

Our Group Philosophy

SHIONOGI Group Heritage

**SHIONOGI strives constantly
to supply the best possible medicine
(healthcare solutions)
to protect the health and wellbeing of
the patients we serve.**

SHIONOGI Group Vision

Building Innovation Platforms to Shape the Future of Healthcare

SHIONOGI is transforming itself from a drug discovery-based pharmaceutical company to a HaaS* company in order to pursue the health that people truly desire and to deliver unprecedented new value to society.

*Healthcare as a Service: Provide a range of healthcare services in line with customer needs, rather than only providing pharmaceuticals.

Our Philosophy

The Company Policy of Shionogi

Shionogi's Purpose

Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve.

For this purpose, Shionogi will need to

Pursue the search for even better medicines.
Produce even better medicines.
Promote awareness of these better medicines to more people so that more people will be able to use these medicines.
Research, produce, and promote in an even more economical manner.

For this purpose, Shionogi will need to

Strive ceaselessly day after day to improve their skills.
Strive ceaselessly day after day to improve as human beings.

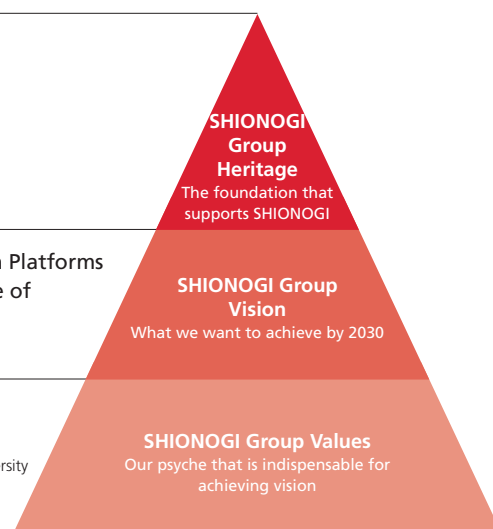
As a result, Shionogi people will

Find even greater satisfaction in their daily work and in their daily lives.
Find even greater improvement in the quality of their lives.
Find even greater prosperity in their lives.

Established in 1957

Building Innovation Platforms to Shape the Future of Healthcare

- Be trustworthy
- Be bold
- Be dauntless in spirit
- Build greatness out of diversity
- Contribute to society



The unwavering purpose of the SHIONOGI Group's corporate activities is expressed in the opening of the SHIONOGI Group Heritage as the image of what SHIONOGI should be and the Company's social existence values.

As people's lifestyles and values are changing irreversibly, their healthcare needs are becoming increasingly sophisticated and diverse. Unprecedented opportunities are emerging before us to deal with various needs that could not be solved in the past. SHIONOGI will continue to transform itself into a company that goes beyond the boundaries of a pharmaceutical company to provide the best healthcare solutions by being closely attuned to desires of people everywhere with regards to health.

We are committed to making people's dreams for the future of healthcare into reality.

*SHIONOGI is an abbreviation for the SHIONOGI Group

SHIONOGI is uniting globally to take a new step forward in transforming itself into a HaaS company

Capability and Vision, unified.

"Capability" that
has been built up



Reliable Weight
"Trust" and "Accuracy"

+

"Vision" for
evolution



Dynamic One Ring
Dynamic expansion and unity

=



SHIONOGI
Group Brand Logotype
Design that gives a sense of security
and trust

Our minds on the new group brand

The "FUNDOH" weight mark which stands "accuracy", "honesty", and "trust" has been a longtime Group Brand Symbol of Shionogi & Co., Ltd and its group companies.

Reflecting SHIONOGI's intention to transform to a global HaaS company, we have refined the Group Brand Symbol and logotype design and evolved it into an identity that embodies the new SHIONOGI.

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Forward-looking statements

This report contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks, and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions, such as general industry and market conditions, and changes of interest rates and currency exchange rates. These risks and uncertainties particularly apply to forward-looking statements concerning existing products and those under development. Product risks and uncertainties include, but are not limited to: completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms; and changes of laws and regulations.

For existing products, there are also manufacturing and marketing risks, which include, but are not limited to, inability to build manufacturing capacity to meet demand, unavailability of raw materials, and competition with other companies' products. The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events, or otherwise. This report contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy of these pharmaceuticals nor provide medical advice of any kind.

■ External evaluation

ESG index



2022 CONSTITUENT MSCI JAPAN
ESG SELECT LEADERS INDEX

2022 CONSTITUENT MSCI JAPAN
EMPOWERING WOMEN INDEX (WIN)



External recognition related to IR and sustainability



Other

Selected by domestic equity managers at the Government Pension Investment Fund as having an "Excellent Integrated Report" (second consecutive year)

■ Commitment to society



SHIONOGI has endorsed and supported the United Nations Global Compact. See our website for more information.
<https://www.shionogi.com/global/en/sustainability/ungc.html>

■ Editorial Policy

In order for stakeholders*1 better understand SHIONOGI's corporate value, we conduct integrated reporting based on integrated thinking.

■ Period covered

Results for fiscal 2021 (April 1, 2021 to March 31, 2022). Some of the activities after the same period are included.

■ Target organizations

This report covers 53 Group companies (the Company, 48 consolidated subsidiaries, 3 affiliated companies, and 1 jointly controlled entity). The scope of our environmental activities covers all of Shionogi & Co., Ltd business sites and major domestic group companies. For some indicators, major overseas group companies are also included in the scope of coverage.

■ Reference Guidelines

IIRC*2 "International Integrated Reporting Framework," "GRI (Global Reporting Initiative) Sustainability Reporting Standards," "ISO 26000," Ministry of the Environment "Environmental Reporting Guidelines 2018," and Ministry of Economy, Trade and Industry "Guidance for Collaborative Value Creation"

*2 IIRC was reorganized as the Value Reporting Foundation (VRF) in June 2021. VRF was integrated into the ISSB of the IFRS Foundation in August 2022.

■ Disclosure and engagement

Financial information

IR Library

<https://www.shionogi.com/global/en/investors/ir-library.html>

Securities report (JP)

<https://www.shionogi.com/jp/ja/investors/ir-library/securities-report.html>

Non-financial information

Sustainability

<https://www.shionogi.com/global/en/sustainability.html>

Policies

<https://www.shionogi.com/global/en/company/policies.html>

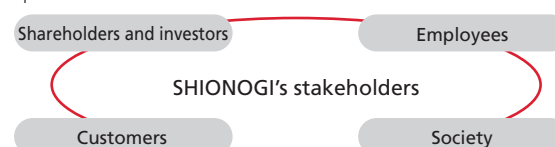
Basic Views and Guidelines on Corporate Governance

<https://www.shionogi.com/global/en/company/cg/basic.html>

Environmental Initiatives

<https://www.shionogi.com/global/en/sustainability/environment.html>

*1



**Special
Feature**

COVID-19 Initiative Results and Learning

Results

Commitment to fighting COVID-19

Pre-symptomatic phase/detection



- Provide wastewater epidemiological surveillance service by establishing AdvanSentinel Inc.
- Launch of mutational analysis service

Prophylactic vaccines



- Research and development of a recombinant protein vaccine
- Research and development of a nasal vaccine
- Research and development of a universal antigen vaccine

Diagnostic drugs



- Sales of antigen test kit products
- Sales of SARS-CoV-2 antigen test kit products for assisting in predicting exacerbation
- Sales of Th2 chemokine TARC kit for assisting in predicting exacerbation
- Online sales of PCR testing services for COVID-19 (SARS-CoV-2)

Therapeutic agents



- Research and development of antiviral drugs

Exacerbation suppression



- Research and development of pharmaceuticals to prevent severe disease

Support to local governments



- Support to health centers in Tokyo and Osaka prefectures

Ensuring a stable supply of pharmaceuticals



- Inventory management in cooperation with raw material suppliers and procurement contractors
- Thorough-going employee health management and measures to prevent the spread of infections

Providing disease information



- Providing information via websites

Business continuity initiatives



- Respond in line with our business continuity plan (BCP)
- Introduced systems in response to new workstyles, such as telework and staggered work hours

Cooperation/alliances with international societies



- Described our programs in a video submission to the UN's #Uniting Business to Respond to COVID-19 campaign

Initiatives for total care

As a leading company in infectious diseases, it is SHIONOGI's mission to combat the threat of COVID-19, which is having a significant impact on the lives, livelihoods, and economies of people worldwide. SHIONOGI has been working with public institutions, academia, and our partner companies to help bring COVID-19 to an early end through research, development, and provision of a wide range of medical solutions from a total care perspective, including detection (epidemic forecasting), prevention, diagnosis, treatment, and exacerbation suppression. In particular, the development of oral therapeutics that are effective, safe, and convenient is highly anticipated worldwide as we learn to live with COVID-19. Based on the results of the Phase 3 clinical trial of S-217622 (ensitrelvir), we will accelerate our efforts to commercialize the drug in

Japan and globally. In addition, we have made progress in several late-stage clinical trials for prophylactic vaccines, including comparative studies with existing vaccines, aiming for both initial immunity and booster immunity. We plan to file for approval as soon as the necessary data and production framework are prepared. Furthermore, in efforts related to epidemic forecasting, we have taken a major step toward social implementation of wastewater monitoring by establishing Advan-Sentinel Inc. with Shimadzu Corporation. In addition to this, we were able to start providing diagnostic drugs and kits that predict not only the presence of infection, but also individuals at risk of severe exacerbation. A Phase 2 clinical trial is in progress at our partner company for the development of a drug candidate for exacerbation suppression.

Things we were able to do because we are SHIONOGI

As a drug discovery-based pharmaceutical company boasting an internally-discovered pipeline ratio of 73% (as of March 2022), SHIONOGI places the highest priority on solving the problems of patients and society in its daily drug discovery activities. Small-molecule drug discovery in particular is one of our long-cultivated strengths. For example, information on the anti-HIV drug *Tivicay* was utilized in the chemical structure conversion of the influenza antiviral drug *Xofluza*, and great use was made of the knowledge gained from the discovery of *Xofluza* in the new COVID-19 therapeutic drug S-217622. Furthermore, the basic skeleton of S-217622 also utilizes the structure of S-600918, which is being developed for the treatment of chronic cough. SHIONOGI's accumulated experience

in antiviral research and small-molecule drug discovery has made it possible to create promising compounds with such amazing speed. In the evaluation of the drug efficacy of compounds, we have a library of bacteria and viruses that we have accumulated over the years, and we have a system in place that allows us to efficiently utilize this library in combination with our library of compounds. In addition, SHIONOGI's strength lies in its broad base of researchers who handle viruses in our Biosafety Level 3 (BSL-3, a Japanese standard) laboratories which only trained personnel are allowed to work with. We believe that these are the factors that enabled us to push through the challenge of COVID-19 with such promptitude.

Helping to restore the safety and well-being of society

We believe that helping to restore the safety and well-being of society through the early termination of the pandemic is our true contribution to the SDGs. If we gain favorable results from the Phase 3 clinical trial of S-217622, a therapeutic agent that enables early treatment of COVID-19 patients,

including those who are not at risk of severe exacerbation, we believe that this will contribute to the restoration of a society where people can live with peace of mind. Shionogi is making concerted efforts to achieve this goal.



How

As a leading company in infectious diseases, SHIONOGI is working with public institutions, academia, and our partner companies to develop therapeutic agents for COVID-19. We are building a distribution system so that we can deliver these therapeutic drugs to patients as soon as possible, progressing from drug discovery to clinical research to filing for approval at an unprecedented speed, as we adapt to constantly changing circumstances.



Takafumi Sato

Vice President, Laboratory for Drug Discovery and Disease Research
(At the time: Research Project Manager, Pharmaceutical Research Division)

Aware of the risks, taking up the challenge of “clinical trials within six months”

The research project manager guides the selection and evaluation of candidate compounds for development based on the lead compound (the predecessor compound of development candidates) found in the research theme and the drug discovery logic (evaluation methods, etc.). The COVID-19 project required a different level of speed. We were being asked to expedite the process of drug discovery, which normally takes three to five years, so that, through resource investment, we could begin clinical trials within six months. We could not possibly fulfill the deadline using our conventional step-by-step approach. We had to decide on taking the risk to manufacture the necessary drugs in order to quickly advance compounds that met certain criteria in the exploratory compound evaluation to the nonclinical pivotal studies conducted in compliance with the regulatory standards. The series of difficult stages proceeding the decision for clinical development cannot be described here in full. However, we were able to achieve early creation of S-217622 thanks to close strategic coordination between the President, division head, and project members under a general policy of “narrowing down actions to the minimum necessary and proceeding with risk-taking”; thanks to the laboratory’s concerted efforts based on our strengths in small-molecule and infectious disease drug discovery; and thanks to the cooperation of our external business partners who readily agreed to my reckless request to “bring all Japanese companies together” in response to the national crisis of COVID-19.



