



**Helping people lead healthier,
happier lives**

Annual Report
2021



**Our mission is to be
a meaningful existence in the healthcare
field by playing an indispensable role.**

Business Philosophy

Helping People Lead Healthier, Happier Lives

Management Policy

Customers: Supply Unique and High-quality Products

We will develop and supply pharmaceuticals that are safe and highly effective relative to other drugs, and that in some way contribute to a better quality of life in patients, first and foremost for patients who suffer from illnesses. We will develop and supply high-quality functional food that meets the needs of customers.

Society: Earn the Trust of Society

We will achieve regulatory compliance and adherence to internal rules, and always remember our corporate social responsibility and behave according to high ethical standards.

Employees: Develop Each Employee

We will develop each employee through goal-setting and positive challenges in work.

Guidelines for Action

Challenge: Meet Challenges

We will always take a positive approach in pursuing our goals, with a firm belief and sense of responsibility rooted in an ethical approach.

Speed: Speedy Action

We will always take speedy action to make certain to seize opportunities.

Investigation: Spirit of Investigation

We will carefully investigate and analyze information that we have broadly gathered, and carefully plan to achieve our goals, and make certain to implement plan-do-check-action (PDCA) cycles.

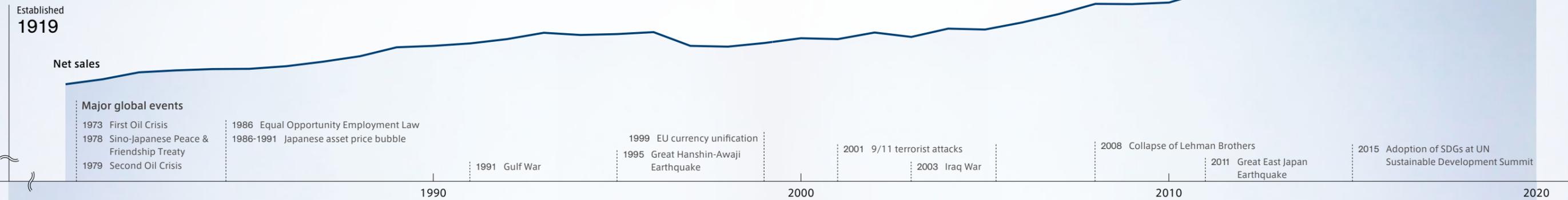
Smile: Keep on Smiling

We will always act with a smile to make certain of smooth communication.

History of Nippon Shinyaku

FY2020 Net Sales
¥ 121,885 million

Using original technology to give hope to those suffering from intractable diseases and to create healthier lives with unique functional foods, we are committed to enhancing life in this new age.



1970s–1980s Forging an independent path as business conditions evolved

As the period of high economic growth rates ended, Japanese society underwent a major transition with the introduction and development of the social welfare system. The pharmaceutical industry saw demand increase for products that were proved safe and not just efficacious. The system of national health insurance introduced in the 1960s began to prepare for the anticipated aging of Japan through measures to restrict healthcare spending.

1990s Start of global business development and drug discovery

The 1990s were a so-called "lost decade" for Japan after the bursting of the asset price bubble. This led to calls for drastic reform of the drug pricing system as part of fiscal reconstruction. System revisions systematically cut the NHI reimbursement prices of prescription drugs, leading to a new structure in which wholesalers would compete on price at the point of delivery.

With economies and societies starting to globalize, Japan's pharmaceutical industry began to look to overseas markets.

2000s Reinforcement of business foundation to respond to drastic changes in conditions

At the start of the 21st century, advances in life sciences focused attention on new drug-discovery methods and targets. Amid continued globalization, competitiveness in global markets became the core basis for decision-making in drug development. In Japan, measures to restrict social insurance costs amid rapid falls in birth rates created headwinds for the pharmaceutical sector, prompting consolidation of the industry.

2010s Aiming for global respect as manufacturer in the healthcare field

Measures to restrict healthcare spending accelerated in Japan amid a rapid shift to aging demographics. Drug makers looked for ways to maximize value from soaring R&D costs, including re-evaluating how to manage off-patent products and building new business models to cope with altered conditions. The strategic necessity became to focus R&D on therapeutic areas with high unmet needs and identify targets by focusing on domains of special expertise.

Actions by Nippon Shinyaku

Anticipating the introduction of mandatory Good Manufacturing Practice (GMP: a set of standards for pharmaceutical production and quality control) across the industry, we ensured that our production facilities at Odawara and other sites maintained high quality and were fully GMP-compliant, while also working to keep costs low. We invested in biological research laboratories for mandatory drug safety testing. In 1982, we completed construction of the central research laboratory as a GLP-compliant facility for non-clinical safety testing as part of major investments to upgrade our R&D capabilities. We also led the industry in introducing a 6-month training program for MR education to support professional drug detailing activities.

Our annual net sales passed the ¥10 billion mark in FY1970. By our 60th anniversary in FY1979, net sales had grown rapidly to ¥32.7 billion. Responding to strong social demand for effective pharmaceuticals, we built up our business base while keeping abreast of industry trends.

Opening offices in Germany and the US, we began to base the development of our international operations on the three poles of Japan, the US and Europe. We upgraded our capabilities for drug discovery and nucleic acid medicine development, constructing a second building at the Discovery Research Laboratories and a new R&D facility in Tsukuba. The first half of the 1990s saw a flood of product launches, and we focused our sales resources to cultivate blockbuster drugs. We also built a new API production facility at Chitose and established the new Functional Food Division as we started to supply health food ingredients.

As business conditions became steadily more challenging, annual net sales passed the ¥50 billion mark in FY1992 before staying around that level for several years. We upgraded our environmental protection initiatives in the 1990s, instituting a set of global environment guidelines in 1992, followed by the Nippon Shinyaku Basic Environmental Policy in 1998.

To create a business foundation to respond to the altered business environment, we formulated medium-term management plans based on a vision aligned with our business philosophy. We reorganized internal structures, creating the Corporate Strategy Office; flattening the research organization for efficient development of drug candidates; and creating a dedicated training center to upgrade our education systems for MRs. In 2002, as part of the global development program, we relocated NS Pharma to New Jersey to support local clinical development.

We also focused our R&D on cutting-edge nucleic acid medicines in a bid to build Nippon Shinyaku's global reputation as an R&D-led specialty pharmaceutical maker. These marked the first steps on the road to creating a new generation of high-quality medicines needed by society.

To create a new therapeutic area to drive the growth of the business, we initiated Japan's first antisense oligonucleotide research program. We also invested in related manufacturing infrastructure to support business expansion, constructing new production facilities for clinical trial APIs in Kyoto and for highly active solid formulations in Odawara to enable the development of nucleic acid medicines and other highly active pharmaceuticals.

With the "pursuit of originality" as our management theme, we focused in-house drug discovery and in-licensing efforts on niche areas where major pharmaceutical firms are less involved, actively targeting diseases with unmet medical needs based on a philosophy of delivering new hope to patients. We created a stream of new products while applying product life cycle management (PLCM) methods to manage the portfolio of existing drugs.



Odawara plant (now Odawara Central Factory) Main central research lab (now Discovery Research Laboratories Building No. 1)



Discovery Research Laboratories Building No. 2 Discovery Research Laboratories in Tsukuba



MR training session NS Pharma



Clinical trial API manufacturing facility Highly active solid formulation production facility (Odawara Central Factory)

Challenges We Face

Challenge #1 Patients affected by rare diseases

400 million

Compared with cancer, diabetes or other conditions that affect many people, rare diseases affect relatively small numbers of people. Different definitions exist, but more than 7,000 rare diseases have been reported that affect roughly 400 million* people worldwide. Many rare diseases are intractable, with no cure or effective treatment. This leaves patients with an uncertain future, and, in many cases, requiring lifelong medical care. There is a clear need to develop treatments to help these patients as quickly as possible.

* Source: RARE Disease Facts, Global Genes (NPO)

Challenge #2 Food waste

1.3 billion tons/year

Each year approximately 1.3 billion tons of food, equivalent to roughly one-third of global food production, goes to waste. In Japan, annual food waste is estimated at 6.12 million tons* (FY2017). Some of this waste is unsold goods and returns by retail stores (commercial waste), and some is classified as domestic food waste by households. The Japanese government has set a target of halving food waste by FY2030 compared with FY2000 levels.

Neglecting the issue of food waste risks environmental degradation or future food crises if human populations continue to increase. Reducing food waste is a vital issue that must be addressed globally.

* Source: Consumer Affairs Agency (reference materials on food waste reduction, November 30, 2020)

Challenge #3 Worst-case temperature rise by 2100

Approx. 4°C*

The world faces growing environmental impacts each year from extreme weather events and natural disasters. The COP21 conference in Paris saw global leaders agree to the goal of restricting the rise in global temperatures by 2100 compared with a pre-industrial baseline to no more than 2°C, and if possible to a rise of just 1.5°C. Ensuring future generations inherit the bounty of nature means recognizing that business activities must co-exist in harmony with the Earth's environment.

* IPCC Fifth Assessment Report (published 2014)

Nippon Shinyaku's Approach

Approach #1

Find small molecule or oligonucleotide drugs through innovative R&D

Based on innovative in-house R&D, Nippon Shinyaku has developed small molecule and oligonucleotide drugs as treatments for two rare diseases: Uptravi for pulmonary arterial hypertension, and Viltepso for Duchenne muscular dystrophy. These products offer new and effective therapeutic options for patients affected by these rare and previously intractable diseases.

Yet many rare diseases still lack effective treatments. Our goal is to develop more treatments for rare diseases with high unmet medical needs, focusing not only on small molecules and oligonucleotide drugs, but also on new drug discovery modalities such as gene therapy. Through R&D, we aim to offer hope to patients and their families by delivering new and effective medicines for rare conditions.



Approach #2

Help to reduce food waste

Developing long-life foods is an effective way of reducing food waste. Utilizing in-house R&D, Nippon Shinyaku is working to develop original technology to create long-life formulations for different foods. Incorporating AI-based technologies, we are developing preservatives to enable longer shelf lives for foods without loss of taste or quality. Such products can play a role in reducing global food waste.



Approach #3

Take positive action on climate change

Having previously identified measures to address climate change as a materiality issue, Nippon Shinyaku has instituted the Basic Environmental Policy to define our corporate social responsibilities towards the environment while guiding the efforts to mitigate environmental impacts across our entire business operations as a critical management issue. We have set related environmental performance targets that are reviewed and managed using a 3-year PDCA cycle. Under the 6th Nippon Shinyaku Environmental Targets Plan (FY2020–2022), we aim to reduce CO₂ emissions by 25% relative to the baseline year of FY2013 by FY2030. Programs to reduce emissions are focused on cutting energy consumption and generating more energy from renewable sources, among other measures.



CONTENTS

Nippon Shinyaku's Mission

- 1 Business Philosophy / Management Policy / Guidelines for Action
- 2 History of Nippon Shinyaku
- 4 Challenges We Face / Nippon Shinyaku's Approach
- 6 Contents / Editorial Policy
- 7 External Recognition / Participation in Initiatives / Nippon Shinyaku Website

Management Message

- 8 Message from the Chairman
- 10 Message from the President

Feature

- 16 **01** Getting Viltepso to the Patients Who Need It
 - 17 Japan
 - 18 Overseas
- 20 **02** Nippon Shinyaku's Initiatives in Response to the COVID-19 Pandemic
- 22 **03** Initiatives to Promote Digital Transformation (DX)

Nippon Shinyaku's Value Creation

- 24 Business Segments
- 26 Financial and Non-Financial Highlights
- 28 Value Creation Story
- 30 Materiality
- 34 Medium-term Management Plan (MTMP) Overview

Strategies for Value Creation

- 38 Pharmaceuticals
 - 38 R&D
 - 40 Sales
 - 42 Resource Procurement, Production & Assurance
- 44 Functional Food

Editorial Policy

This report was composed so that all of our stakeholders can further understand our corporate value. Accordingly, we have created an integrated report to include not only financial information, but also non-financial information such as that relating to the environment, society, and governance.

Period Covered

Fiscal 2020 (April 1, 2020–March 31, 2021). Some sections of the report also discuss initiatives from April 2021 onwards.

Companies Covered

Information in this report pertains to Nippon Shinyaku Co., Ltd. and its Japanese and overseas group companies. However, some sections apply only to Nippon Shinyaku Co., Ltd.

