medical Affairs and Pharmacovigilance Departments.

In the US market, our target is a specialty domain that does not require a large-scale sales organization. Specifically, in the pursuit of our business expansion in the US, we will launch two to three in-house developed products in the niche domain, including VELEXBRU Tablets, put them on a steady growth track, and expand our product line to include those that require larger-scale operation.

Our focus of globalization is placed not solely on the US. After establishing our own sales organization in the US, we will further expand our development and marketing operations on a global scale. We strive to expand our operations not only in Europe, but also in China and ASEAN countries, thereby delivering valuable new drugs to patients around the world.

Growth Strategy 4 Strengthening Corporate Infrastructure

Enhancing our IT and digital infrastructure and launching new human resources development program

Our focus in strengthening corporate infrastructure is to enhance our IT and digital infrastructure in order to achieve digital transformation (DX). In early 2019, we designated the year as the first year of digitalization and established the Data Strategy Department in October the same year. With the department playing the central part, we have been working on the efficiency improvement of corporate activities and value creation by promoting company-wide use of real-world data (RWD). RWD refers to medical big data comprised of anonymized data about patient health status that can be utilized in many ways. For example, in a clinical study, if a placebo group can be replaced with a group whose data were acquired from RWD, it is not necessary to include a placebo group in the study, so that the associated cost and time can be significantly reduced. Moreover, RWD can be used for more sophisticated decision making in research and marketing, analysis of unmet needs, post-marketing surveillance, etc. Hence utilization of RWD has been actively promoted by pharmaceutical companies. Obviously, we have to keep pace with such a trend. To this end, we included digital infrastructure development in the previously mentioned investment policy and have been striving to establish an environment where big data and artificial intelligence (AI) can be effectively utilized (see pp.38-40).

Another focus in strengthening corporate infrastructure is human resources development, which is a key theme of our company. In order to create new innovations, it is essential to develop human resources who will contribute to innovation creation as well as to develop a corporate culture that helps employees take up challenges. In this context, in May 2021, we launched the Ono Innovation Platform, a program to support employees who take on challenges (see pp.49-50). The employees participating in the program are given opportunities to learn and experience how to create an innovation, and to take on challenges. For example, there is a program in which an employee is dispatched to a startup to carry out collaborative work, joint research, etc. to gain experience that is not available in-house. Although the initiative has just begun, there are more applicants than expected. We are looking forward to seeing their future endeavors. Thus, we encourage our employees not only to do assigned jobs but also actively take on challenges to enhance their capabilities to create innovations.

Steadily performing the PDCA cycle to continuously strengthen ESG initiatives

In our environmental, social and governance (ESG) initiatives to support sustainable growth of society, we carefully listen to stakeholders and define materiality (i.e. important corporate social responsibility [CSR] issues) to be addressed. Then we perform the PDCA cycle to cope with individual issues, thereby strengthening our ESG initiatives.

In relation to activities to address environmental challenges, under the medium- and long-term environmental vision called "ECO VISION 2050" established in June 2019, we have defined and been working on three important items as "realization of a decarbonized society," "realization of a water recycling society," and "realization of a resource recycling society." In particular, regarding realization of a decarbonized society, we have set a high target of reduction of greenhouse gas emission (scopes 1 + 2) to zero by 2050, which is classified by the Science Based Targets initiative (SBTi) as the most ambitious science-based "1.5°C target." We also expressed our support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) and joined the RE100 international initiative in June 2020. The RE100 is an international initiative that aims to have companies utilize 100% renewable energy for electricity used in their operations, and we are the first Japanese pharmaceutical company to join the initiative. As a company that aims to become a leading environmental company in the pharmaceutical industry, we vigorously pursue challenging targets, leading the whole industry.

Regarding issues facing society, we are committed to the creation of innovative drugs, which is our most important task as a pharmaceutical company. Meanwhile, in FY2020, which was the last year of our five-year action plan formulated in response to the Japanese government's enactment of the Act on Promotion of Women's Participation and Advancement in the Workplace, we showed visible results including achievement of our target of raising the retention rate of female employees to 90% or higher for five consecutive years. While we pursue diversity of our human resources in terms not only of gender but also of age, nationality, disability, etc., promotion of female employee participation in the workplace is one of the symbolic themes of diversity and inclusion. We will further strive to promote diversity and inclusion to become a company where everyone wants to work.

Meanwhile, we have been promoting strengthening of corporate governance over the past 10 years. In FY2020, we appointed our first female external director. On revision of the Corporate Governance Code stipulated by the Tokyo Stock Exchange in June 2021, companies are increasingly required to improve transparency and soundness of management. We continue to be committed to improving our governance system to respond to these social demands.

In FY2021, in response to changes in the social environment and in light of the opinions of stakeholders, we conduct a review of materiality. In accordance with the newly defined materiality, we continue to promote ESG initiatives that meet the needs of the times.

Future Prospects and Aspirations

Presenting a more specific blueprint for growth and proceeding to a new stage as passionate challengers

We aim to establish ourselves as Global Specialty Pharma that discovers original and innovative drugs to compete in the global arena. This is our ultimate goal. ONO is a pharmaceutical company that carries out activities from R&D to approval application and marketing in Japan. Overseas, however, ONO is merely a startup and licenses out its compounds to partner companies that carry out clinical studies, approval application, and marketing. Hence we have been exerting our efforts to become a true global pharmaceutical company for more than 10 years.

The next 5- and 10-year periods are extremely important periods for ONO in our pursuit of becoming a Global Specialty Pharma. To this end, we need to think backwards from the goal, carefully define milestones for individual stages, and draw a detailed blueprint that I sincerely wish to share with all stakeholders.

Our employees have joined the company because they were moved by our corporate philosophy "Dedicated to the Fight against Disease and Pain" and our vision "Be Passionate Challengers." Needless to say, they take on challenges with powerful passion. Where there is true passion, what we have to do is to define the right goals; people, money, and compounds naturally come together to realize creation of new drugs. Hence, we must always define goals carefully and meticulously. Specifically, since ONO is to explore new uncharted areas in the next 5- and 10-year periods, it is vital to set clear goals and present a blueprint for growth in order to keep the flame of passion of employees burning. In this context, I will start by drawing a fine-tuned blueprint for the next 5-year period by the end of this year.

The new stage for ONO that I envision is a stage where productive tasks steadily proceed toward the achievement of the defined goals. If the goals are in line with our corporate philosophy, our endeavors to achieve the goals will inevitably contribute to society, thereby giving employees a sense of motivation and purpose to work. Keeping these in mind and always going back to our corporate philosophy when in doubt, we provide an environment where everyone can put their passion into work. As a matter of course, ONO will continue to be a company of passionate challengers. As always, I really appreciate the continued support and cooperation of all stakeholders.