Masato Gomi

Formulation R&D Laboratory

Delivering easy-to-administer formulations to patients as quickly as possible

We took on the challenge of developing drug formulations at an unprecedented speed while adapting to the fast-moving changes in the development situation within a short period of time. We are designing a multi-dose formulation that can handle a wide range of clinical doses and a manufacturing process that enables seamless vertical start-up of commercial production, as well as planning a regulatory strategy to establish a maximum duration of use in a short period of time. Through these we were able to complete the application for manufacturing and marketing approval and begin commercial production (establishing a supply system for one million people in FY2021) within just ten months from the start of formulation development. We also made bold efforts to reduce the size of tablets in order to provide a high value-added formulation with an advantage over leading competitors’ products. This process was not always a walk in the park, but the whole team worked together to overcome these challenges and quickly devise ways to improve the situation. This allows us to complete our mission of delivering therapeutic drugs to patients as soon as possible. Our next mission is to provide this formulation globally and help patients in need all over the world.



Yuko Tsuge

Development Project Leader
Clinical Research Department

“All SHIONOGI” to take on a global mission

The Research Division staked its reputation as an infectious disease company on S-217622, a development compound to formulate entered the clinical stage in July 2021. At this point, there was no oral COVID-19 treatment in practical use, and there was a need for an innovative oral therapeutic that could be easily prescribed to a wide range of patients in order to control this unprecedented pandemic. From here, the fight began for the development project to deliver S-217622 to patients in Japan and around the world as quickly as possible. The development of S-217622 is a social responsibility, and the “All SHIONOGI” team, transcending organizational boundaries, aimed to obtain approval as quickly as possible. Through daily discussions with project members and management, I felt a sense of company-wide unity and the powerful impetus that comes with it. As a result of everyone’s continuous efforts to do their best, we were able to file for approval within a short period of about seven months from the start of Phase 1 clinical trial. We will continue the ongoing clinical trials to completion without any relaxation of efforts, aiming to obtain official approval.

**Yasuhiro Makino**

Regulatory Affairs Department

The challenge of filing for approval at an unprecedented speed

Our mission is to deliver S-217622 to society, healthcare professionals, and patients as soon as possible in response to the emergency of the COVID-19 pandemic. Although we are working to deliver the product as quickly as possible, we still have to ensure its safety and efficacy as we do with all other pharmaceuticals to date. In the pre-application state, it was crucial that we were able to seek solutions to various issues related to screenings and investigations and carry them out. It was also necessary to take prompt action to resolve issues from an early stage through close communication with the authorities. SHIONOGI began submitting relevant materials to the authorities in October 2021, filed for approval in February 2022 using the conditional approval system, and switched to the emergency approval system in May 2022. Based on the progress of the Phase 3 trial, the matter was continued for further discussion, but we will continue to work with the authorities to deliver the therapeutic drug as soon as possible.

**Yudai Iwaki**Shionogi Pharma Co., Ltd.
Technology Development Division

Pursuing quality along with speed

This COVID-19 project needed to be handled at a speed that would have been unthinkable in the past, as the commercial manufacturing system was to be established and ready for initial manufacturing in four months, before the results of the Phase 1 clinical trial would be available. While various matters such as formulation dosage, packaging capacity, and product name had not yet been decided, we shared and discussed numerous issues across the organization and proceeded with speedy decision-making and implementation in order to clear the extremely high hurdle of establishing an appropriate manufacturing system that complies with Good Manufacturing Practice (GMP). In addition, SHIONOGI Pharma was able to establish a commercial manufacturing system in the fastest possible timeframe by “Be bold” — developing efficient validation strategies to assure the quality of pharmaceutical products based on scientific evidence — while leveraging its accumulated experience and technology, and by making a concerted company-wide effort.

**Nobuaki Tanaka**

New Product Planning Department

In order to deliver to patients promptly and reliably

As the commercial team, we united under the shared mission of the research and development project teams to deliver S-217622 to patients as soon as possible, and collaborated in building a distribution system. We were required to finish as quickly as possible while responding flexibly to the ever-changing social environment and needs, such as the transition to the Omicron variant and the emergence of oral therapeutics. By making full use of our experience and know-how in building prescription registration systems for Vyvanse and OxyContin, we were able to build such a system (which is required post-approval) that meets all the necessary conditions in just three months from the start of the project. We are still working to build a system that will enable us to start providing S-217622 as quickly as possible by mobilizing the power of our team and responding to each of these ever-changing circumstances by adding the necessary support and expanded functions.

Learning from here

Since the outbreak of the pandemic in 2020, SHIONOGI has given top priority to the development of various solutions to achieve total care for COVID-19, while also making bold resource shifts. In the area of therapeutic drugs, SHIONOGI has promoted the establishment of R&D and production systems at an exceptional speed, and filed for manufacture and sales approval in Japan just about seven months after the start of clinical trials in July 2021. And we have learned a lot from our experience in this exceptional environment.

What SHIONOGI has learned

Importance of the ability to innovate

The COVID-19 pandemic instantly shattered preconceptions about the pharmaceutical business, where it is said to take 10 to 15 years before a new drug is launched. Without this experience, we could not have developed the risk-taking and speed-oriented way of proceeding in an emergency and the decision-making and judgment skills necessary to determine the effectiveness and safety aspects of a project. We have already begun to replace some of our Standard Operating Procedures (SOPs) for normal times with these emergency R&D procedures and have begun to deploy them in initiatives other than COVID-19. In addition, there are currently only two pharmaceutical companies in the world that have launched oral therapeutics that have been proven effective and safe, and that can be taken easily, and we are the closest to becoming the third company to do so. We were also able to reaffirm that SHIONOGI has the capability to create drugs at a high level, as it is taking on the challenge of developing drugs that can be used by a wider range of patients than the two preceding drugs. It was also an opportunity to recognize once again that SHIONOGI cannot continue to demonstrate its value to society unless it transforms its desire to solve the world's problems into "the power of *monozukuri* (product creation)" and continues to innovate.

Determination to deliver globally with our own hands

In the development of our COVID-19 treatment, we have to ask ourselves why there was such a large difference in the timing of our market launch compared to the two companies that preceded us, despite the fact that there was only a few months difference in the time it took to create the compound that would form the base of the drug. Various causes have been identified, such as differences in the countries where development took place and differences in the prevalent strains at the time of clinical trials. One possible cause raised is a "lack of commitment to global development". Until now, SHIONOGI has relied on its business partners for much of its global expansion, despite creating drugs that have attracted worldwide attention, such as dolutegravir-related products and *Xofluza*. An over-emphasis on entrusting global matters to our partners can limit the options for finding the fastest, most optimal solution. We at SHIONOGI are confident in the drugs we create, and are committed to delivering them on a

global scale by negotiating with governments and regulatory authorities in various countries. And we will continue to contribute to global health by clearly defining where we will put in the hard work and where we will entrust it to our partners.

Pursuing a sustainable infectious disease business model

This pandemic has given us an opportunity to clarify the reasons why SHIONOGI has been able to continue its infectious disease business to date and the challenges we must confront in order to sustainably continue our infectious disease business in the future. One of the reasons why we have been able to sustain our infectious disease business to date is that we have been dealing with drugs for chronic infectious diseases, such as HIV. Unlike acute infectious diseases, chronic infectious diseases require continuous treatment over a long period of time, and thus can be expected to provide a stable revenue stream. On the other hand, acute infectious diseases, such as seasonal influenza, are an extremely difficult business, as revenues are largely dependent on the presence or absence of epidemics, and even if an innovative new drug is launched, revenues can be significantly lower than expected for three consecutive fiscal years, as with *Xofluza*. As the world has reaffirmed during the recent pandemic, this business is indispensable for social and economic stability. Therefore, as a leading company in infectious diseases, we must urgently establish new business models in this area in order to continue in efforts to "protect people worldwide from the threat of infectious diseases", which we have identified as a key material issue.

■ SHIONOGI's Goals for FY2022 and Beyond

FY2021

Learning in the exceptional environment of a pandemic

- Significant resource shifts and process changes drove R&D and production at a new and amazing speed
- Recommendations for policy changes through the pharmaceutical industry



FY2022 and Beyond

Establishment of a sustainable infectious disease business model

- World-class drug discovery capability with speed, advanced decision-making, and effective resource allocation honed during the COVID-19 situation
- Further strengthening of the vaccine business
- Global expansion of the infectious disease business

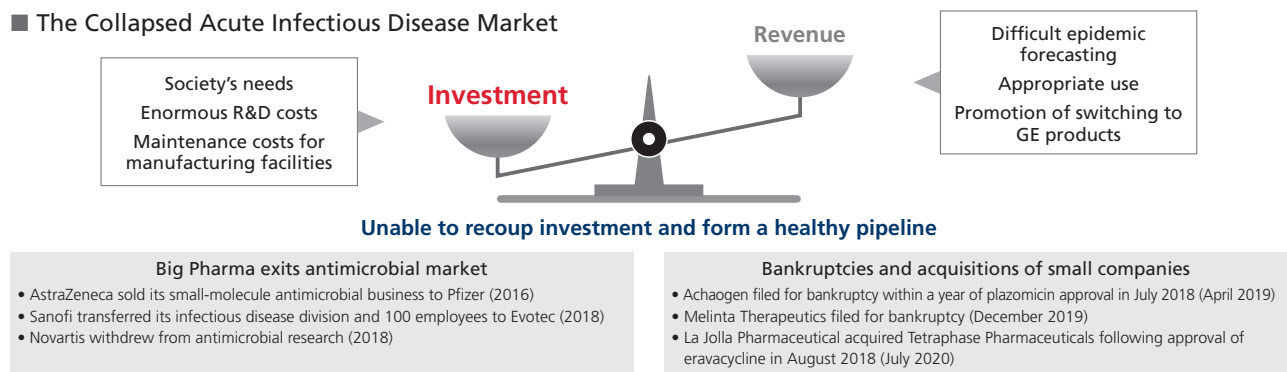
Leveraging the experience of the pandemic, continue pushing forward to achieve our goals without changing gears

Difficulties in the Infectious Disease Business

When we look at the global acute infectious disease market, we see cases of successful drug development that fail to pay back their investment and are subsequently bankrupt or acquired because not only is the market less predictable than in other disease areas, but also more powerful drugs are used only when other drugs are not effective in terms of proper use to prevent the development of new resistant bacteria or viruses. Even major pharmaceutical companies are withdrawing from this market one after another, citing inability to

recoup their huge R&D costs and maintenance costs for manufacturing facilities. If this situation continues, the number of specialized personnel conducting research in the area of infectious diseases, where investment is scarce, will also decrease, and the market will become less and less dynamic — a vicious circle that will keep expanding. Although dealing with infectious diseases is an indispensable initiative for society, it is an extremely challenging business model for pharmaceutical companies.

■ The Collapsed Acute Infectious Disease Market

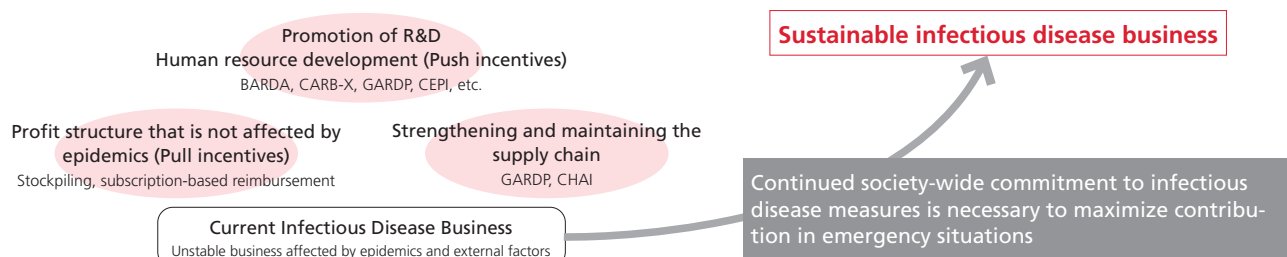


Building an Infectious Disease Business Model and Transforming to a HaaS Company

In order to build a sustainable infectious disease business model, SHIONOGI intends to combine efforts in chronic infectious diseases and vaccines, for which a healthy pipeline can be formed through stable earnings, and acute infectious diseases, for which profitability is difficult to predict but essential, to create an infectious disease business that is sustainable in its totality. The key issue for making this business model work is still how to manage the acute infectious disease business, but this is not a problem that can be solved by one company alone. The COVID-19 situation has triggered, especially among G7 countries, a renewed awareness of the importance of strengthening preparedness for global health threats, such as antimicrobial resistance (AMR), and has accelerated discussions on how to resolve this issue as an international community. In Japan, society as a whole is beginning to accelerate its efforts to strengthen preparedness. For example, the proposal for the formulation of the “Basic Policy for 2022” includes the early

establishment of an incentive system to ensure sustainable innovation in antimicrobial drug research and development. In addition to the pull incentives represented by the subscription model and stockpiling, we believe that enhancing mechanisms to promote pipeline formation through push incentives, which are support to promote research and development, will help maintain stability in the infectious disease market and, as a result, enhance preparedness for new pandemics. Of course, companies that receive incentives must always be prepared to make their maximum contribution in the event of an emergency, including the drugs they provide and the human resources to respond. It is essential that not only companies but also society as a whole have a system to continuously tackle infectious diseases. We aim to become a company that can grow sustainably with society by establishing a platform that can provide total care for infectious diseases to prevent a repeat of pandemics or otherwise minimize their damage.