ESG Management

- 46 How We View Sustainability
- 47 Initiatives for the Environment
 - 47 Environmental Management
 - 48 Climate Change Alleviation
 - 49 Promoting the Recycling of Resources
 - 50 Promoting Proper Management of Chemical Substances
 - 51 Conservation of Biodiversity
- 52 Initiatives for Society
 - 52 Promoting Employee Health Management and Workplace Safety
 - 54 Achieving a Work-Life Balance and Allowing Every Employee to Grow and Thrive
 - 56 Promoting Diversity and Inclusion
 - 58 Community Life
 - 60 Responsible Procurement
- 61 Governance
 - 61 Corporate Governance
 - 65 Compliance
 - 66 Risk Management
 - 68 Messages from External Directors
 - 70 Board of Directors, Corporate Officers and Corporate Auditors

Corporate Information

- 72 Ten-Year Financial Data
- 74 Non-Financial Data
- 76 Management's Discussion and Analysis
- 78 Consolidated Financial Statements
- 83 Notes to Consolidated Financial Statements
- 93 Independent Auditor's Report
- 98 Corporate Data / Investor Information

Forward-Looking Statements

Statements contained in this report concerning plans, predictions, and strategies to improve future performance ("forward-looking statements") are based on information currently available to the Company's management, and inevitably involve a certain element of risk and uncertainty. Actual results may therefore differ from those in the forward-looking statements.

* Figures presented in this report are taken from Nippon Shinyaku's Financial Report for the year ended March 31, 2021. As figures have been rounded, totals may not exactly equal the sum of their composite statistics.

* Product names featured in this report are registered trademarks of Nippon Shinyaku or affiliated companies.

* All information in this report, including comments, has been obtained in an appropriate manner.

External Recognition



JPX Nikkei Index 400

Nippon Shinyaku has been selected as a constituent of the JPX Nikkei Index 400, a stock index jointly managed by the Japan Exchange Group (JPX), Nikkei Inc., and the Tokyo Stock Exchange.



"White 500" program

Nippon Shinyaku gained selection as a White 500 company in the Certified Health & Productivity Management Outstanding Organization Recognition Program for 2021. Run by the Ministry of Economy, Trade and Industry and Nippon Kenko Kaigi, the program aims to recognize large companies and SMEs that have an excellent track record in health management.



Nikkei SDGs Management Survey

Initiated in 2019, this survey conducted by Nikkei Inc. evaluates companies based on the fit between the SDGs and operational management. It uses a five-step evaluation across the four factors of "economic value," "social value," "environmental value," and "governance." Nippon Shinyaku received three stars in the latest survey.



Sports Yell Company

This designation from Japan Sports Agency recognizes companies that actively work to promote the health of employees through sports-based initiatives.



Nikkei Smart Work Management Survey

This annual survey has been conducted by Nikkei Inc. since 2017. Nippon Shinyaku received a mark of 3.5 stars (out of five) in the fourth Nikkei Smart Work Management Survey.



MSCI Japan Empowering Women Index (WIN)

Nippon Shinyaku is a constituent of the MSCI Japan Empowering Women Index, one of the ESG indexes adopted by Japan's Government Pension Investment Fund.

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All Japanese Listed Companies' Website Ranking of 2020 by Nikko Investor Relations Co., Ltd.

The ranking is created from a survey of all 3,844 listed companies, using an objective evaluation from the three perspectives of the corporate website's ease of use, ease of understanding, and quantity of information. The overall ranking for Nippon Shinyaku's website placed it in the "AA" category.

Participation in Initiatives



United Nations Global Compact (UNGC)

As a signatory to the UNGC since January 2020, Nippon Shinyaku is committed to supporting ten principles in the four areas of human rights, labor, the environment, and corruption prevention. We are conducting a range of related activities.

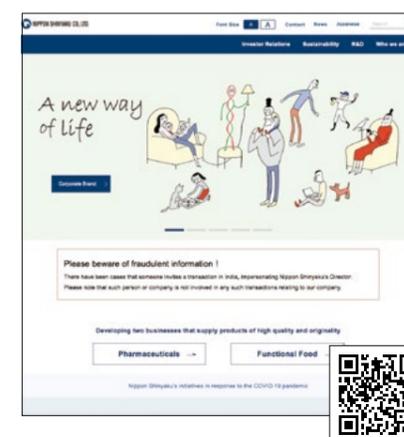


Sustainable Development Goals (SDGs)

This report details how our activities are related to the UN-adopted SDGs, which are a set of international goals with a target date of 2030 (see individual pages for details).

Nippon Shinyaku Website

Our website also contains some additional information not covered in this report.



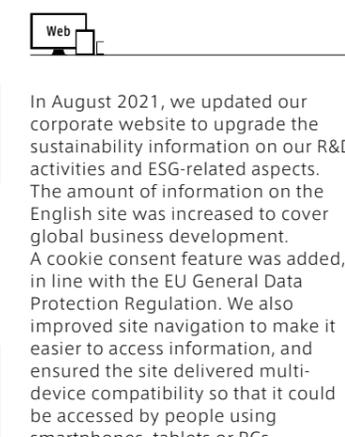
Home page URL (English site):
<https://www.nippon-shinyaku.co.jp/english/>



Investor Relations section URL (English):
<https://www.nippon-shinyaku.co.jp/english/ir/>



Sustainability section URL (English):
<https://www.nippon-shinyaku.co.jp/english/sustainability/>



In August 2021, we updated our corporate website to upgrade the sustainability information on our R&D activities and ESG-related aspects. The amount of information on the English site was increased to cover global business development. A cookie consent feature was added, in line with the EU General Data Protection Regulation. We also improved site navigation to make it easier to access information, and ensured the site delivered multi-device compatibility so that it could be accessed by people using smartphones, tablets or PCs.

Message from the Chairman



Helping people to lead healthier,
happier lives by providing
distinctive products of high quality

S. Maekawa

Shigenobu Maekawa
Chairman

Move to new management structure

The global COVID-19 pandemic has led to continuing uncertainty, which in turn has resulted in business conditions for Nippon Shinyaku remaining in a state of rapid flux.

If we are to build on the unique business presence that we have in healthcare to become an indispensable player capable of sustained growth, we must accelerate our global development and redouble our focus on developing overseas markets.

To support a more international outlook under these conditions, we decided to move to a new management structure in which I would be succeeded as President by Mr. Toru Nakai, who has the required international business experience to help us respond flexibly to societal changes that demand speed and diversification.

In my new role as Chairman of the Board of Directors, I will support our efforts to realize the growth of Nippon Shinyaku's business over the medium and long term by enhancing our corporate governance.

What it takes to be “a company with a meaningful existence in the healthcare field”

Nippon Shinyaku's business philosophy is about helping people lead healthier, happier lives by supplying unique and high-quality products; by earning the trust of society; and by developing each employee. Under this policy, we are seeking to generate sustained growth by developing groundbreaking new drugs and functional foods that deliver original value, while at the same time playing our proper social role as a corporate citizen to contribute to community development. In the pharmaceuticals business, we are primarily targeting diseases with unmet treatment needs in four therapeutic areas, giving hope to patients suffering from illnesses by supplying medicines that are distinctive and of high quality. In the functional food business, we seek to use our high level of technical expertise as a pharmaceutical maker to create products with high added value to satisfy market needs.

Leveraging our traditional strengths in drug discovery based on small molecules and nucleic acids, we aim to launch new products that cater to market needs by further enhancing our R&D capabilities as well as accepting the challenge of new modality development. We are working to boost productivity through active AI utilization and promotion of advanced IT, along with the deployment of digital transformation (DX) technologies. Our aim is to develop our operations globally by creating new business opportunities.

We also continue to upgrade our focus on ESG (environmental/social/governance) management so we can continue to play a critical role in a sustainable society. An essential aspect of managing the business going forward is to accept the materiality of our efforts to help achieve the UN Sustainable Development Goals (SDGs). Our business activities are not just about pursuing sales and profits: by helping to address societal issues, our aim is to raise corporate value while aspiring to remain a company with a meaningful existence in the healthcare field.

A robust governance structure is essential to support these kinds of activities. Our aim is to ensure sound management that operates with a high degree of integrity and transparency as we work to respond promptly to change. Besides ongoing gains in corporate value, we are targeting enhanced Board effectiveness, along with further improvements in our systems for executing business policies.

Message to stakeholders

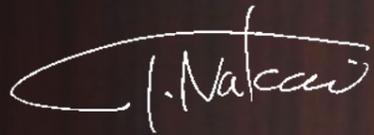
This report aims to inform stakeholders about the initiatives at Nippon Shinyaku that aim to promote sustained growth. We hope it will provide a useful tool for communicating with stakeholders.

With the end of the pandemic in sight, we are focused on conducting business activities with integrity while actively undertaking dialogue with stakeholders so that we can earn the trust of society as we work to build our business.

Realizing sustained growth is a constant challenge. We hope that you will extend Nippon Shinyaku your continued support and understanding.

Message from the President

What it takes to be “a company with a meaningful existence in the global healthcare field”



Toru Nakai
President



On my appointment as President

I was appointed President in June 2021.

Since joining Nippon Shinyaku in 1995, I have worked in many divisions and roles: as a medical representative, in charge of NHI pricing, and in marketing, among others. One highly valuable experience was working in the Global Business Division, which included some time spent overseas. While I was heading up this division, I pushed ahead with the development of a global pharmaceutical business by building up the organization and working in partnership with

related divisions such as R&D, manufacturing, distribution, sales, and administration. The constant collaboration with partners inside and outside the company based on repeated trial-and-error has afforded me a deep insight into the Group's operations. I believe one of my strengths is that I can use this unique bird's-eye perspective to take appropriate management decisions quickly. I recognize that it is my duty as President to be thinking constantly about what Nippon Shinyaku needs to do, and to display the leadership to help harness our collective abilities to those ends. I see the qualities needed to fulfil

this duty as the ability to launch into the unknown; to be unafraid of change; to see it through to the end; to think for oneself habitually; and to be inclined to accept diversity.

I take on this heavy responsibility of the top job with a sense of urgency to apply our efforts to accomplishing everything that we should do or want to do for the future of Nippon Shinyaku. We do not want to look back later and regret having failed to do these things.

The role and mission of Nippon Shinyaku

We celebrated the centennial of Nippon Shinyaku in 2019. At the time that it was founded, most medicines were imported into Japan from overseas. The name of the company, which means “new drugs from Japan,” reflects the founder's desire to produce high-quality medicines with Japanese expertise, and build a company that would develop its business overseas.

Since its inception, the creation of novel medicines has been at the core of Nippon Shinyaku's identity. Our recent growth in sales has been driven by distinctive new products such as Defitelio, Gazyva and Upravi. Annual global sales of Upravi, which was developed in-house, exceed ¥100 billion, putting it in the blockbuster category. In 2020, we launched Viltepso, a treatment for Duchenne muscular dystrophy (DMD), in the US and Japan. It is the first antisense oligonucleotide discovered in Japan, and is contributing to further steady growth in sales.

For Nippon Shinyaku to enjoy sustained growth while pursuing an independent path, we must have our eye fixed on the global challenge as we work to generate a constant stream of highly innovative and distinctive new products to introduce to world markets. To this end, I believe it is essential that we continue to improve our existing technologies in small molecules and nucleic acid medicines, while also looking to

develop and acquire new drug discovery technologies to find therapies for diseases with unmet therapeutic needs and for rare and intractable diseases that currently have no treatment. Focusing on the fields where the major players are not involved can be a significant factor in the growth of Nippon Shinyaku, while also providing us with a *raison d'être*. Even if the number of patients who benefit from the medicines we develop is small, our goal must still be to create the medicines that alleviate suffering from the disease.

In our other core business of functional foods, we are working to supply markets with unique products in four focus areas – health food ingredients, preservatives, protein preparations, and supplements. These products are contributing to better health and enriched lifestyles.

The role and mission of Nippon Shinyaku is to help as many people as possible at the earliest juncture by supplying high-quality medicines and functional foods. It is my firm belief we must aim to expand the business by aspiring to be a company with a meaningful existence in the global healthcare field.

Modern society is seeing the emergence of many issues. Besides environmental problems, we also have the demographic challenge of a smaller workforce caused by low birth rates and an aging population. At the same time, the COVID-19 pandemic has resulted in a significant shift in lifestyles and the way we do many things. At Nippon Shinyaku, we have responded by introducing new ways of working, using new flextime and telework systems to help employees find their most productive work-life balance while improving the office environment. Through such initiatives, we are building workplaces where our employees find it easier to work so that we better respect different values. This in turn will help us to fulfill the company's role and mission.

Message from the President

Our three commitments

Creating a meaningful existence in the global healthcare field

Gauged using multiple business metrics, Nippon Shinyaku achieved significant growth under my predecessor Shigenobu Maekawa, the current Chairman. We will follow the path he created in policy terms while also doing more to respond to the trends of the time such as diversification of drug discovery modalities, globalizing markets, evolving workstyles, and greater diversity of values. Achieving these goals translates to three commitments, which I outline below.

1. Continue to launch at least one distinctive product each year

I believe we want Nippon Shinyaku to be a company that contributes to society by constantly delivering value in the form of distinctive new drugs offering benefits to patients and their families. The three core pillars supporting this mission are still in-house drug discovery, in-licensing, and product life cycle management (PLCM). However, we must be prepared to revise the specific details of these programs continually and promptly, without being swayed by earlier success or precedents.

2. Generate at least 50% of consolidated sales from overseas

Our operating margins bear comparison with the profitability metrics of major or second-tier pharmaceutical companies. In terms of the proportion of sales derived from overseas, however, the figure of 26.0% that we achieved in fiscal 2020 is lower than these companies, where the ratio is typically at least 30%. It is vital that Nippon Shinyaku develop a stronger presence in overseas markets if we are to forge sustained growth in the future. This means our policy must be to develop operations not just in the US, but also in Europe, China and other markets, so we



can target a higher proportion of overseas sales. Although the Japanese market is struggling for various reasons, we can continue to show our value as a company by developing and launching a continual stream of distinctive new products.

3. Target at least 100% gains in net sales and operating income

We must also be committed to building a foundation to expand Nippon Shinyaku's net sales in the future to ¥300 billion, and from there to ¥500 billion.

Let me outline the specific policies that we will pursue. In pharmaceuticals, we will invest aggressively to upgrade our R&D capabilities through advanced drug discovery technologies, and to develop new drug-discovery modalities outside of nucleic acid medicines. Our core disease targets will be areas of unmet therapeutic need, focusing mainly on the four areas of urology, hematology, intractable and rare diseases, and gynecology. We will seek to develop and upgrade an R&D pipeline filled with products with global potential. In functional food, we will use our advanced expertise as a manufacturer of medicines to supply high-value-added products that address societal needs such as reduction of food waste and efforts to combat aging. Our overall aim remains to generate sustained growth and increased corporate value.

6th Five-Year Medium-term Management Plan

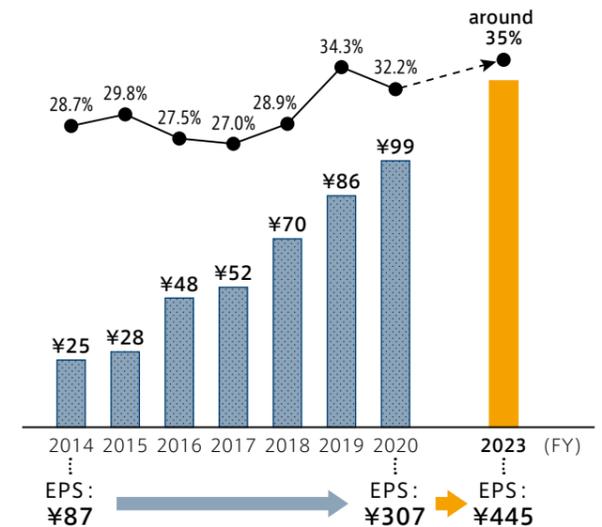
Under the 6th Five-Year Medium-term Management Plan covering the period to the end of March 2024, our targets for the final year of fiscal 2023 are net sales of ¥150 billion and operating income of ¥40 billion. Compared with the results in the final year of the 5th Five-Year Medium-term Management Plan (FY2018), these targets represent a 30% gain in net sales (equivalent to a CAGR of 5.5%) and a 90% gain in operating income (or CAGR of 14.2%). The aim of the 6th Plan is to expand the earnings base developed in the 5th Plan so that it is robust enough to support sustained future growth. We have set a range of quantitative targets that we aim to achieve through "six actions."

Separately, we are actively investing in the tangible and intangible asset base of Nippon Shinyaku's human, knowledge and information resources, along with our experience and facilities. Investments aim to upgrade our R&D, human capital and IT capabilities, and to foster gains in productivity. Specific objectives include upgrading the development pipeline by strengthening our R&D set-up; investing in technology for the Discovery Research Laboratories; capital spending to increase the efficiency of existing technologies; and actively utilizing AI, IoT and robotic process automation

(RPA) to help raise productivity. These growth investments are part of achieving another goal of the 6th Plan, to maintain double-digit ROE. We achieved this in fiscal 2020, when we recorded ROE of 13.5%.

Our policy is to balance the investment of profits to create a stronger earnings base with the returns to shareholders. Under the 6th Plan, we are targeting a dividend payout ratio of approximately 35%, with dividends per share (DPS) expected to rise along with earnings per share (EPS). DPS was ¥99 in fiscal 2020, comprising an interim dividend of ¥49 per share and a final dividend of ¥50 per share. We plan to increase DPS by ¥4 in fiscal 2021, to ¥103.

Dividend per share / Payout ratio



6th Five-Year Medium-term Management Plan numerical targets for FY2023

(Consolidated)	FY2018 results	FY2020 results	FY2023 target	CAGR ^{*1}
Net sales	¥114.7 billion	¥121.8 billion	¥150.0 billion	5.5%
Pharmaceuticals	¥100.2 billion	¥106.4 billion	¥133.0 billion	5.8%
Functional Food	¥14.4 billion	¥15.4 billion	¥17.0 billion	3.4%
Operating income	¥20.6 billion	¥26.1 billion	¥40.0 billion	14.2%
Net income attributable to owners of the parent	¥16.3 billion	¥20.7 billion	¥30.0 billion	13.0%
EPS ^{*2}	¥242	¥307	¥445	13.0%
ROE ^{*3}	12.5%	13.5%	10% or more during term of 6th Plan	

*1 CAGR: Compound Annual Growth Rate

*2 EPS: Earnings Per Share

*3 ROE: Return On Equity

Message from the President

ESG-based management

To create a future of sustainable growth for Nippon Shinyaku, we must contribute to efforts to realize a sustainable society through ESG-based management. This means focusing more on non-financial aspects such as addressing environmental issues or supporting employee wellbeing. We review regularly both the content and goals of our ESG initiatives, in line with our materiality analysis, so that we can improve while also responding flexibly to societal changes. We will continue doing what we can to support the creation of a sustainable society by helping to achieve the SDGs, which in the process will help us to increase our corporate value.

1 Environmental [E]

We are further upgrading environmental initiatives aimed at addressing issues that relate to climate change, based on lower greenhouse gas emissions and a range of other measures. This will help us achieve the 6th Nippon Shinyaku Environmental Targets Plan that we formulated in fiscal 2020, and, later, the long-term goals we identify as material.

Since fiscal 2020, our emissions disclosures encompass not only Scope 1 and Scope 2 emissions, but also the Scope 3 emissions related to our supply chain. The massive production and consumption of limited planetary resources associated with our way of life entails a huge environmental impact. As a company, we are working to assess our emissions more precisely and manage hazardous substances to support more eco-friendly production activities.

2 Social [S]

One of Nippon Shinyaku's management policies is to "develop each employee." We recognize human resources as the driving force for sustained growth. We aim to cultivate pleasant working environments full of smiling people and vitality, and to support the physical and mental health of employees as well as the families who support them. As we work to develop our global business, we must also respect diversity and treat people the same, irrespective of factors such as age, gender, ethnicity or nationality. At a time when conditions are changing rapidly, the risks of making decisions as an overly homogenous group are magnified, and it is vital

to promote initiatives that support greater diversity and inclusion. Over 60% of the workforce at our US subsidiary NS Pharma are local hires. One of the next steps is to ensure we have more globally minded people working at our head office in Kyoto.

Personally, I try to communicate actively with employees as much as possible. I want every employee to feel motivated to take on bright and exciting challenges in pursuit of the next goal, never settling for the status quo.

3 Governance [G]

Effective governance is essential if we are to be accountable to all stakeholders. Mindful of the risks associated with any serious breach of compliance, we have established a compliance management system and instituted measures to support the effective functioning of the Board of Directors and the Board of Auditors. We are also working to enhance transparency and independent oversight by reinforcing the supervisory functions of the external directors, among other measures.

Closing remarks

One of my favorite aphorisms is the advice to go find the 'mountain of flowers' where no one else goes before its blooms disperse. The phrase is frequently used as a maxim for stock market investors, advocating the contrarian thinking that profits can often be made by going against the excessive movements caused by herd psychology, or by deliberately investing in the areas where others have not focused attention. I believe this is in line with our style of management at Nippon Shinyaku because of how highly we value originality. The second half of the phrase captures the need to act both decisively and quickly, whichever path you choose. As stated in Nippon Shinyaku's guidelines for action, it is important to meet challenges with a sense of urgency when you are operating in a rapidly changing environment.

Under the new management structure, we will continue to aspire to be a company with a meaningful existence in the global healthcare field, and will target sustained growth by creating distinctive products of high quality, based on the spirited pursuit of originality by every employee. In closing, I ask all stakeholders for their continued support and understanding.



Getting Viltepso to the Patients Who Need It

A core R&D challenge faced by Nippon Shinyaku is the development of therapies for intractable and rare diseases with no established treatment. Approved in Japan in March 2020 for Duchenne muscular dystrophy (DMD), Viltepso is the result of many years of research into nucleic acid medicines at our Discovery Research Laboratories in Tsukuba. Having gained approval from the U.S. Food and Drug Administration (FDA) in August 2020, we are now undertaking a range of activities in Japan and the U.S. to provide information to raise understanding of the disease among patients and people around them.



Japan

DMD is an inherited condition affecting boys at a frequency of about one case per 3,500 births. The estimated DMD patient population in Japan is about 5,000. There has been no established treatment except the use of steroids for symptomatic relief. We started researching oligonucleotide drugs to target the gene that causes DMD in 2009. The nucleic acid drugs work by targeting specific gene sequences to help regulate the production of proteins. They offer the possibility of treating diseases where conventional small molecule drugs have proven ineffective.

Viltepso: from development to gaining to manufacturing and marketing approval

Developed in a joint research program with the National Center of Neurology and Psychiatry (NCNP), Viltepso was the first antisense oligonucleotide discovered in Japan. It is made up of a chain of 21 morpholinos, or modified nucleic acids. DMD patients have gaps in the gene that codes for the protein dystrophin, with the DMD subtype related to the site of the missing exons (43–52, 45–52, 47–52, 48–52, 49–52, 50–52 and 52). By binding to the exon 53 site, Viltepso enables cellular machinery for gene transcription to skip over exon 53, resulting in dystrophin that is shorter than usual but still functional.

We received Sakigake designation from the MHLW for Viltepso in October 2015, followed by its orphan drug designation in August 2019. It was designated as a drug applicable for conditional early approval in October 2019. Based on the results of the clinical trials in the U.S. and Japan, it was granted an approval by the MHLW in March 2020 for patients with forms of DMD amenable to exon 53 skipping.

Provision of information

To support better therapeutic outcomes after the drug's approval, we have been conducting a range of activities aimed at providing patients and people around them with information to increase understanding of the disease so the value of Viltepso can be properly realized by medical institutions and patients.

If DMD patients are to live a longer and fuller life in the future, family members and other adults need to recognize signs of the disease at an early stage to enable opportunities for appropriate treatment. This calls for activities to support greater education. On March 20, 2021, we hosted an online seminar on Nippon Shinyaku's YouTube channel entitled, "Creating Better Futures for Children: Muscle-related Pediatric Diseases" (the event was also sponsored by the Ministry of Education, Culture, Sports, Science and Technology, and the Japan Muscular Dystrophy



Generic name: viltolarsen

This treatment for DMD is an antisense oligonucleotide consisting of modified nucleic acids called morpholinos. DMD is an intractable and progressive disease that has lacked any fundamental therapy until now. Viltepso was developed to help address the cause of this disease.

Association). The live event featured presentations by three specialists in the field to support enhanced understanding of DMD. We are also using this YouTube channel to host DMD-related content in cooperation with patients and their families affected by muscular dystrophy, including accounts of their experiences with confronting the disease firsthand and related thoughts.

Our hope is that events such as these can provide the opportunity to take the first optimistic steps towards a better life for patients by helping parents and others to understand how the therapeutic landscape has changed for DMD.

By continuing activities to help educate DMD patients and their families about the disease, we hope this will translate to opportunities for patients to live better.

Overseas

In a bid to deliver supplies of the drug to medical institutions and patients as early as possible, sales of the DMD treatment Viltepso in the U.S. started on August 19, 2020, just one week after we received accelerated approval for the product from the U.S. FDA.

Viltepso is the first product that we are marketing in the U.S. using our in-house resources. Medical representatives and medical affairs personnel from the Group subsidiary NS Pharma, Inc. (NSP), which is based in New Jersey, are involved in detailing the product and gathering data to help us gauge how to satisfy clinical demand. Following the launches in Japan and the U.S., we have filed a submission for regulatory approval in China, and are in discussions with regulators in Europe to secure approval at the earliest juncture. We are also looking at how to help DMD patients in other parts of the world gain access to Viltepso.