■ Toward Building a Sustainable Infectious Disease Business



Message from the CEO



Isao Teshirogi, Ph.D.

Representative Director,
Chairman and President

Aiming to transform ourselves into a HaaS company, we will not slow down as we continue the full-throttle drive toward the realization of transformation centered on infectious diseases

Looking back on our business in fiscal 2021

First of all, I would like to express my deepest condolences to those who lost their lives due to COVID-19, which continues to infect people around the world, and my sincere wishes for the speedy recovery of all those who have been affected and those who are suffering from the aftereffects of the disease. I would also like to express my deepest respect to the many people, including medical personnel, who have been working hard to provide patient care, prevent the spread of infection, and maintain the medical system in the face of recurring outbreaks.

SHIONOGI has contributed to the development of health-care based on its Company Policy (SHIONOGI Group Heritage) of “constantly supplying the best possible medicine (health-care solutions) to protect the health and wellbeing of the patients we serve”. In fiscal 2021, we continued to respond to the urgent demands of society by making Group-wide efforts to deliver COVID-19 solutions to all people in Japan and around the world. At this point in time, we have not been able to fully meet the expectations of society and our shareholders by actually providing a therapeutic drug or vaccine. We take this situation very seriously. On the other hand, it is also true that we have evolved as a company by investing a great deal of management resources, learning from the risks we have taken, and changing various processes.

First, for the therapeutic drug S-217622 (ensitrelvir), we started nonclinical studies in May 2021 and clinical trials in July of the same year. Just seven months later, in February 2022, we filed an application for approval in Japan, having results up to the Phase 2b trials. Of course, this was a provisional application, so to speak, for review under the conditional approval system (currently the newly introduced emergency approval system) in consideration of the urgency of the situation. We accelerated the Phase 3 study during this review period, and by July 2022 we had enrolled a total of more than 2,900 patients in the Phase 2/3 study. While it is said that it usually takes 9 to 17 years for the research and development of a new drug, we were able to advance the project, including preparations for commercial production, at an unprecedented speed of approximately two years from the start of drug discovery research for the target 3CL protease to

the completion of registration for Phase 3 trials. We are proud of this great accomplishment. During the course of the project, we faced some difficulties when the fifth wave of infections had settled and the number of infected patients had dropped to almost zero, and in the sixth wave when medical institutions were too overwhelmed to conduct clinical trials, but we worked hard to obtain cooperation from medical institutions and local governments to accelerate the accumulation of cases with the help from other industries that have strengths in online services. The achievements of launching Japan’s first clinical trials in hotels and at home have become valuable assets for SHIONOGI, which will continue to take on the threat of infectious diseases in the future.

As for S-268019, a prophylactic vaccine, it was a year in which we appropriately dealt with many difficulties and changes in the environment and accumulated capabilities. As mRNA vaccines have become widely available globally and it has become difficult to verify their efficacy in prevention of disease onset conventionally using large-scale clinical trials, we have repeatedly exchanged opinions with relevant ministries and regulatory authorities in order to have the need for an alternative evaluation method communicated from Japan. As a result, in September 2021, the International Coalition of Medicines Regulatory Authorities (ICMRA) announced its policy to use neutralizing antibody titers after vaccination as an alternative indicator of efficacy in preventing disease onset. We believe that this was an important achievement of public and private sectors in collaboration, linking to the potential of a vaccine produced in Japan. In parallel, we were able to discuss cooperation in conducting large-scale clinical trials with Vietnam and other Asian countries, which was another major step toward preparing for the next pandemic. Meanwhile, SHIONOGI made the decision in July 2021 to switch out the formulation it had been evaluating. The switch was made in anticipation of greater emphasis being placed on neutralizing antibody titers as the aforementioned alternative indicator. There were heated debates in the same vector among the respective value chains on how to make up for the development delays that would occur while striking a balance between efficacy and safety. I feel that SHIONOGI has grown

Message from the CEO

as a company in the way it has responded to these issues and advanced to this point. The later the vaccine is developed, the more tests are required before filing for approval in Japan, such as additional inoculation tests and more case studies of children and the elderly, but we are currently obtaining favorable results in several final tests. Although we are still working on scaling up production, we have been able to move forward to the point where we are just one step away from filing for approval. Although this is the first time SHIONOGI has developed a vaccine, we are determined to make it a success so that we can make it into a core business in the medium- to long-term, and expand into dealing with mutant strains and other diseases, and expand into new technologies such as nasal vaccines.

In June 2021, the wastewater epidemiology surveillance service to monitor the prevalence of infection and the emergence of mutant strains launched, and in early 2022, a joint venture with Shimadzu Corporation for the purpose of sewage monitoring and other public health risk assessments called AdvanSentinel was launched and is off to a good start toward establishing itself as social infrastructure.

Through these activities, we have reaffirmed that the desire to solve the issues of people and society and to deliver solutions at any cost, are what nurtures people and organizations, and produces innovations that are globally competitive.

SHIONOGI will continue to reflect the efforts, experience, and innovations we have accumulated over the past two years in our vaccines, treatments, and other solutions, and will continue to make it our top priority to deliver them as soon as possible.

Although we had the highest amount of R&D expenditure in the history of SHIONOGI due to intensive investment in the development of COVID-19 drugs and vaccines, revenue and profit exceeded our targets and we were able to increase both figures for the first time in three years. I believe that we were able to fulfill our responsibilities to a certain extent in that we achieved our earnings forecast despite aggressive R&D investments. On the other hand, there were some exceptional factors that contributed to our performance, such as the one-time income from the settlement of the dolutegravir patent infringement lawsuit, and we continue to face challenges in terms of growth through expansion of our so-called base businesses, i.e., domestic and overseas businesses over which we have control. We will invest resources in COVID-19-related products and other growth drivers, and make strenuous efforts to continue and expand the trend of increased sales and profits toward the goals set forth in our medium-term business plan "Shionogi Transformation Strategy 2030 (STS2030)."

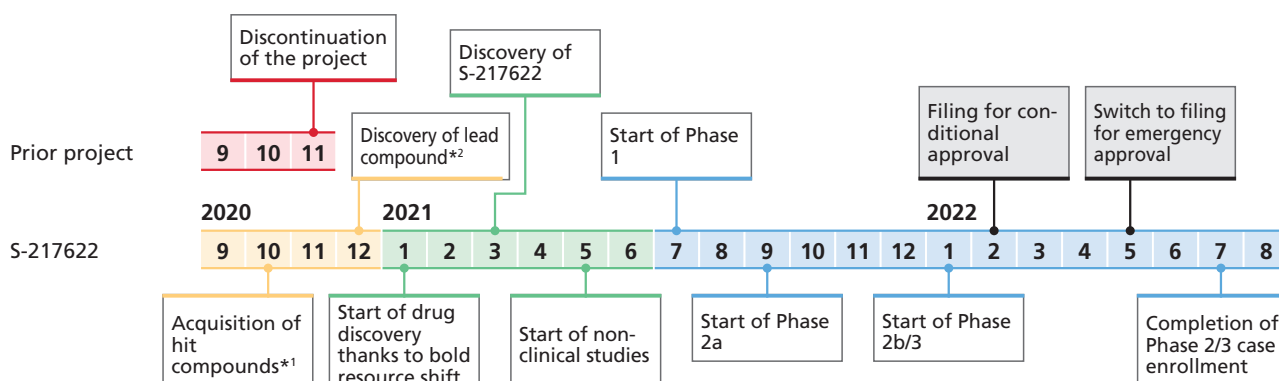
Lessons learned from the COVID-19 pandemic and future trends

Becoming a company that begins with "the issues"

In recent years, the social environment and the needs of stakeholders have diversified and changed at a very rapid pace, and the COVID-19 pandemic has greatly accelerated this trend. Even taking the example of expectations for thera-

peutic drugs, as vaccines uptake becomes more widely spread, needs are shifting from patients with severe disease to those with mild disease, and from patients with risk factors for severe disease to a wide range of patients with or without risk factors. One of the reasons for the sluggish performance of new products, which I recognize as one of the negative

COVID-19 Treatment R&D Timeline



*1 Hit compound:

An active compound found in a compound library screening test.

*2 Lead compound:

A compound which becomes more activated than hit compound by in vivo evaluation or other means. It is the basis for further improvement of activity, solubility, stability, pharmacokinetics, safety, etc. through chemical synthesis.

points to reflect upon in SHIONOGI's previous medium-term business plan, was the plan's so-called "product-out" approach. IT was based on the assumption that customers would opt for small-molecule drugs with superior efficacy and safety at relatively low prices. However, it is clear that this approach is no longer applicable to pharmaceuticals, which are protected by patents for a limited period of time. In order to continue to provide products and services that are chosen by our stakeholders going forward, we must stay close to the needs of our customers and society, anticipate and incorporate into our business activities, not only the needs that exist today, but also the healthcare needs of 10 to 20 years from now. This way, we can continue to provide new value to our customers and society to satisfy those needs. To this end, in addition to the above-mentioned mindset of "the desire to respond to issues," there is an urgent need to develop an organization and employees who are eager to acquire new perspectives to identify the essence of these issues and the capability to lead to solutions. We are in the process of reviewing our system for strengthening human resources.

Discerning what must not change and what must continue to change

This pandemic has truly brought us so many changes. Some of those changes were things that needed to change for the future that suddenly appeared before us, and others that were a temporary adjustment but will come back, albeit in a slightly different form. It is important to differentiate what is part of the new normal and what are the values that cannot and shall not be changed. For example, the COVID-19 pandemic led to a review of processes, and the speed of pharmaceutical R&D, which accelerated quickly, is already becoming the global standard as an irreversible change. In this emergency situation, SHIONOGI has also been advancing R&D at a speed that exceeds previous concepts. Now the test will be

how we can apply the lessons learned and experiences gained during the pandemic to other items and projects and raise our work methods to the new global standard. I keenly recognize that we have entered an era in which companies will be eliminated unless they continue to take risks and evolve without fearing change, while remaining constantly aware of the scientific ability to create new value and of patient safety — two things which must not change — and deliver them to the world as quickly as possible.

Sophistication of decision-making

Speedy and sophisticated decision-making is required in order to respond quickly to changes in the environment and societal needs, provide new value to customers and society through business activities, and achieve sustainable growth. In 2020, SHIONOGI introduced a system (SHIONOGI new Approval Management System 2020: SAMS) to enhance the sophistication of decision-making, and established a system that records the work processes of "who, what, when, where, and how decisions are made," making them completely transparent, and enables tracing of the execution of measures decided upon. In addition to continuing to strengthen management, which is the key to this transparent process, we are also comparing ourselves and our operations with those of the world's most advanced companies to increase transparency and traceability as we work to transform ourselves into a globally competitive company.

From fiscal 2022 onward, we will accelerate our efforts to become a HaaS company through the implementation of STS2030, a strategy to achieve the SHIONOGI Group Vision of "building innovation platforms to shape the future of healthcare." In fiscal 2022, we will contribute to the early end of the pandemic by providing COVID-19 therapeutic drugs and prophylactic vaccines, while steadily advancing toward the realization of the SHIONOGI Group Vision.

Our medium- to long-term growth strategy

As the COVID-19 pandemic drags on, the world "order" continues to change dramatically with the China-U.S. trade war, the worsening situation in the Middle East, and Russia's invasion of Ukraine. Each of these regions is searching for how they will characterize themselves going forward, i.e., how they will "grow" qualitatively and quantitatively. And these changes in the world will continue to occur. On top of that, we must always be trying to envision SHIONOGI's next stage of development, predicting what it will look like 10 to 20 years from now.

These changes in the external environment have reminded us that our focus areas of infectious diseases and psychoneurological diseases are disease areas that humanity must con-

sider in times of emergency, even more so than in ordinary times. That there is a great need for drugs against infectious diseases goes without saying, but many people are also suffering from psychoneurological diseases due to COVID-19 and the worsening global situation. These diseases, however, have virtually no fundamental solution and there are many unmet needs remaining. Furthermore, I believe that vaccines as preventive medicine will continue to grow as a necessary healthcare solution for society going forward, in that they are often targeted to healthy people, whereas curative medicines are targeted to people with diseases. In addition, I believe that our participation in remote/online medical care (provided by Stream-I, Inc, a joint venture with M3, Inc.) and our joint ven-

Message from the CEO



ture with the Ping An Group, scoping China and Southeast Asia, will be extremely important strategies or growth drivers for SHIONOGI in the future.