Status of DMD therapy in America

As in Japan, DMD affects approximately one in every 3,500 male newborns in the U.S. Of these, we estimate Viltepso could be administered to roughly 400 patients from an ambulatory stage. However, it is not an easy road for potentially eligible patients to gain access to Viltepso.

The universal health insurance system in Japan means patients cannot be refused treatment if they are covered under the system, irrespective of the treatment or medical institution involved. Financial costs for the patient's family consist of a co-payment of 10–30%.

The health insurance system in the U.S. is significantly different. Whether the cost of a drug such as Viltepso is reimbursed depends largely on the type of insurance policy covering the patient's family. As well as the public schemes Medicare and Medicaid, many Americans have private health insurance. Around 10% of patients in the U.S. are uninsured. This means it is necessary to provide support to ensure all the patients who need Viltepso can access the drug. NSP has established a support hub called NS Support to assist those families coping with DMD.

Role of NS Support

Variations in the insurance coverage of patients mean that eligibility for drug cost reimbursement by the insurer must be determined prior to medical treatment on an outpatient basis. Physicians in the U.S. often carry the administrative burden of determining these questions with the patient's insurer.

Another major challenge in the U.S. due to its geographical size (approximately 26 times larger than Japan) is the difficulty that many patients face to attend regular appointments at the specialist facilities that provide DMD therapy. In such cases, the drug is administered at home, implying a need for secure deliveries and good communications with the hospital.

NS Support provides a comprehensive care coordination and support service to assist DMD patients and their families and to help reduce the burden for treating physicians. NS Support offers guidance to families and physicians navigating the administrative procedures involved in the insurance reimbursement of Viltepso, and helps families administering the drug at home with supplies and related issues.

Development of in-house sales/ marketing system for the U.S. market

Unlike in Japan, where Viltepso can be prescribed once a physician has decided the best treatment option based on patient consent, negotiations with the individual insurance companies are required in the U.S. to gain approval for reimbursement of Viltepso. Managing this process is NSP's market access team, a function unique to the U.S. market. Locally recruited staff are tasked with following up each individual case. With many working from home due to the COVID-19 pandemic, the operations demand excellent communication skills to help build the necessary mutual trust. In this way, securing the patient's access to Viltepso is reliant on sustained efforts by dedicated teams to negotiate with insurers and resolve other related issues.

NS Pharma, Inc. (NSP)

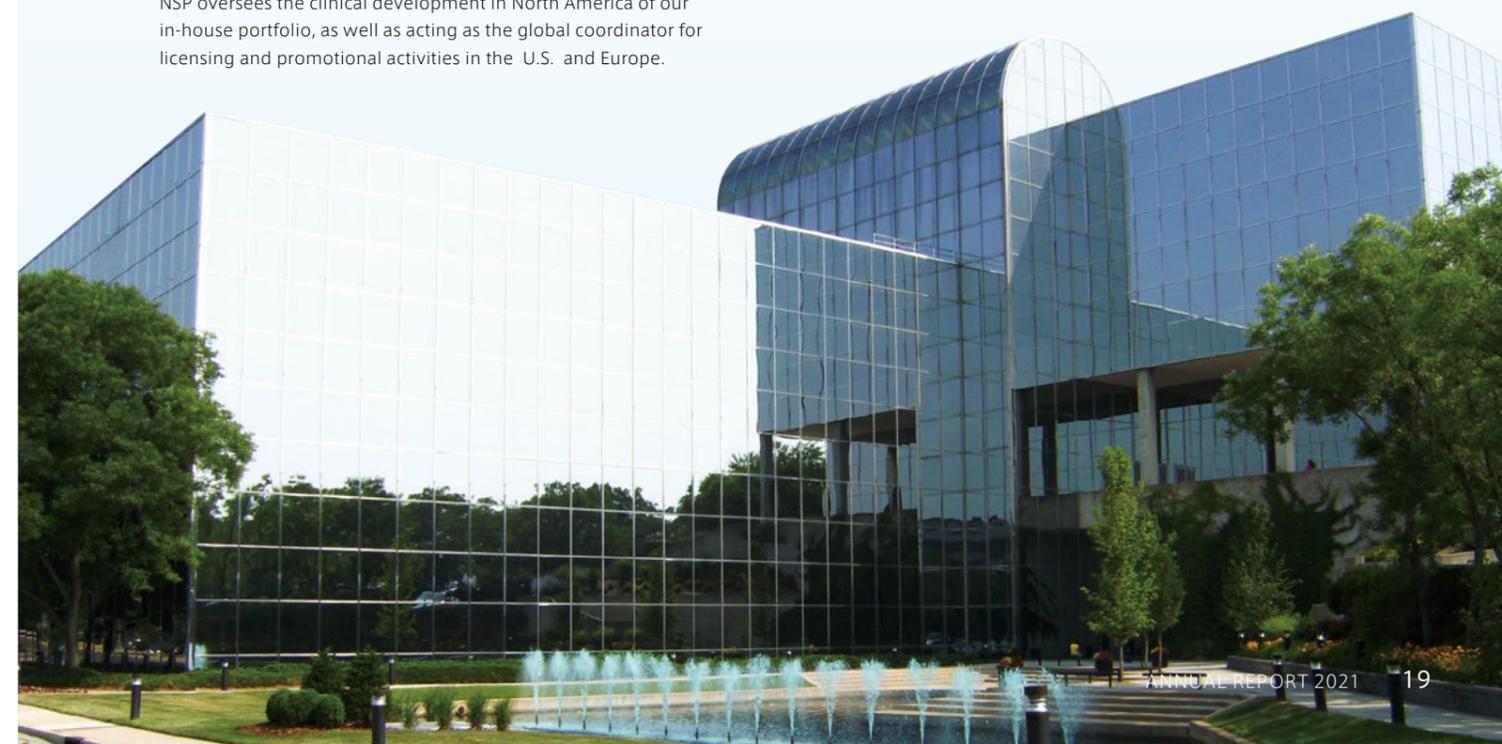
NSP was established in July 1999 to enable the collection of information in the U.S. to support the early development of investigational compounds with global potential. Based in Paramus, New Jersey, NSP oversees the clinical development in North America of our in-house portfolio, as well as acting as the global coordinator for licensing and promotional activities in the U.S. and Europe.

Future global development

In the U.S., NSP began selling Viltepso in August 2020 through our in-house sales set-up. Elsewhere, efforts are continuing to gain regulatory approval in China, Europe, and other markets as early as possible. An NDA was filed in June 2021 in China, where discussions with regulatory authorities are ongoing. We are considering which approach is optimal in each market based on our in-house resources in that market and our strategic partnerships with other companies.

NSP is also coordinating the global Phase III clinical study and other clinical trials of Viltepso. We continue to gather clinical data and plan to effectively use the data to enable provision of more detailed therapeutic information.

To support the provision of our distinctive and high-quality products to patients and medical institutions worldwide, our focus going forward remains on the accelerated global development of our operations by expanding on the existing business to build an organization that is well-suited to developing a global business, covering every stage from R&D to manufacturing, distribution and sales. We are focusing on the development of the Group's global product pipeline under the 6th Five-Year Medium-term Management Plan through prioritized investment in Viltepso, other successor exon-skipping therapies, and other drugs with global sales potential.



Nippon Shinyaku's Initiatives in Response to the COVID-19 Pandemic

We would like to express our sincere gratitude to the healthcare professionals working on the frontlines of the fight against the COVID pandemic.

As a company concerned with human life and health, Nippon Shinyaku strives to maintain flexibility in order to continue fulfilling our goals as a pharmaceutical company, not only supplying pharmaceutical products in a stable manner by ensuring the safety of employees amid the risk of infection, but also pursuing R&D into potential treatments.

Stable product supply

To ensure a stable supply of pharmaceutical drugs, we practice effective and efficient risk management, adopting business continuity plans (BCP) at manufacturing sites and establishing our own checklists, thus maintaining the safety stock. Against risks involved in the procurement of active pharmaceutical ingredients (APIs), we have enlisted multiple suppliers and reinforced our ties with suppliers and other business partners. As a result, we are proud to say that our systems of pharmaceutical manufacturing and product supply to healthcare institutions are free of problems at the moment.



Research and development of therapeutics

Drawing on Nippon Shinyaku's strengths and capabilities in the area of nucleic acid drugs, we are pursuing research and development of anti-viral medicines using long-chain RNA, and the reprofiling of low-molecular-weight drugs.

Coronaviruses are single-stranded RNA viruses and therefore have high mutation rates. Nippon Shinyaku is looking into how nucleic acid drugs can be made into long-lived antiviral medicines suitable for treating not just COVID-19 but indeed any mutant coronavirus, in addition to the SARS and MERS viruses of the past and any new coronavirus infections that may emerge in the future.

Some 20 years ago, Nippon Shinyaku succeeded in the synthesis of long-chain RNA linking over 100

nucleotide bases, and we are now leveraging that proven platform technology in developing not only COVID-19 medications but also guide RNA for genome editing, for example.

The company also is investigating the potential of reprofiling, using existing drugs and drugs now in development. Sudden worsening of COVID-19 symptoms is closely associated with the hyperreactivity of the immune system (cytokine storm). If this can be controlled, it should be possible to prevent severe respiratory failure. Research has shown that cytokine storms can be curtailed by inhibiting intracellular signaling pathways such as Janus kinase (JAK) or interleukin-6 (IL-6), and Nippon Shinyaku is pursuing this angle further.



Telework system

From January 2018, we initiated a telework system to enable people to work from home for any teleconferences with areas in different time zones.

From April 2019, we extended the system to allow flextime workers to work from home or a rented conference facility under circumstances where it is difficult to commute to the designated workplace due to illness or injury, childcare or nursing care commitment or suspension of public transport due to bad weather.

Since April 2020, "all employees" have been eligible to work from home, and can do so simply to avoid infection with COVID-19, without needing to comply with the aforementioned conditions. Many

employees have taken up this offer. Nippon Shinyaku believes that telework contributes to a flexible and efficient working environment that in turn improves operational efficiency, reduces commuting time and effort, and helps employees to balance childcare and nursing care with work. In November 2020, we overhauled our telework system to enable all employees to fulfill their duties outside the workplace depending on their job and work-life balance (other than individuals unable to do so for security or job-specific reasons).

We are working to improve communication and ensure the psychological well-being of teleworkers through greater availability of digital devices, with a view to encouraging further uptake of telework and enhancing productivity.

Initiatives to prevent the spread of infection

Working modes	<ul style="list-style-type: none"> In principle, employees work from home to the extent that teleworking is possible. Employees who need to come to company workplaces make active use of the flextime system and/or staggered commuting hours to reduce potential viral exposure in crowded public transportation systems. Special leave is provided in daily or hourly units to employees receiving COVID-19 vaccinations.
In-house meetings and external assignments	<ul style="list-style-type: none"> In principle, all in-house meetings are held online. When an in-house meeting is held in person, a maximum duration of 30 minutes is recommended. In principle, all business trips, including inter-prefectural travel, have been suspended. The company's conference rooms, offices and cafeterias are equipped with acrylic partitions to prevent the spread of droplets, and hand disinfectants are provided at the entrances/exits of the buildings and the rooms.
Non-work employee events, gatherings, club activities, etc.	<ul style="list-style-type: none"> All non-work events, gatherings, club activities and the like that are usually held among employees on the company premises outside the regular working hours have been suspended.
Sales activities	<ul style="list-style-type: none"> Employees are advised to accurately inform themselves of the situations at the places they intend to visit for sales activities and act in compliance with the prescribed rules.
Thorough implementation of preventive measures	<ul style="list-style-type: none"> All employees coming to the company workplaces are strictly ordered to take their temperature beforehand and effectuate other health checkups and keep records. Employees are ordered to thoroughly implement basic measures to prevent infection, such as wearing masks, washing their hands and adopting protective gestures when coughing.
Responses in regions under state of emergency	<ul style="list-style-type: none"> In principle, teleworking (working from home) is the standard working mode. Necessary measures are devised in consideration of the respective office spaces and operational characteristics of different departments of the company to maintain the percentage of personnel coming to the company workplaces at around 30%. For sales activities, priority is given to web- or telephone-based meetings, and personnel effectuating in-person sales visits are advised to go directly to their destinations and go straight home afterwards.
Workplace vaccinations	<ul style="list-style-type: none"> In the headquarters area in Kyoto, the Company administered first and second doses of the new coronavirus vaccine to about 1,000 applicants, including employees, temporary staff, and suppliers, in early July and early August, respectively.

Initiatives to Promote Digital Transformation (DX)

At Nippon Shinyaku, we are promoting digital transformation (DX) based on the idea that effective utilization of digital technology constitutes a key element in management geared toward sustainable growth. In fiscal 2020, we created a division dedicated to DX and related affairs (the Digital Planning and Promotion Section) within the Information System Department. At the same time, we launched an inter-departmental DX promotion project to accelerate the promotion of DX on a company-wide scale.