Although the pandemic has greatly accelerated social changes, I am proud that the premise of STS2030 is a strategy that anticipates these global changes to some extent and is consistent with our direction. I am confident that by following the SHIONOGI Group Vision and STS2030 and working toward becoming a HaaS company, we will be able to flexibly respond to these major changes in the environment. As a result of our bold response to the changes brought about by COVID-19, the path toward the SHIONOGI Group Vision is becoming clearer, and we are now considering updating our plan with a view to evolving onward to the next step under STS2030.

Building an infectious disease business model

Despite how obvious the reasons were for the withdrawal of many pharmaceutical companies from the field of infectious diseases, the measures taken were mainly push incentives focused on the discoveries of new drugs, and there was insufficient understanding of the issues surrounding the infectious disease business and insufficient measures to address them. While this is not a problem that can be solved solely through

the efforts of individual companies, it is essential for SHIONOGI to build a sustainable business model in order to continue contributing to this field. Although I speak of “infectious diseases”, to be precise our efforts to date have been focused on treatment. However, we cannot truly solve social issues from the perspective of protecting people from the threat of infectious diseases and protecting society from the ravages of pandemics, as well as preparing for the next threat, unless we consider the total picture of infectious diseases, from detection (epidemic forecasting) to prevention, diagnosis, treatment, and exacerbation suppression.

The three pillars of chronic, acute, and vaccines

In order to build a sustainable business in the area of infectious diseases, which is known to have low profitability, we will continue to work with a clear awareness of the three pillars of our business: chronic, acute, and vaccine. We are confident that we can build a sustainable business by dividing our portfolio into these three pillars, even in the low-profitability infectious disease business. To achieve this, it is important to secure stable revenues from chronic infectious diseases such as HIV infection and from vaccines, while at the same time, for acute infectious diseases such as COVID-19, influenza, and AMR, to balance pull incentives, represented by subscription-type reimbursement models and stockpiling, with push incentives that support the promotion of R&D. By doing so, we believe we can build an infectious disease business that is sustainable in its totality by creating a model that can be sustained as a business even if there are some fluctuations in sales.

Global development of the infectious disease business

Until now, global development of dolutegravir and *Xofluza* was led by our partners. From now on, we have established a policy that we will take on as much as possible of the role that has been played by our partners, including negotiations with governments in various countries, and that we will deliver SHIONOGI’s products to emerging countries on our own. Of course, there is no change in our direction insofar as collaborating with external partners to leverage each other’s strengths on activities that are inefficient or impossible for us to do on our own. At this point, it is difficult for SHIONOGI to provide cefiderocol to low- and middle-income countries on its own, so we have chosen to collaborate with GARDP and CHAI while contributing to global health through our own hard work. On the other hand, the experience of COVID-19 has expanded the scope of what SHIONOGI can handle on its own, and we will work to maximize value, including the returns we can obtain, by doing what we can on our own as much as possible.

Realization of the HaaS model in areas such as psychoneurological diseases

In the area of psychoneurological diseases, including pain, which is another area of focus, we are also aiming to provide services that go beyond pharmaceuticals by focusing on the needs of patients and society.

Psychoneurological diseases are considered areas of high unmet medical need, despite the fact that, a variety of treatment options are available due to the difficulty in identifying the cause of illness. Because symptoms vary from patient to patient, uniform treatment cannot provide maximum benefit. There is a need to establish techniques and methods that enable objective and early diagnosis even in cases of complex complications of various diseases, and to aim at providing individualized and optimal treatment and services according to disease background and symptoms. Dementia, for example, impairs cognitive functions such as memory, learning, language, and judgment, which not only reduces the quality of

life (QOL) of the patients themselves, but also leads to physical, mental, and financial burdens for caregivers, and has a tremendous impact on society. However, satisfaction with existing treatment methods is low, and there is longstanding demand for new treatment methods. In addition to working on the development of therapeutic drugs, SHIONOGI and its partners have begun joint research to see if dementia care can be realized by stimulating the natural senses in a way that is integrated into daily life, using, for example, sound, which has the potential to enhance specific rhythmic activity in the brain (gamma waves), with the aim of improving cognitive function.

In addition, we are working with partner companies and academia to develop solutions that go beyond pharmaceuticals, such as apps for ADHD, sleep treatment, and brain wave measurement, and we hope to help build a society in which everyone can live a vibrant, authentic life by expanding healthcare services and contributing to the improvement of the social environment.

Toward the realization of our business model

Organizational evolution and human resource development

As our business model becomes clearer and what we want to achieve becomes more defined, the capabilities and mindset that SHIONOGI should possess in this global competition are also coming into view. While it is of course necessary to develop new capabilities to meet changing needs, the most important thing for SHIONOGI in the future is to continue to

enhance its strengths and expertise in order to compete on a global scale, and this applies to the organization and to each and every employee in the Group. While mutually questioning whether we are disciplined enough on a daily basis to be globally competitive, we will continue to refine our strengths and work on the evolution of our organization and the development of our human resources to become a hub of co-creation that other companies and different industries will choose to partner with.

To all our stakeholders

On July 1, 2022, SHIONOGI announced the establishment of a new group brand and a new group brand mark. The purpose of this rebranding is to demonstrate both internally and externally the company's commitment to pursue innovation, shape the future of healthcare, and sustainably grow while helping to meet the healthcare needs of society on a global scale. The new brand symbol contains the two conceptions: that which must not change, i.e., that which must be protected, and that which must continue to change, to evolve. Change is accompanied by pain and resistance, but the entire SHIONOGI Group shares this belief that we must shed our

skin and be reborn anew, while absolutely preserving what is important to us, and enjoying the transformation process. As mentioned above, we have decided to take this opportunity to personally deliver SHIONOGI's products and services to emerging countries as well. This may not be an easy task, but we will continue to take on the challenge of change so that SHIONOGI can truly provide value on a global scale and be recognized by stakeholders around the world as a company that will be needed in the future. We look forward to your continued guidance and support.

Our History

Both the world and SHIONOGI have changed significantly over time, but we have not forgotten our founding spirit, and our head office is still located where we were founded, in Osaka's Doshomachi. Here, we describe how SHIONOGI has grown in response to the changes that have taken place over the past century and a half.

Chronology

1870

1878

Founded

On March 17, 1878, his 24th birthday, Gisaburo Shiono, Sr., who learned about the drug wholesaling business from his father, Kichibe, strikes out on his own and establishes a drug wholesaling business named Shiono Gisaburo Shoten at 12, Doshomachi 3-chome in Osaka.



Founder
Gisaburo Shiono, Sr.

1886

From Japanese and Chinese medicines to Western medicines

At that time, Western medicines were available through foreign trading houses in Yokohama and Kobe, but they were expensive because drug wholesalers who were not familiar with trading bought the medicines at whatever price the foreign traders asked for. Gisaburo soon added people experienced in trading and fluent in English and imported medicines directly so that even the common people would be able to buy them at a reasonable price.

1909

Registered the corporate emblem FUNDOH

Reliability and trust are necessary qualities for corporate management. Since our founding as Shiono Gisaburo Shoten, we have regarded reliability and trust as our most valuable "capital." SHIONOGI's Group brand symbol is derived from the fundoh, which is the balance weight traditionally used to weigh medicine on a scale. The FUNDOH also symbolizes "accuracy," "honesty," and "trust," meaning that we always pursue accuracy.



FUNDOH from
the Edo era



Group brand symbol
(From July 2021)

1910

Constructed the Shiono Seiyakusho manufacturing plant

A new pharmaceutical manufacturing plant, called Shiono Seiyakusho, was built in Nishinari-gun, Osaka (the present-day Fukushima-ku, Osaka) to formally launch the business of manufacturing new drugs. This gave Shionogi a pharmaceutical division in both name and reality and was also the moment that SHIONOGI embarked on a new path as a drug manufacturer. Gisaburo's second son and director of the plant, Chojiro, wanted to get the company through tough operating conditions, so he invited Heizaburo Kondo, a doctor of pharmacology who had just returned from studying in Germany, to serve as an advisor.

1940

1943

Renamed the Company Shionogi Seiyaku K.K. (now Shionogi & Co., Ltd.)

In 1919, Shiono Gisaburo Shoten, the drug wholesaler led by Gisaburo's eldest son, Shotaro, and Shiono Seiyakusho K.K., the pharmaceutical business led by his second son, Chojiro, were merged in order to further expand the company. The new company was named Shionogi Shoten Co., Ltd. In 1943, the name was changed again, to Shionogi Seiyaku K.K. (the present Shionogi & Co., Ltd. in English) to demonstrate that the company would focus on the drug manufacturing business.

SHIONOGI and society

Salvarsan

SHIONOGI's first step in fighting infectious diseases

In the early 1900s, syphilis was a serious infectious disease for which no cure existed. We started importing *Salvarsan* in 1911, two years after it was developed overseas in 1909, and this was a major step in the treatment of patients suffering from syphilis.

Sinomim

Our first in-house developed drug that made a global contribution

In the 1950s, infectious diseases like tuberculosis and pneumonia ranked among the most common causes of death. We therefore began R&D into infectious diseases, having made the management decision to become fully involved in the major social issue of infectious disease. *Sinomim*, a sulfonamide we launched in 1959, was out-licensed to Roche of Switzerland, and it has been instrumental in treating infectious diseases throughout the world. Even now, more than 60 years since its launch, it continues to contribute to people's health as *Baktar*, a combination with trimethoprim.

Tivicay

Contribution to HIV treatment

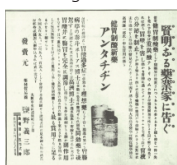
In 1988, we founded our Institute for Medical Science and began researching HIV and other antiviral medicines. After many failures, we launched the HIV drug *Tivicay* in 1994. *Tivicay* possesses superior effectiveness and safety, and it is an HIV integrase inhibitor for which it is difficult to develop resistance. We are therefore making a major contribution to treating people around the world so that they can live with HIV and have a better quality of life.

Major products

1900

1909

Our first in-house drug, the anti-indigestion *Antacidin*



Advertisement for
Antacidin

1910

1911

The syphilis treatment *Salvarsan*

1912

The new cardiac drug *Digitamin*

1950

1950

The analgesic *Sedes*

1953

The multivitamin supplement *Popon-S*



Popon-S

1959

The sulfonamide drug *Sinomim*



Sinomim

1980

1982

The oxacephem antibiotic *Shiomarin*



Shiomarin

1988

The oxacephem antibiotic *Flumarin*

1990

1997

The cephem antibiotic *Flomox*

1950

1957 SHIONOGI's Company Policy (now SHIONOGI Group Heritage) established

Since our founding, SHIONOGI has survived the changing times and developed our own philosophy and thinking. Our Company Policy, which is our eternal goal, has enabled us to move forward without losing sight of our basic direction as a pharmaceutical company, which is "to serve people's health."

1980

1983 Construction of the Kanegasaki Plant

The Kanegasaki Plant was built in the town of Kanegasaki, Iwate Prefecture where a large factory site was secured as one of our key factories, based on a long-term plan for the future expansion of our pharmaceutical manufacturing facilities.



Kanegasaki Plant

1990

1998 Establishment of the Shionogi Code of Conduct

The Shionogi Code of Conduct was established to complement the SHIONOGI Group Heritage as a criterion for behavior as the company went global and developed into a global corporation. The Company Policy describes our business purpose, while the Code of Conduct sets forth the type of conduct that SHIONOGI should practice as a member of society and as a pharmaceutical company.

2020

2020 Revising our management philosophy

To continue growing as the external environment and values evolve, we need to reflect society's and customers' needs in our targeted Vision and in the Values that are essential to achieving this Vision, and to have the flexibility to take action. We therefore established a new Vision and Values for our Company Policy, which is the foundation we call Heritage that serves as the basis for all of our activities.

2022

Launch of a new brand

SHIONOGI has declared to the outside world that the entire SHIONOGI Group will work together to vigorously promote business transformation and develop a new brand with the aim of gaining wider recognition and appreciation for SHIONOGI's activities among stakeholders in Japan and overseas. The corporate emblem, the FUNDOH, has also been renewed, reaffirming our commitment to embodying Heritage.

Xofluza

An influenza antiviral drug with a new mechanism of action

We launched the influenza antiviral drug *Xofluza* in 2018. By combining the power of our value chain and alliances and utilizing the SAKIGAKE designation system, we were able to obtain approval in Japan and launch the drug with the short time period of about three years from the start of Phase 1 clinical trials. This drug is both effective and convenient, and it is helping influenza patients and their families, as well as the healthcare community.

Fetroja

The trump card in antimicrobial infectious disease treatment

In 2020, we launched the multi-drug resistant antibiotic *Fetroja* in the U.S. This drug could become the trump card for saving patients whose lives have been endangered due to the lack of treatment options. We are providing cefiderocol to many countries and regions, including low- and middle-income countries, through alliances and other means by employing Managed Access Programs (MAPs), thus contributing to the treatment of patients.

Cabenuva, Apretude

Contributing to improving the quality of life of people living with HIV

In 2020, *Cabenuva* (cabotegravir + rilpivirine), a long-acting HIV drug, and, in 2021, *Apretude* (cabotegravir), a long-acting HIV prophylactic drug, were launched. The launch of these drugs has made it possible to treat and prevent HIV, which hitherto required daily doses of drugs, with a once-every-two-month injection, contributes to improving the quality of life of people living with HIV.

2000

2003

The cancer pain analgesic
OxyContin

2005

The hyperlipidemia treatment
Crestor

The carbapenem antibiotic *Finibax*



Finibax

2008

The hypertension treatment *Irbesartan*
The acne vulgaris treatment *Differin*
The idiopathic pulmonary fibrosis treatment *Pirespa*

2010

2010

The influenza antiviral drug *Rapivacta*
The antidepressant drug *Cymbalta*

2012

The injectable cancer pain analgesic *OxiFast*
The hypertension treatment *Aimix*

2013

The hypertension treatment *Irtara*

2014

The anti-HIV drug *Tivicay*



Tivicay

2015

The anti-HIV drug *Triumeq*
The allergen immunotherapy *Actair*
The thrombocytopenia treatment *Mulpleta*

2016

The hypercholesterolemia treatment *Crestor OD* tablets

2017

The cancer pain treatment *Methapain*
The attention-deficit/hyperactivity disorder (ADHD) treatment *Intuniv*

The opioid-induced constipation treatment *Symproic*

The chronic cancer pain treatment *OxyContin TR* tablets

2018

The influenza antiviral drug *Xofluza*



Xofluza

2019

The attention-deficit/hyperactivity disorder (ADHD) treatment *Vyvanse*

2020

2020

A multidrug-resistant Gram-negative bacterial infection treatment *Fetroja* (cefiderocol)



Fetroja (cefiderocol)

The long-acting anti-HIV drug *Cabenuva* (cabotegravir + rilpivirine)

The IgG/IgM antibody test kit for COVID-19 (research reagent)

2021

The long-acting HIV prophylactic drug *Apretude* (cabotegravir)

Value Creation Process

Building Innovation Platforms to Shape the Future of Healthcare

SHIONOGI strives constantly to supply the best possible solutions to protect the health and wellbeing of the patients we serve.

Material issues addressed by SHIONOGI p.26-27

- Material issues to create new value for customers and society
- Material issues to realize a sustainable society and support SHIONOGI's growth

Inputs (FY2021)

■ Human capital

- Penetration of our philosophy 86% (FY2021)
- Education & training expenses ¥107 million
 - SCD^{*1} (now SBP)^{*2} education & training expenses + divisional education and training expenses
 - *1 Shionogi Career Development Center Co., Ltd.
 - *2 Shionogi Business Partner Co., Ltd.
- Human resources development programs
 - Implementation of all manager improvement programs
 - IT human resources development
- Pool of human resources for future management
 - Number of Associate Corporate Officers (cumulative over the past two years) 20 persons
- Work-life balance framework
 - Start applying the Super Flex System
 - Introduction of the side work system
 - Introduction of a voluntary three-day weekends
- Studied or worked overseas 12 persons

■ Intellectual and manufactured capital

- SHIONOGI's unique expertise and technology for R&D
 - Library of bacterial strains, compound libraries
 - Small-molecule drug discovery engine
 - SHIONOGI's proprietary expertise and technology for vaccine R&D (BEVS)
- R&D expenses ¥73.0 billion
- Capital investment ¥27.3 billion (IT investment, plant and equipment investment, etc.)
- R&D laboratories (Kanzakigawa, Kuise)
- Group Company facilities
 - Expertise, technology, and facilities for antimicrobial and medical narcotic drug manufacturing
 - Vaccine manufacturing facility
 - Facilities with continuous manufacturing capability
 - High-potency manufacturing facility

■ Social and relationship capital

- Diverse partnerships (15 new partnerships in FY2021, 21 STS2030 partnerships cumulatively)
- Assistance based on the expectations of national & local governments and society
- Brand strength

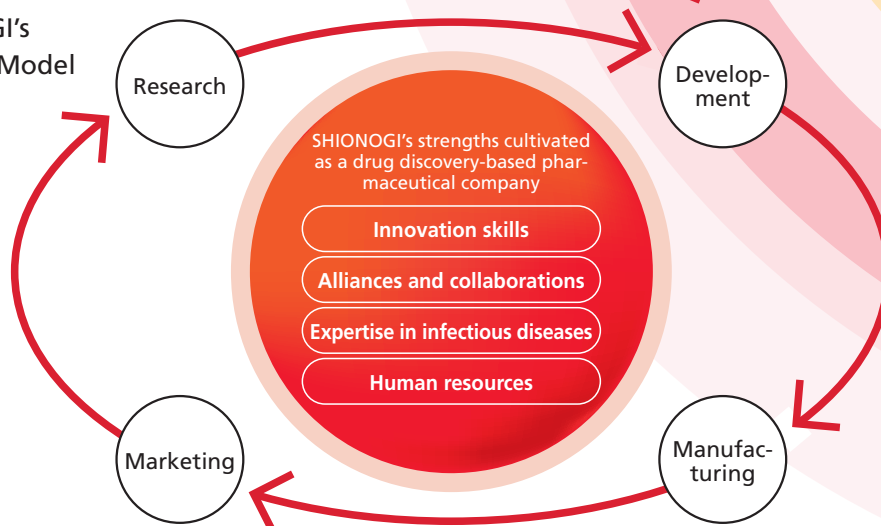
■ Financial capital

- Total capital ¥1,150.6 billion
- Equity attributable to owners of parent ¥975.7 billion
- STS2030 Phase1 ¥500 billion to be invested
- Cash and cash equivalents ¥254.4 billion (rating information: AA-)

■ Natural capital

- Total energy consumption 333,548MWh
- Water consumption 1,366 thousand m³

SHIONOGI's Business Model



Issues and needs

(Contributions to a healthy and prosperous society)
Contribution to SDGs

Extension of healthy lifespans, improvement of quality of life, new value co-creation

Stakeholders

Customers

Employees

Shareholders and investors

A workplace where employees can feel comfortable, motivated and can grow
Sustainable growth, return of profit

Outcomes (as of March 31, 2022)

■ Human capital p.50-53, 97

- Practice of our philosophy 73%
- Achievement of work-life balance
 - Percent of men taking childcare leave 51.4% (up 10.3%pt YoY)
 - Decrease in employees working shorter hours for childcare, increase in full-time employees
Total number of employees working shorter hours for childcare: 113% of the previous year's total, 61% compared to before the revision of scheduled working hours
- Number of appointments to executive officers from the human resources pool (Associate Corporate Officers) (cumulative number of new appointment over 2 yrs.) 4 persons
- Percent of female managers 12.4% (up 0.9%pt YoY)
- Human capital utilization
 - Applicants for the side work program 59 persons
 - Employees who completed IT-related training 44 persons

■ Intellectual and manufactured capital p.40-47

- Accumulated specialized knowledge and technologies in R&D, manufacturing, distribution, marketing and guaranteed reliability of pharmaceutical products
 - R&D speed comparable to other mega pharma companies
- Internally-discovered pipeline ratio 73% (as of March 31, 2022)
- COVID-19 prophylactic vaccine production facility
- COVID-19 therapeutic drug production facility

■ Social and relationship capital p.28-29, 48-49, 54-57, 62-65, 97

- Number of countries where dolutegravir (including the Medicine Patent Pool) was offered: More than 140 countries
- Number of countries where cefiderocol can be offered: 135 countries
- Total website visitors: 9.19 million users (up 248% YoY)
- * Excluding websites for healthcare professionals

■ Financial capital p.30-31, 36-39, 90-96

- Profit before tax ¥126.3 billion
- Annual TSR: 28.4% for the past yr., 6.9% for the past 5 yrs.
- ROE 12.5%

■ Natural capital p.70-71, 97-99

- Effluent management of antimicrobial agents in wastewater (audits of SHIONOGI production sites and relevant suppliers 86% completed)
- Greenhouse gas (GHG) emissions (Scopes 1 + 2) Vs. FY2019 2.4% increase
- Controls on water consumption Vs. FY2020 Increased by 149 thousand m³

Outputs

Fetroja (cefiderocol) for the treatment of multidrug-resistant Gram-negative bacterial infections

Xofluza influenza antiviral drug

Tivicay anti-HIV drug

Wastewater epidemiology service (AdvanSentinel)



Details on the development pipeline

<https://www.shionogi.com/global/en/innovation/pipeline.html>

Value Creation Story



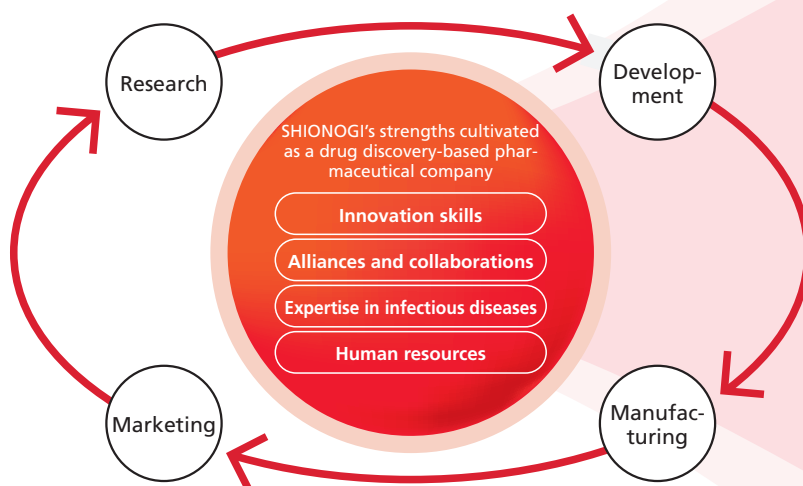
Transformation into a HaaS company

SHIONOGI aims to continue to grow sustainably with society by addressing the needs of patients and the world, and by continuously creating innovations that solve a wide range of healthcare issues. We are committed to transforming ourselves into a HaaS company that provides value beyond the traditional framework of treatment, and are working uncompromisingly every day to deliver cutting-edge healthcare solutions created through innovation to as many people as possible as quickly as possible.