Nippon Shinyaku's initiatives for promoting DX

Actively utilizing AI, IoT and RPA* in the respective departments, we are aware that it is essential to accelerate company-wide DX in a well-organized manner to achieve overall optimization and augment the company's competitiveness. As a milestone on the path to these objectives, we are working toward obtaining "DX Certification" and having the company's stocks selected to be on the list of "DX Stocks." To this end, we are formulating a DX vision and DX strategies, and assembling the infrastructure necessary for DX promotion and governance.

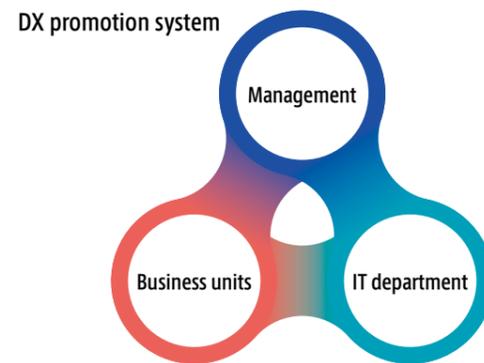
Moreover, we are planning a flexible review of our corporate organization and HR placement to advance measures including a company-wide productivity boost, work style reform, cost optimization, and new business creation, all supported by digitization. For DX-oriented HR development, we have launched several initiatives, including participation in training programs at universities and support for employees in obtaining learning opportunities and acquiring formal related qualifications. We are continuing the policy of training in-house specialists and improving the overall IT literacy of all employees.

* RPA: Robotic Process Automation, also known as "digital labor," refers to a software-based robotic technology that automates processes conventionally operated on a PC.

DX promotion system and DX-oriented HR development strategy

At present, the Digital Planning and Promotion Section is mainly in charge of gathering information on and adopting the latest digital technologies, identifying the needs of respective departments, and pursuing DX-oriented HR development. At the same time, we are aware that accelerating company-wide DX requires an organization and system with reinforced capabilities and authority. Accordingly, in the DX promotion project, we are discussing what shape our DX promotion system should take.

Nippon Shinyaku's DX-oriented HR development centers around two pillars: DX specialist training for candidates selected from among all employees and initiatives for IT literacy enhancement for all employees.

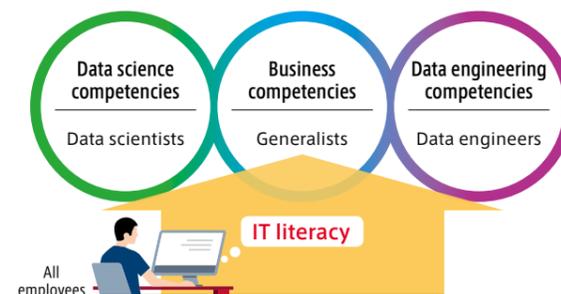


DX-oriented HR development

DX specialist training and education

- Data scientist training and education
- Generalist training and education
- Data engineer training and education

* Online group training for five selected trainees in each category



IT literacy enhancement initiatives for all employees

- In-house digital webinars (10 events, about 1,500 participants in total)
- Web-related skill improvement seminars (two events)
- Publication of in-house digital information magazines (in-house portal; published three or four times each month; a total of 42 issues)
- Programs encouraging the acquisition of an "IT Passport" and other formal qualifications (129 participants)
- Reverse mentoring (one event)
- Anything-about-IT consultations (about 20 cases)

* The figures in () are information on the events held in FY2020.



Case 01 Introduction and utilization of digital solutions

In this age characterized by drastic change and uncertainties, it is essential to be able to capture needs more accurately and rapidly than ever before, and to be flexible in adopting and utilizing digital solutions. In this process, digital solutions, adopted and utilized flexibly, can serve as powerful tools. For this reason, at Nippon Shinyaku, we examine and adopt digital solutions, with the departments concerned with the identification of needs assumed as principal actors and the Information System Department providing technical support. In this way, we can ensure the maximization of digital solutions thus adopted. The concrete digital solutions introduced thus far include AI-enabled voice-to-text conversion for our pharmaceutical consultation service, and an AI chatbot for an in-house product information.

As for RPA of routine tasks, it has been spreading on a company-wide basis, regardless of departments and operations. In FY2020, a total of some 100 tasks have been automated by RPA throughout the company, equivalent to about 10,000 workhours. Since RPA liberates employees from repetitive tasks, enabling them to shift their focus to more creative ones, their level of motivation has improved. For broader and more active RPA application, we are continuing events and activities that involve all employees, including in-house information meetings, development support meetings, and competitions between robots developed by different departments.

As a digital solution that benefits all personnel, an information sharing platform utilizing Microsoft365 and Teams was constructed in FY2020, under the theme of "Connection at any time, from anywhere and with anyone." This has nearly eliminated the difference between working from home and in the office, contributing to the prevention of the spread of COVID-19 at the same time.



We held an "RPA Robot Competition" with entries from the 13 departments utilizing RPA, with the President's Award going to the Odawara Central Factory's Production Planning Department.

Case 02 Enjoyable DX-oriented HR training programs

In FY 2020, Nippon Shinyaku inaugurated in-house DX webinars at the frequency of once to twice per month. The objective of this event is to improve the company-wide level of IT literacy through lectures and presentations on the latest digital technologies and DX-related in-house activities. The web-based sessions are easily accessible via smartphones, tablets, and other smart devices from the company's offices and sites across Japan by rearranging the schedule during the regular working hours. The webinars will continuously be held at least once each month in the future. By providing all employees with equal opportunity to regularly access digital information, the company aims to create an environment wherein personnel can proactively engage in DX while having fun.

In FY2020, we also inaugurated reverse mentoring on the theme of DX: younger employees well versed in digital technologies mentor management team members, with whom they otherwise rarely work together directly, instructing them in digital skills and informing them of the latest trends. We intend to continue organizing this event in the future.



Young employee offering reverse mentoring to director Takashi Takaya

DX is a means and not an end in itself.

DX is a means to change the way we work, to improve productivity, to create new businesses, and so on, and it is not an end in itself. Therefore, I think that involving all employees in promoting DX is a great opportunity for us in terms of corporate culture reform and HR development. The introduction of digital solutions and the training of DX-oriented personnel can prompt employees to review what they do at work and how they do it in their respective areas of responsibility. This can further prompt them to develop and improve their skills more proactively, adding assets to the company and leading to sustainable development in the future.

To that end, we will continue to pursue various initiatives supporting DX promotion, maintaining a focus on fun and positivity to put a smile on the faces of all employees.

Comment from DX promotion coordinator

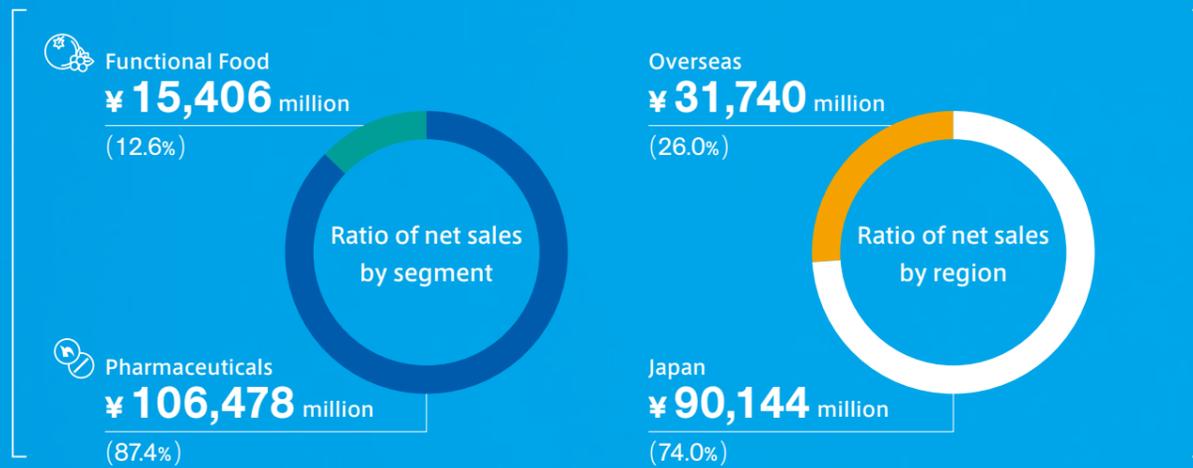


Kenji Matsunaga
Digital Planning and Promotion Section Manager
Information System Department

Business Segments

Net sales

¥ **121,885** million (Up 4.5% YoY)



Operating income

¥ **26,134** million (Up 20.6% YoY)

Net income attributable to owners of the parent

¥ **20,702** million (Up 22.7% YoY)

EPS

¥ **307** (Up 22.7% YoY)

ROE

13.5% (Up 1.5pt YoY)

Developing two businesses that supply products of high quality and originality worldwide.

Pharmaceuticals

With our core focus on four therapeutic fields (urology, hematology, intractable and rare diseases, and gynecology), we are targeting areas of disease with unsatisfied therapeutic needs and supplying distinctive products of high quality to give hope to long-suffering patients.

Main Products

1. Urology

- For urinary disorder caused by benign prostatic hypertrophy
Zalutia
- For erectile dysfunction
Cialis
- For prostate cancer
Estracyt
- For pollakiuria
Bladderon
- For benign prostatic hypertrophy
Eviprostat



3. Intractable and Rare Diseases

- For Duchenne muscular dystrophy
Viltepsa
- For pulmonary arterial hypertension
Uptravi
- For pulmonary arterial hypertension
Opsumit
- For pulmonary arterial hypertension
Addirca



5. Otorhinolaryngology

- Dry powder inhaler for allergic rhinitis
Erizas
- Gargle liquid containing azulene
Azunol Gargle Liquid
- For allergic rhinitis and conjunctivitis
Livostin
- For vertigo
Cephadol
- For oral osmotic diuresis, Meniere's disease
Isobide

2. Hematology

- For sinusoidal obstruction syndrome (hepatic veno-occlusive disease)
Defitelio
- For CD20-positive follicular lymphoma
Gazyva
- For myelodysplastic syndrome or acute myeloid leukemia
Vidaza
- For relapsed or refractory acute promyelocytic leukemia
Amnolake
- For relapsed or refractory acute promyelocytic leukemia and malignant lymphoma
Trisenox
- For relapsed or refractory acute leukemia and malignant lymphoma
Cylocide N
- For solid tumor and acute leukemia
Cylocide



4. Gynecology

- For dysmenorrhea
Lunabell ULD
- For dysmenorrhea
Lunabell LD



6. Others

- Controlled-release treatment for cancer-associated pain and chronic pain
Onetram
- For cancer-associated pain and chronic pain
Tramal
- Aid for maintaining alcohol abstinence
Regect



Functional Food

In the Functional Food business, we seek to leverage our technical expertise as a maker of pharmaceuticals to supply high-value-added products that meet market needs, focusing on four areas (health food ingredients, preservatives, protein preparations, and supplements).

Main Products

1. Health Food Ingredients

Mangosteen Aqua, Hyaluronic Acid 3000, Garcinia Powder J, Bacopa Extract Powder

2. Preservatives

Mirai Ace Nu, Binesh Deli, Mikaku Fine S, Mikaku Fine BK, Mikaku Fine Z

3. Protein Preparations

Lactocrystal plus, PROGEL800, Enlacto HG, Fitness S

4. Supplements

Sports supplements (WINZONE series), aging care supplements (Mangostia, Kioku no Kobako, etc.)