SHIONOGI Today

SHIONOGI's Business Model



Transformation

Medium-Term Business Plan STS2030

p.34-49

R&D Strategy

p.40-43

Top-line Strategy

p.44-47

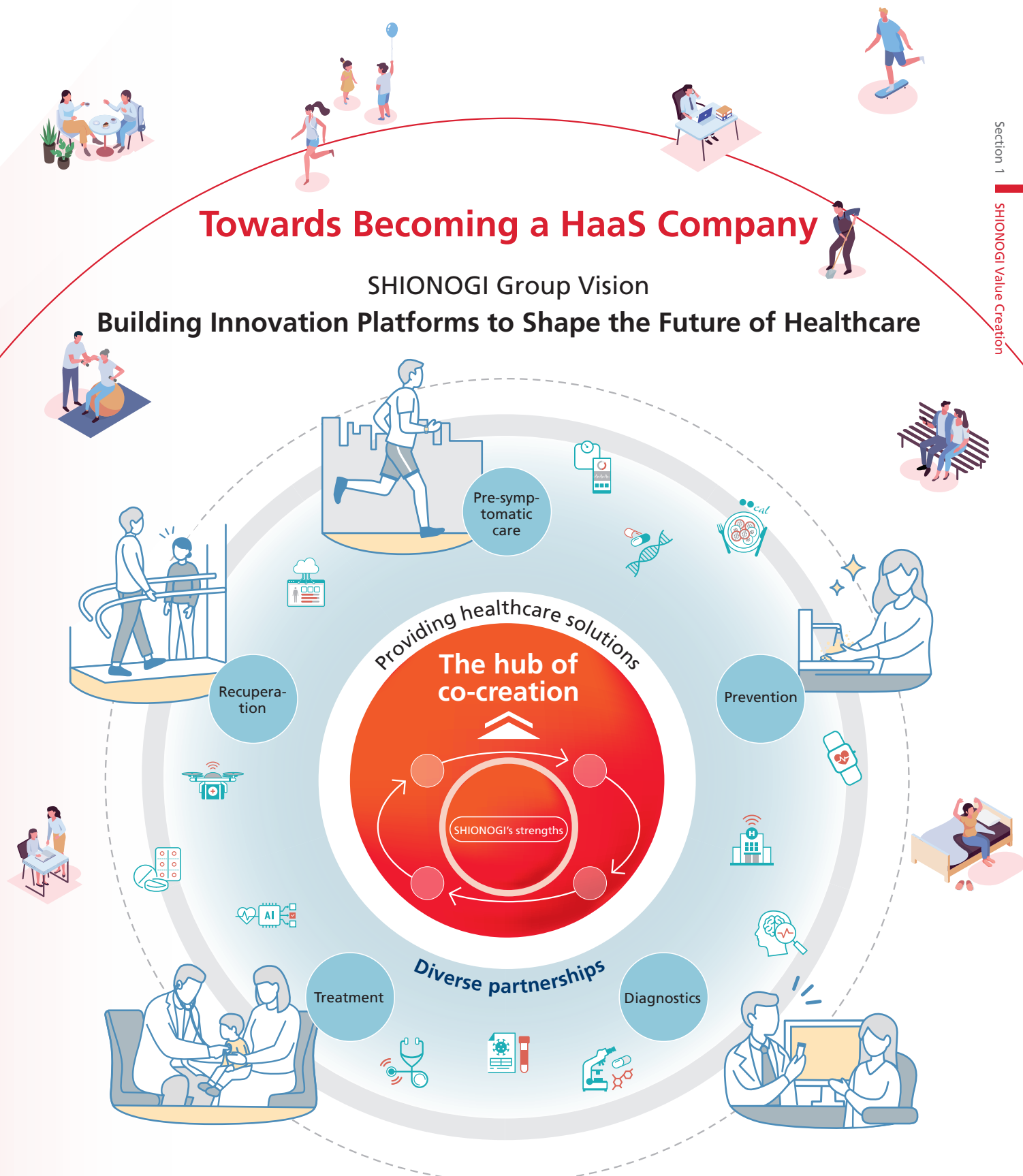
Management Foundation Strategy

p.48-49

 <p>Innovation skills</p> <p>SHIONOGI's internally-discovered pipeline ratio remains high at 73% (as of March 2022). We are fortifying our small-molecule drug discovery engine, which is one of our strengths, and are tackling a number of drug-discovery modalities, including vaccines, medium-sized molecules such as peptides and nucleic acids, and macromolecule antibodies.</p>	 <p>Alliances and collaborations</p> <p>SHIONOGI has achieved growth by entering into win-win partnerships and fusing strengths with partner companies whenever the occasion requires. We will continue to meet increasingly sophisticated healthcare needs by engaging in friendly rivalry with a diverse range of partners, serving as a hub of co-creation.</p>
 <p>Expertise in infectious diseases</p> <p>SHIONOGI has developed and provided society with numerous medicines for infectious diseases for over 60 years. SHIONOGI is leveraging this strength to continue to fight against the threat of infectious disease by expanding our activities of providing therapeutic drugs to include disease awareness programs, detection, prevention, diagnostics, and ways to prevent conditions from worsening, which amounts to total care.</p>	 <p>Human resources</p> <p>At SHIONOGI, each and every one of our human resources are the source of creation of new value that supports the Company's sustainable growth. We are focusing our efforts on developing managers who will drive transformations in the workplace and on nurturing independent-minded human resources who will think and act on their own initiative to solve problems.</p>

Towards Becoming a HaaS Company

SHIONOGI Group Vision Building Innovation Platforms to Shape the Future of Healthcare



While we have an abundance of various information to make use of, the needs in the healthcare field are becoming increasingly sophisticated and diverse. We are on the verge of transforming into a society where people choose their own solutions to protect, promote, and heal their own health. SHIONOGI will thoroughly refine its accumulated strengths to become the partner of choice for a wide variety of companies, breaking through stereotypes to meet the needs of people and society. We are going to transform ourselves into a HaaS company that opens a new era of healthcare as **the hub of co-creation**.

Medicines and beyond, the healthcare SHIONOGI wants to achieve

In response to the changing environment, the SHIONOGI Group Heritage to “constantly supply the best possible medicine to protect the health and wellbeing of the patients we serve” expands the interpretation of “medicine” to healthcare solutions.

Vice President, New Business Promotion Department

Hiroyuki Kobayashi

From globalization, remarkable technological advances in various fields, unexpected outbreaks of infectious diseases, military conflicts and geopolitical clashes, to world affairs and people's lives, the world is rapidly changing and becoming more complex. The healthcare field must also evolve in response to this situation. One example of such evolution is the development of new areas other than conventional diagnosis and treatment, such as the detection and prediction of infectious disease outbreaks and initial symptoms. We believe that the creation of such new businesses is one aspect of “delivering value by providing healthcare as a service (HaaS)” as stated in STS2030.

The mission of the New Business Promotion Department is to create HaaS in order to contribute to society, and to create a mechanism for HaaS creation. AdvanSentinel, which was established in January 2022, is already working on a wastewater surveillance demonstration in collaboration with relevant ministries and local governments as a measure to combat pandemics. In August of the same year, Yui Connection was established with the aim of realizing a society in which people can live their lives to the fullest. This start-up launched a service that visualizes the needs of students at elementary and junior high schools and provides teachers with education plans appropriate for each student.

Going forward, SHIONOGI will continue to contribute to society by creating new sustainable healthcare services, particularly in infectious and psychoneurological diseases, which SHIONOGI has identified as its core therapeutic areas.



Patient journey

- Wastewater epidemiology services
- Disease awareness
- OTC drugs
- Supplements/health foods

Solutions that reduce the risk of future diseases and promote health by incorporating them into daily life

Pre-symptomatic care

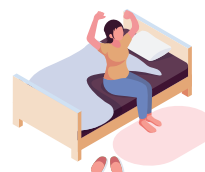


Prevention



- Preventative vaccines
- Disease awareness

Solutions to be applied on a daily or timely basis according to disease characteristics and risk of developing the disease





Diagnostics

- Online healthcare
- AI diagnostic support
- Test kits
- Diagnostic apps
- Diagnosis using brain waves

Solutions leading to early treatment and prevention by quickly and accurately detecting current diseases and their predictive signs

Treatment

- Medical supplies
- Therapeutic apps
- Sensory stimulation
- OTC drugs

Solutions to realize individualized and optimal treatment that is not limited to drug therapy alone

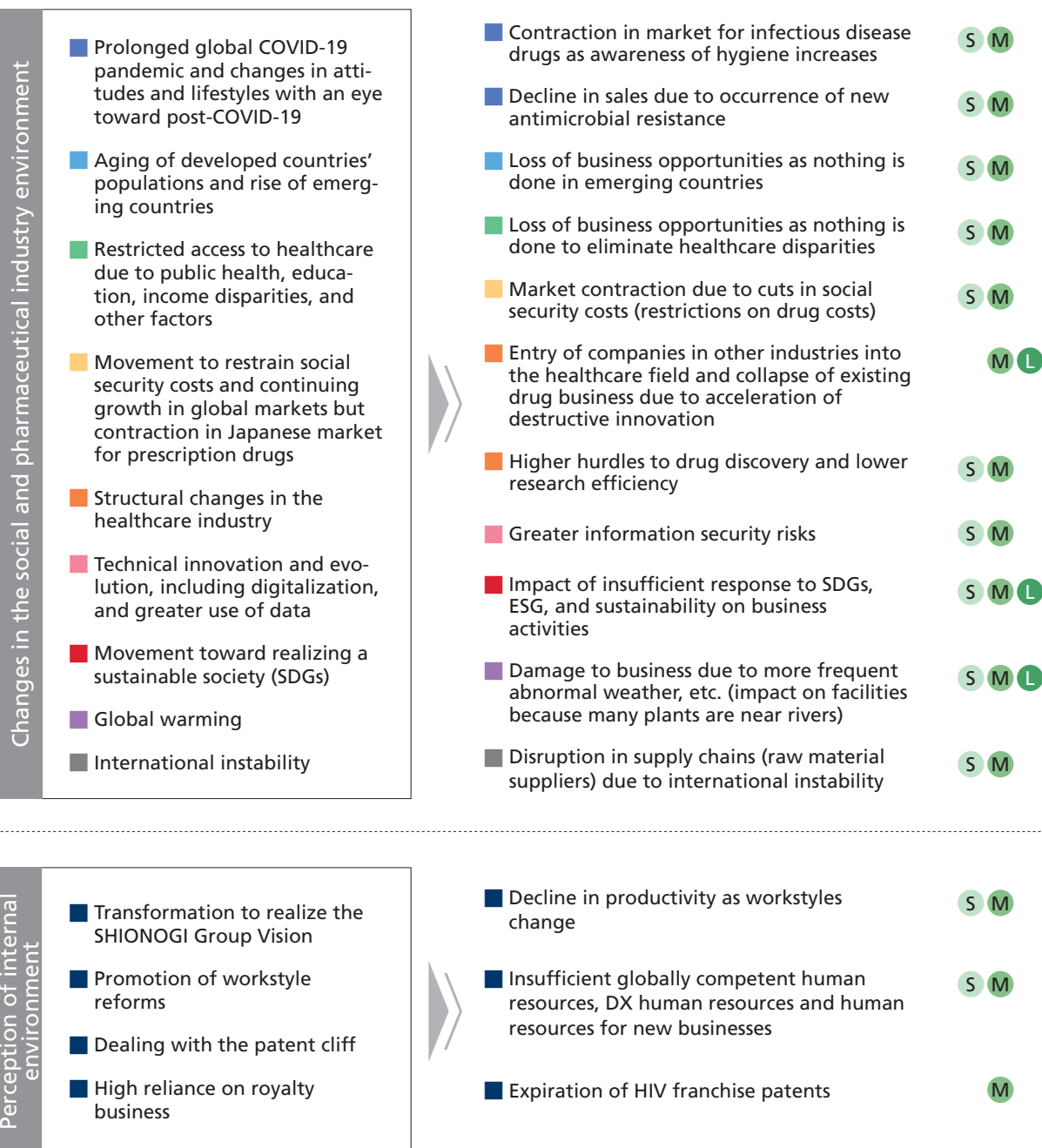
Recuperation

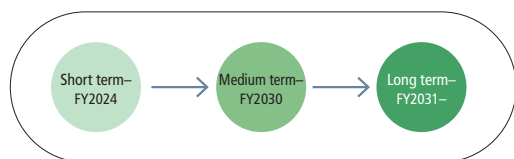
Solutions for continued health and peace of mind after treatment

Risks and Opportunities

In identifying our material issues (materiality), we analyzed and assessed the risks and opportunities for SHIONOGI from internal and external environmental changes. Going forward, as we pursue these initiatives, we will continuously evaluate our risks and opportunities and reflect them in SHIONOGI's initiatives with respect to our material issues (materiality).

Risks





Opportunities

- | | |
|---|-------|
| ■ Greater needs and growth in markets related to prevention, presymptomatic stages, and self-medication, in addition to therapeutic drugs (growth in businesses not dependent on patents) | S M |
| ■ Increased expectations and demand for global infectious disease countermeasures | S M |
| ■ Greater drug discovery opportunities due to occurrence of new antimicrobial resistance | S M |
| ■ Greater demand related to psychoneurological diseases as society ages | S M L |
| ■ Promotion of healthcare access to ensure the health of all people | S M |
| ■ Expectations for drugs with excellent medical economy | S M |
| ■ Collaboration with partners in different industries who possess different strengths | S M |
| ■ Expanded healthcare solutions in fields other than therapeutic drugs through technical innovation | S M L |
| ■ Globalization of infectious diseases due to global warming (broader and quicker spread) | S M L |
| ■ Greater efficiency in the value chain process due to technical innovation | S M |
| <hr/> | |
| ■ Creation of innovation through greater employee awareness about our transformation | S M |
| ■ Greater environment in which diverse human resources can play an active role | S M |
| ■ Construction of a business that does not rely on patents | M |

① Material issues to create new value for customers and society	Protect people worldwide from the threat of infectious diseases
	Improve social productivity and extend healthy lifespans
	Contribute to sustainable social security
② Material issues to realize a sustainable society and support SHIONOGI's growth	Improve access to healthcare
	Secure human resources to support growth
	Respect human rights
	Reinforce supply chain management
	Supply socially responsible products and services
	Strengthen corporate governance
	Ensure compliance
	Protect the environment

Transformation

Medium-Term Business Plan STS2030

p.35-49

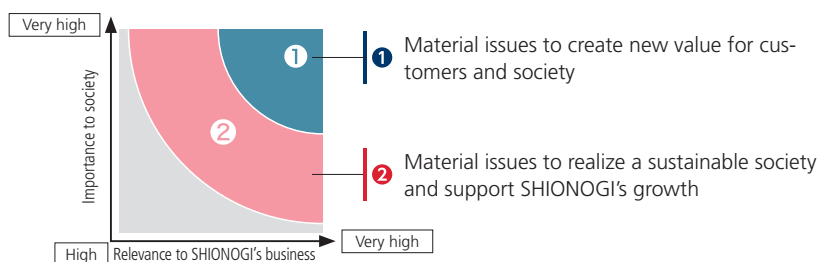
SHIONOGI's Material Issues

Through its business activities and in response to healthcare needs and social issues, SHIONOGI is growing as a company that society needs and aims to share outcomes with our stakeholders. SHIONOGI is therefore identifying material issues (materiality) that we will prioritize in the light of our current situation and needs, as well as our business risks and opportunities.

	Material issues	Major initiatives
1 Material issues to create new value for customers and society	Protect people worldwide from the threat of infectious diseases p.54-57	<ul style="list-style-type: none"> • Provide products and services for acute infectious diseases • Provide products and services for chronic infectious diseases • Build a vaccine business
	Improve social productivity and extend healthy lifespans p.58-59	<ul style="list-style-type: none"> • Discover products and services for disease areas with high unmet medical needs • Raise awareness of the characteristics of the disease and the problems faced by those affected by the disease to promote social understanding
	Contribute to sustainable social security p.60-61	<ul style="list-style-type: none"> • Extend healthy lifespans by providing new treatment options • Promote self-medication
2 Material issues to realize a sustainable society and support SHIONOGI's growth	Improve access to healthcare p.62-65	<ul style="list-style-type: none"> • Develop innovative therapies • Promotion of proper use • Create an environment of improved access • Strengthen health care systems
	Secure human resources to support growth p.50-53	<ul style="list-style-type: none"> • Secure diverse human resources • Nurture human resources who possess exceptional strengths • Foster an environment and culture in which everyone can work comfortably • Health care and occupational safety and health
	Respect human rights p.69	<ul style="list-style-type: none"> • Address human rights issues
	Reinforce supply chain management p.68	<ul style="list-style-type: none"> • Develop policies and codes of conduct • Evaluate sustainability of suppliers
	Supply socially responsible products and services p.66-67	<ul style="list-style-type: none"> • Stably supply products and services • Strengthen monitoring systems
	Strengthen corporate governance p.72-85, 87-89	<ul style="list-style-type: none"> • High-performing corporate governance framework • Strengthen risk management
	Ensure compliance p.86	<ul style="list-style-type: none"> • Instill compliance awareness
	Protect the environment p.70-71	<ul style="list-style-type: none"> • Climate change: Reduce of greenhouse gas (GHG) emissions • AMR: Reduce the impact of antimicrobials manufacturing on the environment

For details and results of each initiative and associated indicators, please refer to the respective pages.

Materiality Map



Main associated indicators

SDGs we contribute to particularly

- Number of acute infectious disease-related pipelines
- Number of serious infectious disease-related pipelines

- Number of HIV-related product pipelines
- Contribution to improvement of QOL with cabotegravir

- Provide COVID-19 vaccine
- Establish vaccine production facilities

- Number of psychoneurological diseases-related pipelines
- Number of oncology-related pipelines
- Number of pain-related pipelines

- Number of educational activities conducted using webinars
- Number of support services provided in the area of developmental disorders

- Percentage of products and services provided per modality

- Number and sales results of OTC drugs

- Global Development Products

- Amount of information supplied for proper use and disease awareness

- Signed agreement for access to cefiderocol
- Number of countries where ViiV offers dolutegravir and cabotegravir globally
- Number of countries adopting subscription-type reimbursement model

- Programs to strengthen healthcare infrastructure in developing countries
- Mother to Mother SHIONOGI Project

- Provide the human resources that each organization needs
- Number of internal recruits
- Number of mid-career hires

- Manager training hours and costs
- Percentage of employees using assistance programs for self-investment
- Human resource pool for future management
- Number of IT/digital personnel trained
- Number of people applying for side work

- Percent of female managers
- Percent taking childcare leave

- Improve health literacy
- Health checkup reception rate
- Percent of employees who smoke
- Severity rate
- Frequency rate

- Conduct human rights impact assessments
- Evaluations of effectiveness by external experts

- Develop policies and provide training for Group employees in Japan

- Percentage of total suppliers evaluated

- Monitor and improve procurement management indicators and delivery indicators set by SHIONOGI
- Conduct regular/non-regular discussions with suppliers to ensure stable procurement
- Periodic evaluation of contract manufacturers and support for establishing business continuity plans (BCP)

- Ensure strict observance of laws, regulations, and guidelines related to the manufacture and sale of pharmaceutical products

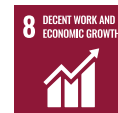
- Disclose the topics deliberated by the Board of Directors

- Build an Enterprise Risk Management framework

- Have all employees identify issues in SHIONOGI corporate culture
- Discuss identified issues by organization, and formulate countermeasures (to be implemented in all organizations and Group companies)

- FY2030: Reduce Scope 1+2 by 46.2% and Scope 3 Category 1 by 20% (FY2019 baseline)
- FY2050: Achieve zero emissions

- Have proper control, including of the supply chain, by FY2030 (completion of audit follow-up)

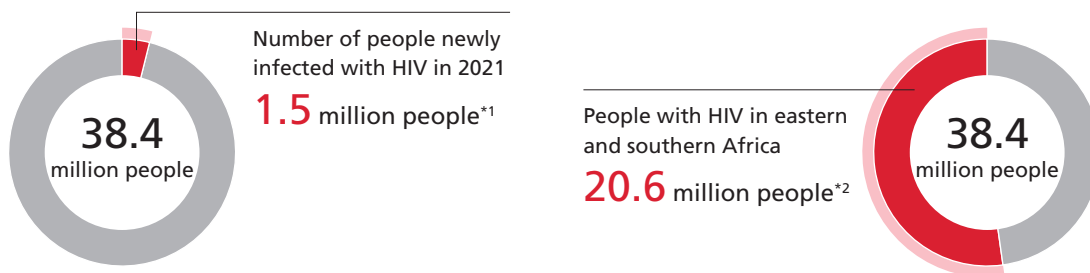


Market and Performance

HIV

Number of HIV-positive people

In 2021, the number of people infected with HIV was approximately **38.4 million**, with more than half of these in eastern and southern Africa. The number of infected people is still increasing. In addition, approximately **650,000** people died from AIDS-related diseases*¹.



*¹ UNAIDS Global HIV Statistics factsheet, updated 2021. Medicines Patent Pool 'Access to Medicines tracker'. Data as of March 2021

*² HIV.gov, The Global HIV/AIDS Epidemic

Market Forecast for Long-Acting Formulations

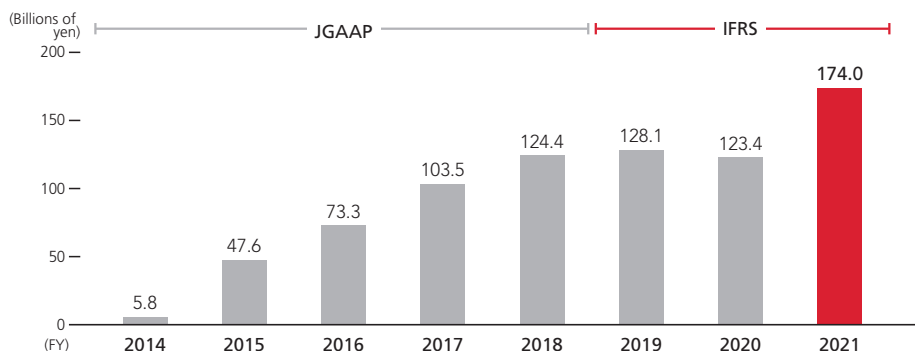
Currently, it is common to take multiple daily oral medications, but by 2030 the market for treatment and prevention with long-acting formulations that enable a higher quality of life is projected to expand.



*³ Meet GSK Management Getting ahead of HIV, 29 Nov. 2021

Royalty income related to HIV franchise from ViiV Healthcare Limited

SHIONOGI receives royalty income on sales of HIV franchises licensed out to ViiV in the UK. As sales grow, royalty income received is also on an upward trend.

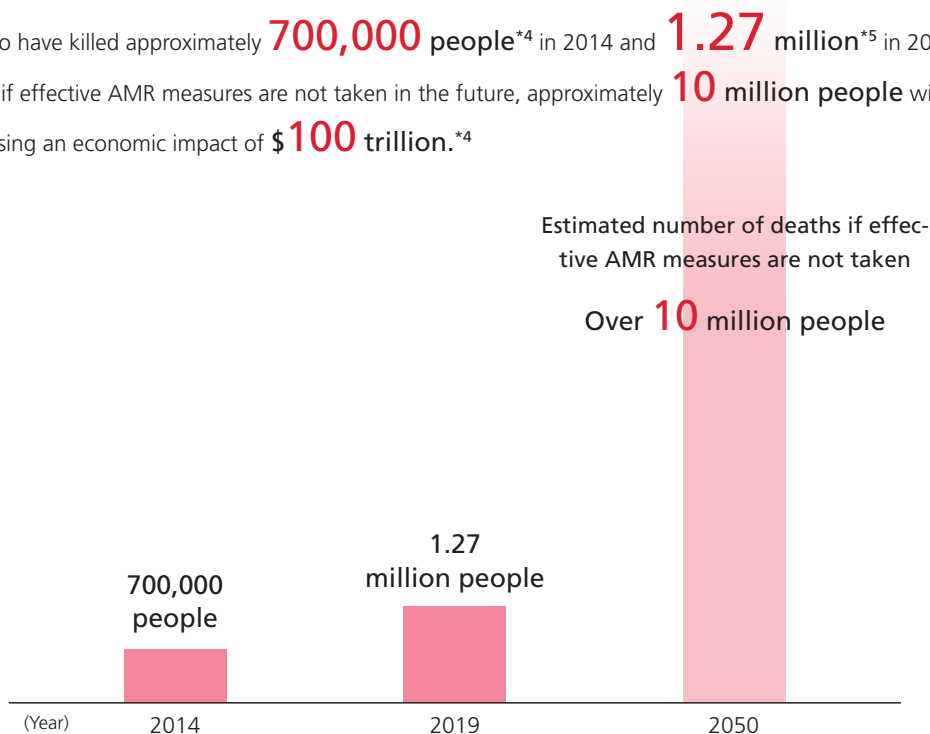


Antimicrobial resistance (AMR)

Deaths due to AMR bacteria (annual)

AMR is estimated to have killed approximately **700,000** people^{*4} in 2014 and **1.27** million^{*5} in 2019.

It is estimated that if effective AMR measures are not taken in the future, approximately **10** million people will die annually by the year 2050, causing an economic impact of **\$100** trillion.^{*4}



^{*4} O'Neill J., "Tackling drug-resistant infections globally: final report and recommendations", London: Review on Antimicrobial Resistance (2016)

^{*5} Antimicrobial Resistance Collaborators, "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis", The Lancet (2022)

Cefiderocol^{*6}, a treatment for multidrug-resistant bacterial infections

Sales of cefiderocol in FY2021 were approximately **¥6.2** billion in the U.S. (up 268.7% YoY) and approximately **¥3.6** billion in Europe (up YoY).

Our partnership with GARDP and CHAI will pave the way for access to cefiderocol for **135** countries, including all low-income countries and most lower- and upper-middle-income countries.

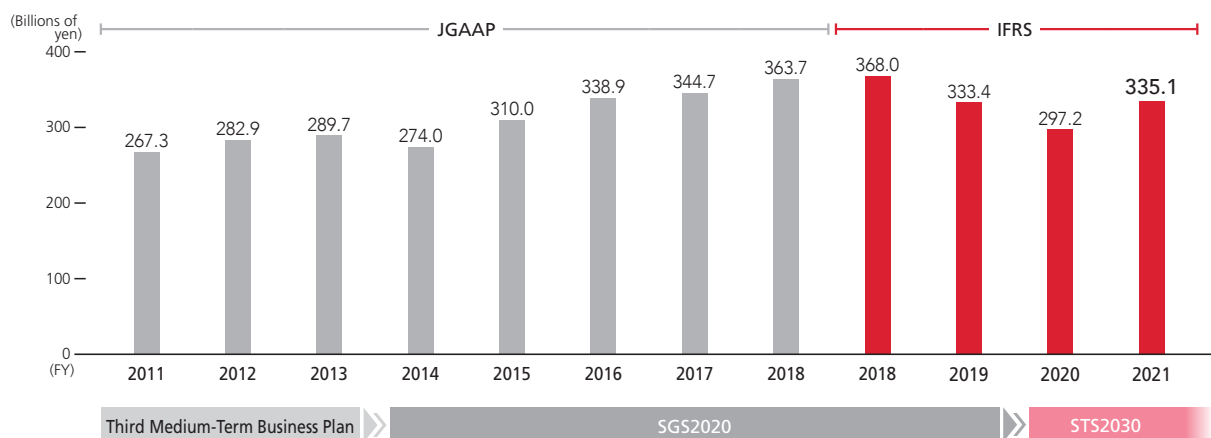
^{*6} U.S. brand name: *Fetroja*; European brand name: *Fetroja*



Financial Highlights / Non-Financial Highlights

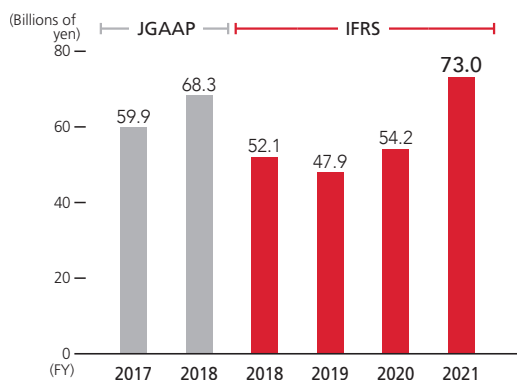
SHIONOGI has adopted International Financial Reporting Standards (IFRS) from fiscal 2019.
The financial figures for fiscal 2018 are shown according to both Japanese Generally Accepted Accounting Principles (JGAAP) and IFRS.