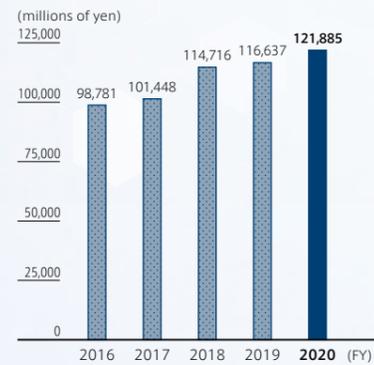


Sports supplements (WINZONE series)

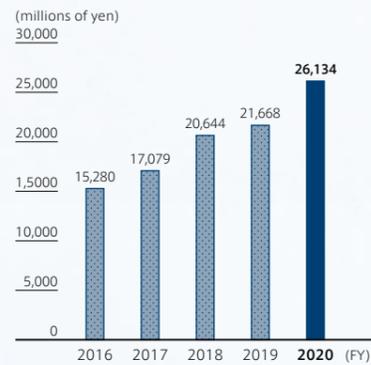
Financial and Non-Financial Highlights

Financial Highlights

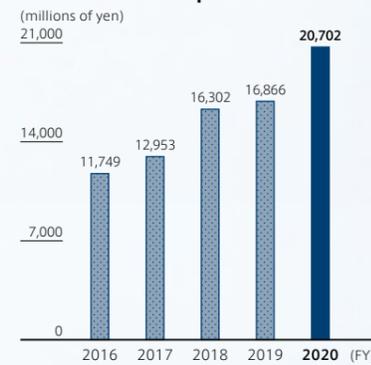
Net sales



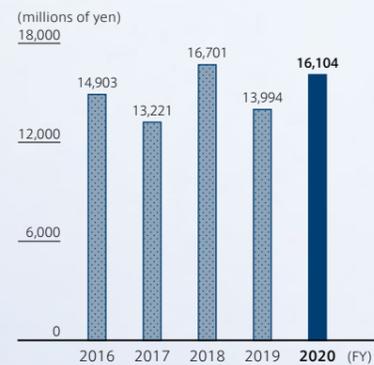
Operating income



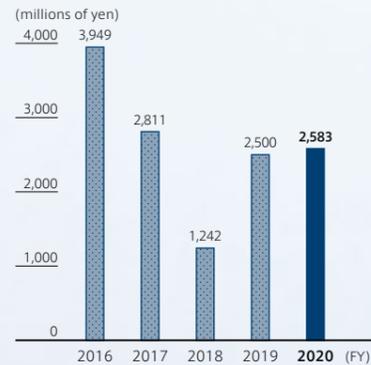
Net income attributable to owners of the parent



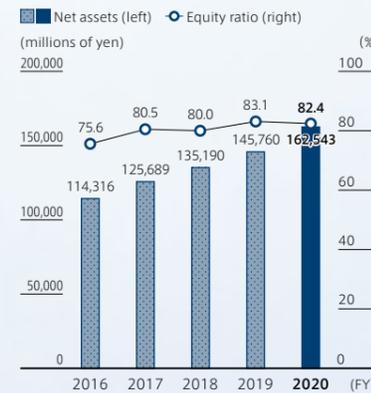
R&D expenses



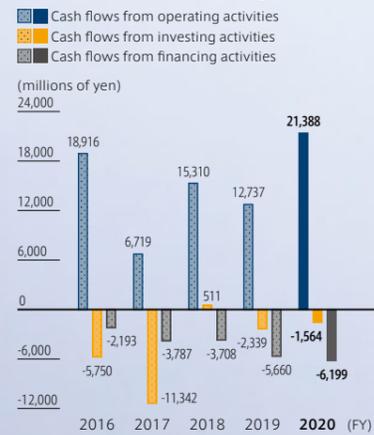
Capital investment



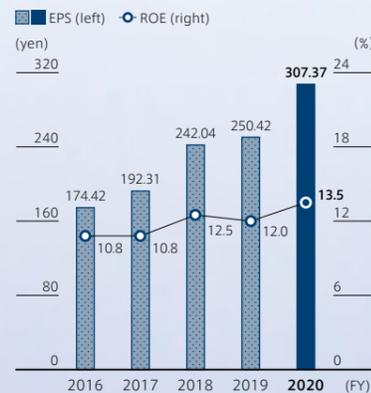
Net assets / Equity ratio



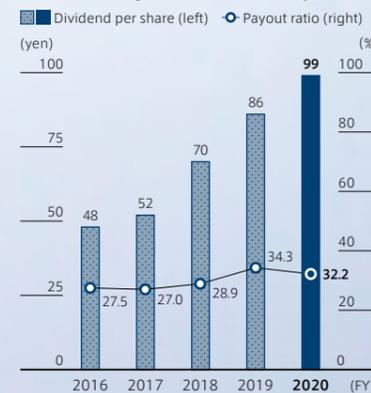
Cash flows from operating activities / Cash flows from investing activities / Cash flows from financing activities



EPS / ROE



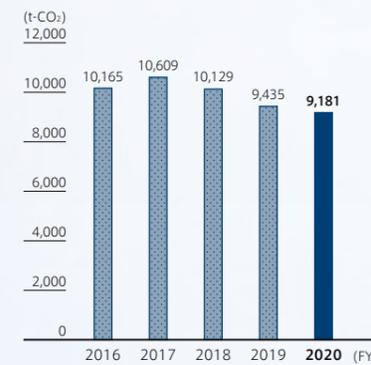
Dividend per share / Payout ratio



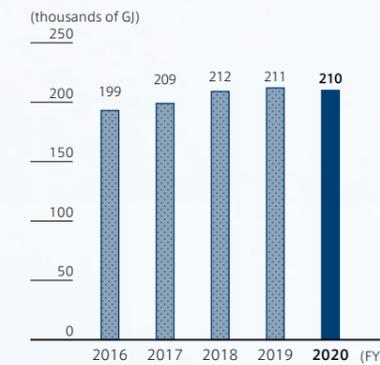
Non-Financial Highlights

Environment

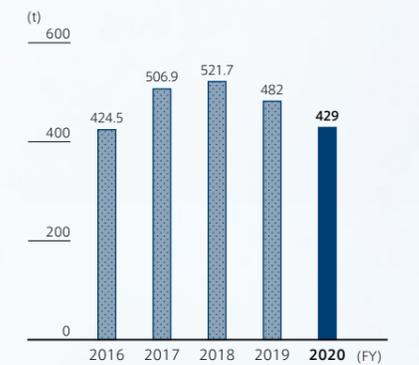
CO₂ emissions (Main business locations*)



Total energy consumption (Main business locations*)

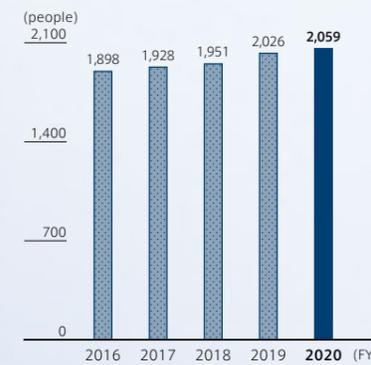


Waste substances generated (Main business locations*)



Social

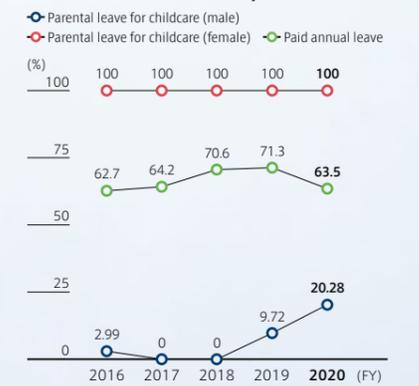
Number of employees (consolidated)



Ratio of female executives / female managers



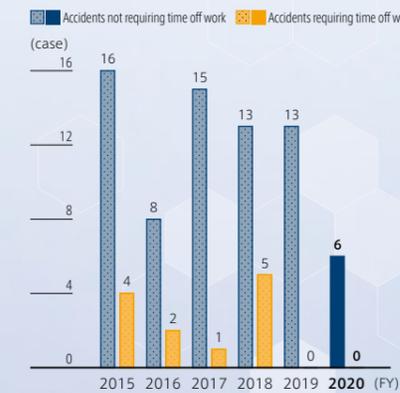
Ratio of employees taking parental leave for childcare / paid annual leave



Ratio of employees with disabilities



Number of occupational accidents (excluding the company's amateur baseball team)



Governance

Number of directors

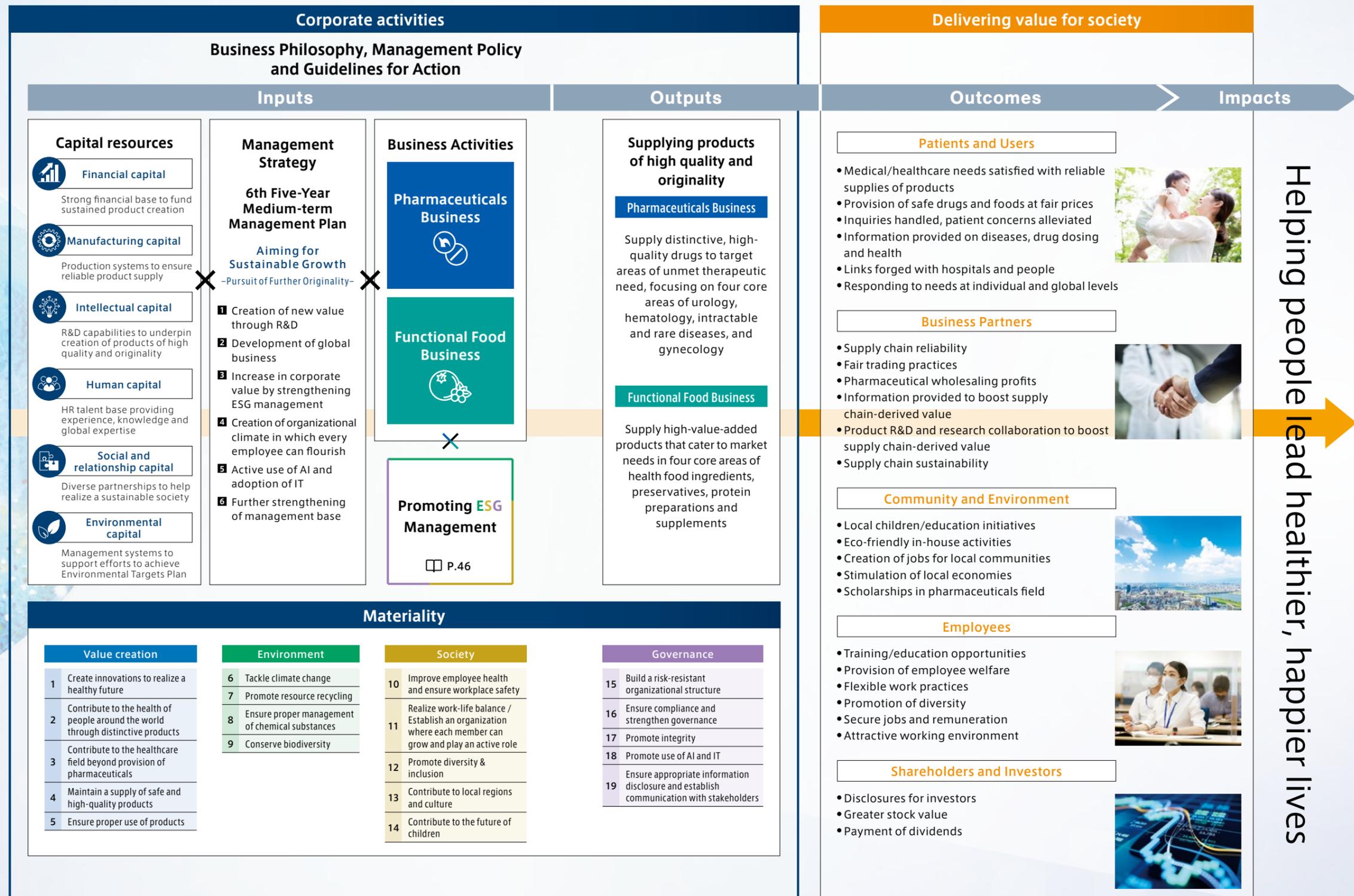


* Main business locations: Head Office area, Odawara Central Factory, Discovery Research Laboratories in Tsukuba

Value Creation Story

Nippon Shinyaku's business activities focus on using various forms of capital to address material issues in response to societal trends. By creating value in this way, we aim to help people lead healthier, happier lives to become "a company with a meaningful existence in healthcare."

- ### Societal trends
- Shrinking Japanese market, expanding global market
 - Higher-intensity natural disasters, more diverse business risks
 - Low birth rate, aging population (Japan)
 - Technological advancement in fields of pharmaceuticals and functional food
 - More advanced digital technologies
 - Increased health consciousness, shift to pre-symptomatic and preventive care
 - More multi-functionality (drugs industry)
 - Healthcare cost restrictions, emergence of personalized medicine
 - More severe environmental issues



Helping people lead healthier, happier lives

To become a company with a meaningful existence in healthcare

Re-investment into financial and non-financial forms of capital

Materiality

The Nippon Shinyaku Group has designated 19 items as its issues of materiality in pursuing sustainability. To determine these issues, we identified the missions that Nippon Shinyaku should fulfill for our communities and stakeholders in each of the fields of value creation, the environment, society, and governance, and we took into consideration the risks and opportunities that may arise in association with changes in society.

Process for determining materiality issues

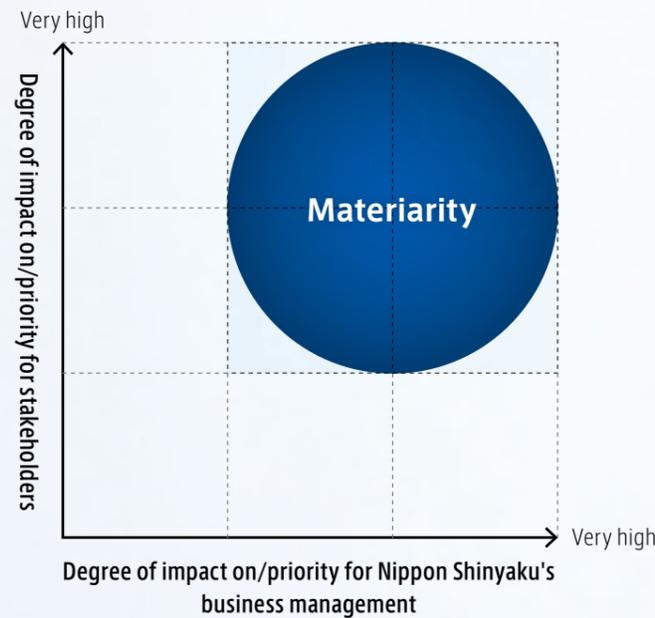
▶ Process 1 Listing issues

Issues of Nippon Shinyaku were listed based on two perspectives as follows:

- Issues that are derived by reference to international guidelines and standards, such as ISO 26000, GRI Standards, and SDGs
- Issues associated with “risks and opportunities” in promoting businesses, which are derived by analysis of social situations, the market environment, and our internal condition

▶ Process 2 Assessing importance of issues

The listed issues were assessed from two perspectives: stakeholders’ perspective (the degree of impact on/priority for activities of each stakeholder) and Nippon Shinyaku’s perspective (the degree of impact on/priority related to business strategies, etc.). The results were mapped on a graph to define the issues of materiality.



▶ Process 3 Formulating plans and obtaining approval

For each of the defined materiality issues, under the initiative of the relevant department in charge of promotion, quantitative and qualitative goals were set, and promotion plans to achieve the goals were formulated.

The goals and plans formulated were reviewed by the CSR Committee and then approved by the Board of Directors. For the goals and plans, the Committee periodically checks their progress in implementation to improve the activities as necessary.

Risks and Opportunities

Determining materiality issues first involves identifying opportunities for growth (such as the development of therapies with new technologies, growth of markets from higher populations, and increasing interest in preventive medicine) and business risks (such as production stoppages due to natural disasters, and rising medical spending). The process also identifies the negative social or environmental impacts from activities throughout the Nippon Shinyaku Group, such as the generation of waste and manufacturing, from the perspective of trying to mitigate such impacts.

Category	Materiality	Major risks	Major opportunities	
Value creation	Health and life	1 Create innovations to realize a healthy future	<ul style="list-style-type: none"> • Lower value of existing therapies from emerging treatments/ approaches based on new technology • NHI pricing system reforms and other measures to promote generics • Greater competition due to new entrants from other sectors • Lower demand for prescription medicines due to better population health • Responses to stricter guidelines 	<ul style="list-style-type: none"> • Creation of new technologies to satisfy demand for more advanced medicines to treat intractable diseases, COVID-19, etc. • Growth of global market from higher population • Higher demand for health-related products as focus shifts from treatment to prevention • Higher medical/healthcare demand due to older population
		2 Contribute to the health of people around the world through distinctive products		
		3 Contribute to the healthcare field beyond provision of pharmaceuticals		
	Reliability assurance, stable supply	4 Maintain a supply of safe and high-quality products	<ul style="list-style-type: none"> • Pressure on profit margins due to higher raw material costs • Higher-intensity natural disasters, more diverse business risks • Impact of loss of end-user trust on business activities 	<ul style="list-style-type: none"> • Higher valuation of safe, high-quality products as consumers place premium on safety/quality • Enhanced competitiveness from establishment of traceability
		5 Ensure proper use of products		
Climate change	6 Tackle climate change	<ul style="list-style-type: none"> • Climate change-related extreme weather and natural disasters • Impact of supply chain interruptions on production activities • Stricter energy efficiency regulations • Greater capital investment in energy-efficient equipment and renewable energy 	<ul style="list-style-type: none"> • Reduced CO2 emissions and facility operating costs due to climate change actions • Increase in business opportunities • Stakeholder trust generated by climate change actions 	
Environment	Recycling-oriented society	7 Promote resource recycling	<ul style="list-style-type: none"> • Environmental degradation from forest fires, plastic pollution in oceans, etc. • Reputational risk from higher waste generation, increased processing costs 	<ul style="list-style-type: none"> • Lower costs due to reduced waste and recycling • Increase in stakeholder trust
	Chemical substances	8 Ensure proper management of chemical substances	<ul style="list-style-type: none"> • Increased environmental impact due to chemical wastes from business activities • Erosion of trust and brand value • Stricter chemical usage regulations 	<ul style="list-style-type: none"> • Stakeholder trust generated by undertaking risk assessments for chemicals
	Biodiversity	9 Conserve biodiversity	<ul style="list-style-type: none"> • Biodiversity impacts from business activities • Erosion of trust and brand value 	<ul style="list-style-type: none"> • Greater trust from stakeholders such as local communities and business partners
Society	Job satisfaction	10 Improve employee health and ensure workplace safety	<ul style="list-style-type: none"> • Lower labor productivity due to occupational incidents • Workforce attrition due to workplace conditions not satisfying needs of individuals • Loss of personnel • Competitiveness loss from eroded human capital 	<ul style="list-style-type: none"> • Higher workforce productivity/motivation from employee health maintenance and more diverse work styles • Better personnel retention by Nippon Shinyaku • A desirable place where people enjoy working • Promotion of diversity as a source of innovation
		11 Realize work-life balance / Establish an organization where each member can grow and play an active role		
		12 Promote diversity & inclusion		
	Local communities	13 Contribute to local regions and culture	<ul style="list-style-type: none"> • Cultural impacts on communities from loss of population • Progressively aging demographics in Japan 	<ul style="list-style-type: none"> • Better local presence due to corporate citizenship • Stakeholder trust generated by children-related support initiatives
14 Contribute to the future of children				
Governance	Governance	15 Build a risk-resistant organizational structure	<ul style="list-style-type: none"> • Stricter international legal compliance • Erosion of trust/brand value from cyberattacks, data leaks or other information security issues • Corruption caused by erosion of integrity and compliance mindset • Erosion of stakeholder trust • Loss of business opportunities from delays in introduction of digital technology 	<ul style="list-style-type: none"> • Governance improvements from international cooperation in ESG field • Greater operational stability • Greater trust in company due to cultivation of compliance mindset and business ethics • Development of more techno-literate workforce by improving IT literacy across Group • Trust generated by appropriate disclosures to stakeholders • Sustained improvements in corporate value
		16 Ensure compliance and strengthen governance		
		17 Promote integrity		
		18 Promote use of AI and IT		
		19 Ensure appropriate information disclosure and establish communication with stakeholders		

Materiality

For more details on ESG, please refer to PP.46-71.

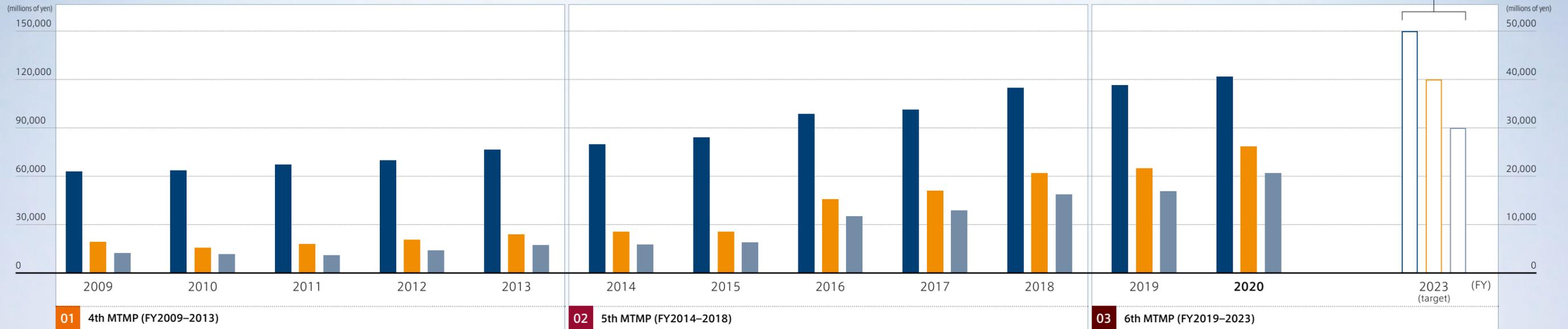
Category	Materiality	Goals	Activities	Related SDGs	
Value creation	Health and life	1 Create innovations to realize a healthy future	Creation of therapeutic agents for intractable and rare diseases for which effective treatment methods have not been established	Taking on the challenge of new drug discovery modalities, including gene therapy based on nucleic acid drug discovery technology	
			Creation of products that contribute to realizing health through food	Regularly launching highly unique healthcare products, materials and milk protein materials into the market to contribute to disease prevention	
			Enhancement of in-house resources to provide a healthy future	Strengthening organizational capacity to respond to changes Strengthening efforts for human resource development in each department	
			Contribution to medical development in the area of intractable and rare diseases	Providing information for medical professionals and familiarizing patients and their families with diseases	
			Contribution to reducing food loss	Contributing to waste reduction by extending the expiration dates by developing a quality stabilizer/preservative that will not impair the taste of food	
			2 Contribute to the health of people around the world through distinctive products	Provision of required therapeutic agents for the world	
	Contribution to the health of people around the world through food	Providing highly unique healthcare products and materials for EC malls in Asian countries			
	Contribution to the science field through research on and development of nucleic acid drugs, etc.	Contributing to the development of related science fields by presenting scientific knowledge through academic papers or academic societies			
	3 Contribute to the healthcare field beyond provision of pharmaceuticals	Support for individuals' health creation that goes beyond treatment	Promoting treatment and medication guidance by digital health	Raising awareness of new diseases by the Web	
			Enhancement of patient support and advocacy activities	Promoting development and sales of anti-aging care products for the purpose of disease prevention	
		Expanded support for medical and scientific research that contributes to the development of medicine	Promoting social understanding of diseases through provision of accurate information on diseases and treatments	Further enhancing open recruitment research grant systems	
			Reliability assurance, stable supply	4 Maintain a supply of safe and high-quality products	
5 Ensure proper use of products	Enhancement of stable supply system with the development of information network throughout the supply chain	Visualizing risks for each item to implement preventive measures	Enhancing supplier management to ensure stable procurement and supply		
	Provision of accurate information for proper use of products	Collecting safety information and further promoting integrity in the sales department	Operating the Anti-Counterfeit Committee to promote information sharing and implement countermeasures		
	Response to counterfeit medicines	Improving business efficiency and customer satisfaction by promoting digital communication	Enhancement of capacity to respond to inquiries from medical institutions		
Environment	Climate change	6 Tackle climate change	2022 target: 6% reduction in greenhouse gas emissions compared to FY2013 2030 target: 25% reduction in greenhouse gas emissions compared to FY2013	Implementing measures to reduce greenhouse gas emissions	
		7 Promote resource recycling	2022 target: 65% of waste plastic recycled	Implementing measures to promote waste plastic recycling	
	2022 target: Recycling rate 55% or higher 70% reduction in final disposal amount compared to FY2005 results		Promoting resource saving, waste reduction and 3Rs		
	8 Ensure proper management of chemical substances		Promotion of proper management of chemical substances	Promoting proper management of chemical substances, including PRT Law-designated chemicals	
		Continuously reducing emissions to the natural environment	Continuously reducing emissions to the natural environment		
Biodiversity	9 Conserve biodiversity	Promotion of social contribution activities related to conservation of biodiversity	Continuing activities to protect and grow endangered species at the Yamashina Botanical Research Institute		