■ Revenue

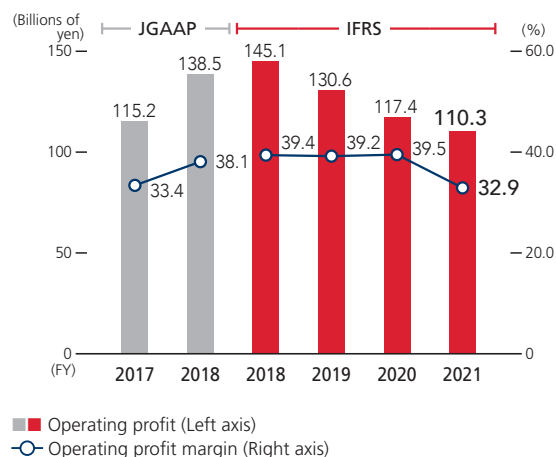


Revenue was ¥335.1 billion, a 12.8 percent increase year on year. Domestic revenue of prescription drugs were ¥89.1 billion, a decrease of 5.9 percent year on year, as a result of the launch of a generic version of *Cymbalta*. On the other hand, revenue from overseas subsidiary sales and exports was ¥34.4 billion, a 39.5 percent increase year on year, due to the growth in sales of cefiderocol in the U.S. and Europe. Royalty income was ¥181.3 billion, a 25.3 percent increase year on year, due to the growth in royalty income from the HIV franchise.

■ R&D expenses

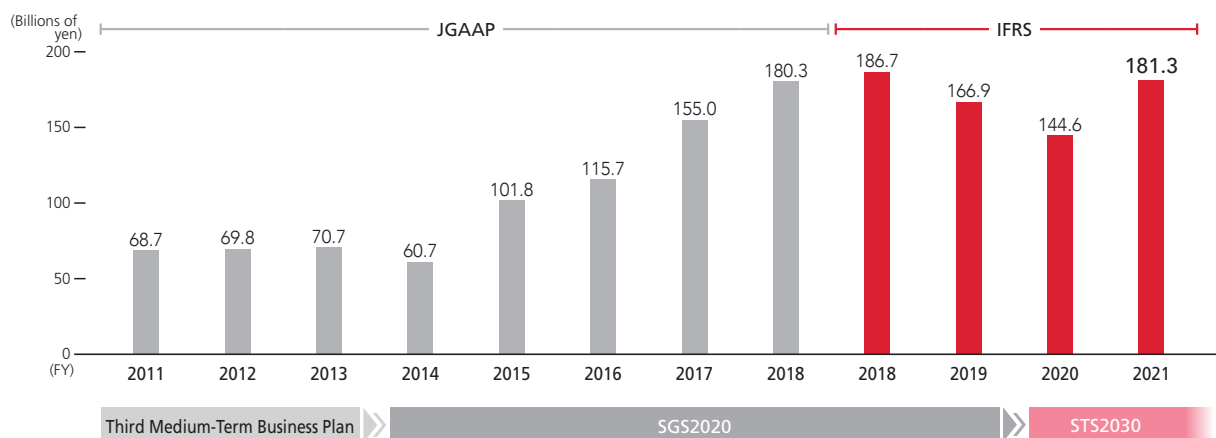


■ Operating profit/Operating profit margin



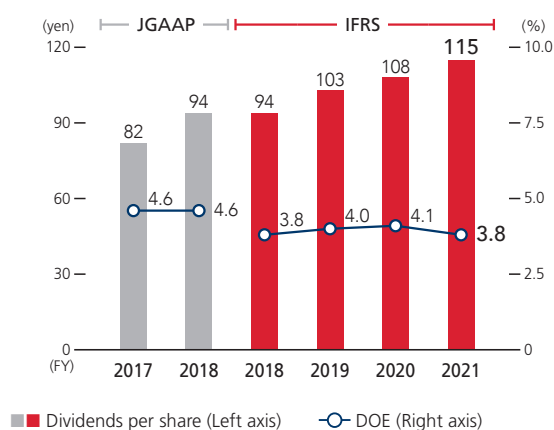
Operating profit was ¥110.3 billion, a 6.1 percent decrease year on year, as research and development expenses increased due to aggressive investment in projects related to COVID-19. Core operating profit, which excludes non-recurring items, was ¥110.6 billion, an increase of 17.7 percent year on year.

Royalty income



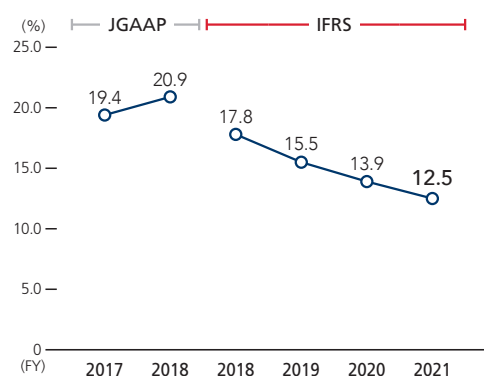
Royalty income was ¥181.3 billion, a 25.3% increase year on year, as sales of the HIV franchise out-licensed to UK-based ViiV Healthcare Limited. grew, and royalty income accompanying the settlement of the patent infringement litigation against U.S.-based Gilead Sciences, Inc. was recorded.

Dividends per share/DOE



Dividends per share were ¥115, up ¥7 from the previous year, making this our tenth consecutive year of dividend growth. DOE was 3.8%.

ROE



ROE was 12.5%. The introduction of IFRS resulted in a lower ROE, due to the impact of an increase in equity items (equity attributable to owners of the parent).

Financial Highlights / Non-Financial Highlights

■ Code of Conduct signature rate (FY2021)

100%

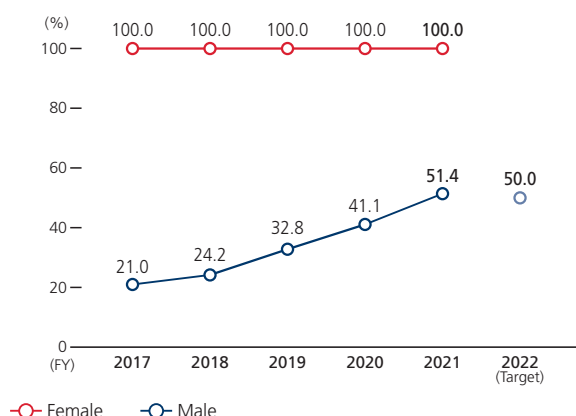
* Shionogi & Co., Ltd. and its domestic group companies

■ Education and training expenses per person (FY2021)

¥48 thousand

*(Education and training expenses + amount of self-investment support)/number of employees (Domestic consolidation)

■ Acquisition rate of childcare leave



FY2022 target (Male)

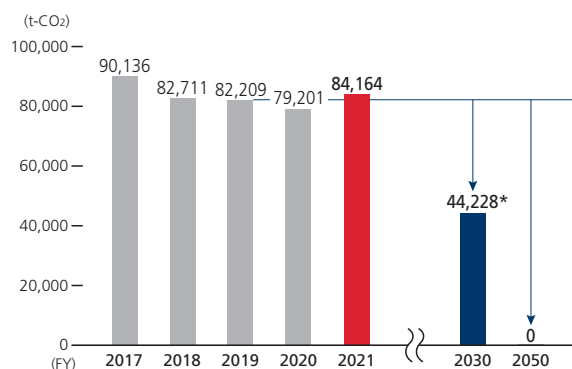
Acquisition rate of childcare leave/days off for childcare purposes of **50%** or more for male employees

■ External evaluations

	FY2019	FY2020	FY2021
CDP	Climate change: A- Water Security: A	Climate change: A- Water Security: A SER*: Leaderboard	Climate change: A- Water Security: A- SER: Leaderboard
FTSE	Not selected/2.9	Selected/3.4	Selected/3.7
MSCI	AA	AA	AA
DJSI	No response/19 points	Response/45 points	Response/53 points
S&P/JPX Carbon Efficient Index	Third decile	Fourth decile	Fifth decile
Toyo Keizai CSR Ranking	63rd of 1,593 companies	34th of 1,614 companies	53rd of 1,631 companies
SOMPO Sustainability Index	Selected	Selected	Selected
Survey on Health and Productivity Management	White 500	White 500	Certified Health & Productivity Management Outstanding Organizations

* SER: Supplier Engagement Rating

■ GHG emissions (Scope 1 and 2)



FY2030 target*

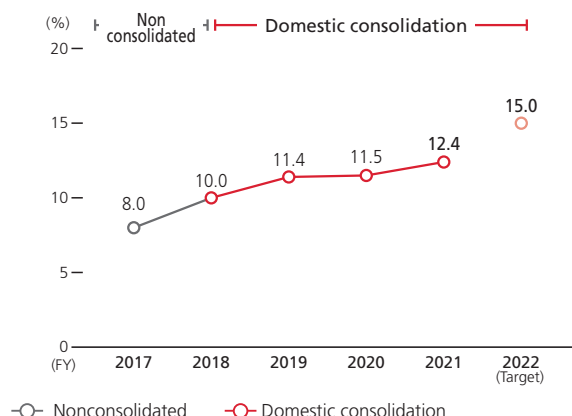
FY2050 target

down **46.2%** (FY2019 benchmark)

Zero

* This includes emissions by UMN Pharma Inc. and Nagase Medicals Co., Ltd., (currently Shionogi Pharma Co., Ltd., Itami Plant) since 2019, the reference year, because that is the boundary for fiscal 2030 targets (SBT).

■ Ratio of female managers



FY2022 target (domestic consolidation)

Rate of female employees occupying management positions: at least **15%**

At a glance

■ Core operating profit margin (FY2021)

33.0%

■ ROE (FY2021)

12.5%

■ Internally-discovered pipeline ratio (as of Mar. 2022)

73%

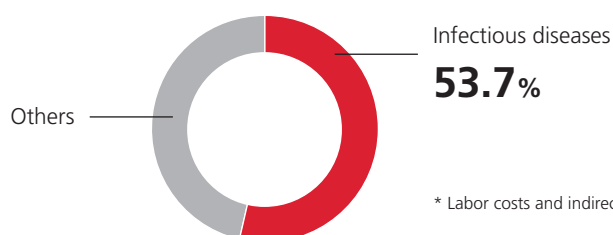
■ COVID-19 pipeline (as of August 1, 2022)

Area	Pipeline	Indication	Status
Infectious disease	S-217622 (ensitrelvir)	COVID-19 treatment	Japan: Application, phase2/3 clinical trials in progress Global: Phase 3 clinical trials in progress
	S-268019	COVID-19 prevention (muscular injection)	Japan/global: Phase 3 clinical trials in progress
	S-555739 (asapirant)	Control of the aggravation of COVID-19	US: Phase 2
	S-875670	COVID-19 nasal vaccine	Nonclinical studies in progress

■ Main pipeline (as of August 1, 2022)

Area	Pipeline	Indication	Status
Infectious disease	S-872600	Influenza nasal vaccine	Nonclinical studies in progress
	S-540956	① Infectious disease ② Cancer	Preparing for Phase 1 clinical trials
Neuropsychiatric disease	S-600918 (sivopixant)	Refractory/unexplained chronic cough	Preparing for Phase 3 clinical trials
	S-812217 (zuranolone)	Depression	Preparing for Phase 3 clinical trials
	BPN14770 (zatolmilast)	Fragile X syndrome	Phase 2b/3 clinical trials in progress
	S-531011	Solid tumors	Phase 1b/2 clinical trials in progress
New growth areas	S-005151 (redasemtide)	① Epidermolysis bullosa ② Acute ischemic stroke ③ Knee osteoarthritis ④ Chronic liver disease ⑤ Cardiomyopathy	① Started additional clinical trials ② Preparing for Phase 3 clinical trials ③ ④ Investigator-initiated clinical trials (Phase 2 clinical trials) in Progress ⑤ Preparing for investigator-initiated clinical trials

■ Proportion of R&D expenses for the infectious disease area (FY2021)



* Labor costs and indirect spending not included.