Category	Materiality	Goals	Activities	Related SDGs	
Society	Job satisfaction	10 Improve employee health and ensure workplace safety	Raised employee awareness of health and productivity management	Enhancing vitality and productivity by maintaining or improving the health of employees	
			Promotion of health and productivity management based on health data analysis 2022 target: Smokers' rate 0%, gynecological consultation rate 70% 2023 target: Rate of employees in BMI normal weight range 75%	Making effective use of health data to understand the health status of employees (improvement or worsening)	
			Implementation of measures to reduce risk of industrial accidents	Further strengthening activities to ensure workplace safety, such as enhancing the industrial accident risk prediction capacity and implementing zero accident campaigns	
			Promotion of health and productivity management based on health investment administration accounting	Establishing a PDCA cycle of "strategy setting," "implementation," "evaluation," and "improvement" for health and productivity management	
			11 Realize work-life balance / Establish an organization where each member can grow and play an active role	Improved employee engagement	
	Promotion of human resource development efforts to foster an organizational culture in which each individual can play an active role	Developing self-independent human resources and global human resources who are motivated to grow			
	Development of a personnel system to promote Nippon Shinyaku's new working style	Promoting various work styles, such as flextime and teleworking, and reviewing operations using ICT			
	12 Promote diversity & inclusion	Local communities	Optimization of work hours by instilling Nippon Shinyaku's new working style	Promoting various work styles, such as flextime and teleworking, and reducing business hours using ICT	
			Promotion and instillation of Nippon Shinyaku's new working style	Revising personnel systems and operation thereof to realize a company that is friendly to and satisfying for workers	
			Jobs created, secured and maintained (jobs created by local employment at overseas subsidiaries)	Promoting recruitment activities in view of diversity and inclusion	
			Promotion of understanding of diversity with the aim of raising awareness of employees	Fostering an organizational culture where "individuals" are respected and their strengths and weaknesses can be frankly pointed out or accepted	
			Greater female participation promoted	Developing a workplace environment where every member can have opportunities to play an active role regardless of gender, and establishing the necessary organizational structure	
13 Contribute to local regions and culture	14 Contribute to the future of children	Employment of people with disabilities promoted	Promoting development of job areas available for people with disabilities		
		Creation of an environment that is friendly to all workers and establishment of an organizational structure therefor	Developing a work environment where employees can work with peace of mind without worry about personal circumstances, such as childcare leave, nursing care, or illness		
Governance	15 Build a risk-resistant organizational structure	Social contribution activities rooted in each region, including the preservation and maintenance of Kyoto culture	Continuously carrying out activities to preserve and maintain Kyoto culture Implementing contribution activities for each region		
		Educational support for children, who will bear the future	Promoting educational support through sports and picture books		
	16 Ensure compliance and strengthen governance	Support for facilities with pediatric patients	Supporting children's mental health through offering picture books, etc.		
		Enhancement of the risk management system	Examining measures appropriate for current risks each year to improve the system Enhancing privacy protection and information security for customers and employees		
		Establishment of business continuity system, examination of the method for emergency supply chain maintenance	Enhancing the system for stable product supply by promoting risk management of plants and suppliers		
	17 Promote integrity	18 Promote use of AI and IT	Enhancement of governance functions	Enhancing governance throughout the Company, including subsidiaries	
			Compliance and prevention of corruption ensured	Fostering compliance awareness and preventing corruption	
19 Ensure appropriate information disclosure and establish communication with stakeholders	Governance	Promotion of integrity	Maintaining fair transactions Fostering high ethical standards		
		Active utilization of AI and promotion of IT to improve business efficiency	Promoting AI/IT themes throughout the Company Improving company-wide IT literacy, developing IT human resources		
		Enhanced engagement with investors	Enhancing IR activities for investors		
Trust gained from stakeholders	Disclosing information to shareholders/investors, employees, business partners, customers (healthcare professionals/patients and their families), and local communities				

Medium-term Management Plan (MTMP) Overview

Prior to the 6th five-year plan, we have achieved steady growth by formulating and implementing medium-term management plans to cope with changing business conditions and related issues.

■ Net sales (left) ■ Operating income (right) ■ Net income attributable to owners of the parent (right)



FY2023 (targets)
 Net sales ¥150 billion
 Operating income ¥40 billion
 Net income attributable to owners of the parent ¥30 billion

► FY2009–2013

01 4th Five-Year Medium-term Management Plan: "Innovation and Growth"

4th MTMP

1 Review

The initiatives during the "Innovation and Growth" five-year plan focused on raising the profile of Nippon Shinyaku to make it "a company with a meaningful existence in the healthcare field." FY2013 results fell short of initial targets despite greater-than-expected growth from sales of new pharmaceuticals, reflecting the impact on sales of existing mainstay drugs from

the measures to promote generics, plus the impact of deflation-induced price erosion in the Functional Food business. Net sales and profits in FY2013 set new records, however, due to success in developing the R&D pipeline and in building an earnings base less reliant on products that had been NHI-listed for a long time.

2 Results

- Pipeline enhancement from in-house drugs NS-018 (myelofibrosis) and NS-065/NCNP-01 (Duchenne muscular dystrophy) and in-licensed products ACT-064992 (pulmonary arterial hypertension (PAH)), NS-24 (cancer pain/chronic pain), GA101 (CD20-positive follicular lymphoma), LunabeII ULD (dysmenorrhea), and tadalafil
- Investment in detailing based on clear allocation of resources in response to promotion of generics; steady progress with new products

- Expansion of Functional Food business
- Cumulative cost-reduction target of about ¥2.0 billion achieved
- Creation of CASA (CAreer Support Academy) for development support/training; initiatives include Terakoya Academy, training for executives, next-generation leader training, level-specific training, support for MBA/PhD qualifications
- Social contribution initiatives: Children's Literary Awards, Nippon Shinyaku Kira-Kira Mirai Kodomo Bokin (Children's Bright Future Fund), Smiles Art Project, Public Service Award for Kyoto Kiwanis

3 Issues for following plan

- Establish clear differentiation with rivals by building base of innovation to achieve sustained growth amid shifts in external conditions such as healthcare spending restrictions and falling birth rates

- Achieve targets through launches of new products and profitability improvements; link qualitative and financial targets

► FY2014–2018

02 5th Five-Year Medium-term Management Plan: "Aiming for New Growth –Pursuit of Originality–"

5th MTMP

1 Review

The focus of the 5th Plan was to establish clear differentiation with rivals based on the pursuit of originality to help develop a business foundation for sustaining new growth. The Pharmaceuticals business was negatively affected by measures to promote generics and fundamental reform of the NHI pricing system, but this was offset by higher-than-expected income from revenues from the licensing of industrial property rights and profit in

co-promotion. Despite slightly-below-target sales in the Functional Food business, operating income and other profit metrics set new records in FY2018 due to development of a stronger earnings base. We broadly achieved the target of launching one product per year, based on the success in enhancing the R&D pipeline through a combination of in-house drug discovery, in-licensing and product life cycle management (PLCM) activities.

2 Results

- Launch of seven products, including Zalutia (urinary disorders caused by benign prostatic hypertrophy) and Upravi (PAH)
- Pipeline enhancement from in-licensing agreements for six compounds, including NS-73 (sinusoidal obstruction syndrome) and NS-32 (iron deficiency anemia)
- Completed clinical trial API manufacturing facility in March 2016; R&D sped up due to faster production of oligonucleotides and other APIs
- New growth drivers from ¥10 billion-plus sales generated by Zalutia and Vidaza (myelodysplastic syndromes)
- Higher profile for Nippon Shinyaku in PAH field from detailing activities linked to launches of Upravi and Opsumit
- Manufacturing plant for highly active solid formulations completed in July 2017

- Manufacturing of Upravi shifted in-house
- Major contribution to growth from launch of Upravi in multiple overseas markets
- NS-065/NCNP-01: preparations made to file U.S. NDA and establish local sales organization
- Significantly higher operating margin achieved in Functional Food business
- Supplement business created within the Functional Food domain, creating base for transformation
- Flextime system introduced for MRs (industry first in Japan)
- Outside specialist personnel recruited
- Recognized as "White 500" firm in Certified Health & Productivity Management Outstanding Organization Program

3 Issues for following plan

- Pursue technological innovation to create new value by supplementing the existing drug discovery base for targeting small molecules and oligonucleotide drugs with new modalities and technologies

- Re-invest profits generated by Upravi in NS-065/NCNP-01 and successor nucleic acid medicines, NS-018, and other drugs, to support accelerated global development

Medium-term Management Plan (MTMP) Overview

▶ FY2019–2023

03 6th Five-Year Medium-term Management Plan Aiming for Sustainable Growth –Pursuit of Further Originality–

6th Five-Year Medium-term Management Plan

1 Overview

	Plans
1. Creation of new value through R&D	·Pharmaceutical R&D Strategy: Create original value by widening scope of drug discovery through addition of new modalities and technologies to the drug-discovery platform that produced NS-304 (small molecule) and NS-065/NCNP-01 (oligonucleotide) ·Functional Food R&D Strategy: Bring to market continuous stream of highly original products by upgrading R&D capabilities
2. Development of global business	·To supply distinctive products worldwide, build organization completely geared to development of global business from R&D to production, logistics and sales; accelerate pace of development in global operations built up in 5th Five-Year Medium-term Management Plan
3. Increase in corporate value by strengthening ESG management	·Boost enterprise value and achieve sustainable coexistence with society by working to reinforce management based on ESG (Environment, Social, and Governance), primarily reflecting development of new treatments for intractable diseases and the supply of medicines to patients, and development of high-value-added consumer supplements
4. Creation of organizational climate in which every employee can flourish	·Based on the concept that "unique products are the product of unique people," maintain respect for employee diversity free from discrimination based on gender, nationality or cultural background, and create an organizational climate where every employee can play a significant role and flourish by providing opportunities for individuals to take on challenges and grow
5. Active use of AI and adoption of IT	·Support sustained creation of new value through aggressive adoption of AI, Robotic Process Automation (RPA) and information technologies to allow faster product development, help streamline operations, and boost productivity
6. Further strengthening of management base	·To achieve sustainable growth within a highly unpredictable and fast-changing environment, pursue greater profitability, improve management of costs and make effective use of resources while rebuilding management systems

2 FY2020 results

The COVID-19 pandemic significantly affected the world economy in the fiscal year ended March 2021, creating major social and economic impacts. Challenging conditions prevailed in the pharmaceutical industry due to continued measures aimed at restricting healthcare costs through the promotion of generics and annual revision of NHI reimbursement prices, along with impacts related to the spread of COVID infections. Conditions in the food industry were also harsh despite the rising demand for functional foods with increased health awareness, with demand being affected by sluggish consumer spending due to higher savings rates and COVID-related impacts such as the cancellation of sports events and reduced visitor numbers to Japan.

Under these business conditions, we posted net sales of ¥121,885 million in fiscal 2020, a rise of 4.5% year on year.

In pharmaceuticals, we generated growth from higher royalty income on overseas sales of PAH treatment Upravi, and from higher sales and co-promotion revenues for Defitelio, a treatment for sinusoidal obstruction syndrome, the CD20-positive follicular lymphoma treatment Gazyva, Upravi, and other recently introduced products. Other contributors to growth included milestone payments for Upravi and the launch of the Duchenne muscular dystrophy (DMD) treatment Viltepso in Japan in May 2020 and the U.S. in August 2020. Net sales of pharmaceuticals rose 4.8% year on year, to ¥106,478 million.

In functional food, higher sales of protein preparations, preservatives and other products contributed to a 2.8% increase in net sales to ¥15,406 million.

In terms of profits, operating income rose 20.6% to ¥26,134 million due to higher sales and a fall in the cost-of-sales ratio, among other factors. Ordinary income increased 19.2% to ¥26,760 million, and net income attributable to owners of the parent rose 22.7% to ¥20,702 million.

As in the previous fiscal year, we posted growth in sales and profits in the second year of the 6th Plan, representing steady progress towards achieving the FY2023 performance targets.

	FY2020 results	FY2023 target
Net sales	¥121.8 billion	¥150.0 billion
Pharmaceuticals	¥106.4 billion	¥133.0 billion
Functional Food	¥15.4 billion	¥17.0 billion
Operating income	¥26.1 billion	¥40.0 billion
Net income attributable to owners of the parent	¥20.7 billion	¥30.0 billion
EPS	¥307.37	¥445.00
ROE	13.5%	10% or more during term of 6th Plan

3 Progress with plan as of end-FY2020

1. Creation of new value through R&D

In the urology field, co-promotional agreements with Janssen Japan enabled the launch in Japan of two new prostate cancer treatments, Erleada (May 2019) and Zytiga (February 2020). In the field of hematology, we launched Defitelio for the treatment of sinusoidal obstruction syndrome in September 2019, and we also gained regulatory approval in March 2021 for an additional indication for Vidaza of acute myeloid leukemia. We launched the oligonucleotide drug Viltepso for treating DMD in May 2020 in Japan and in August 2020 in the U.S.

2. Development of global business

We continue to steadily expand sales of Upravi in Japan and in overseas markets in collaboration with our global licensee, Johnson & Johnson.

Our local U.S. subsidiary NS Pharma leads the sales activities for Viltepso in the U.S. market, where we are building a base for sustained growth through the launch of successor oligonucleotide drugs and other products. In Europe and China, we are looking to build local sales networks by utilizing in-house resources alongside our alliances with strategic partners.

3. Increase in corporate value by strengthening ESG management

We signed the United Nations Global Compact (UNGC) in January 2020. With the aim of building and maintaining the trust of all our stakeholders worldwide, we are committed to working proactively to address societal issues as a corporate citizen.

In April 2021, we identified 19 aspects of materiality that we consider important in working to realize sustainability. We are disclosing our efforts to address issues related to value creation, the environment, society, and governance.

4. Creation of organizational climate in which every employee can flourish

Since October 2019, we have introduced flextime arrangements* across the company aimed at raising productivity by giving individuals more choice in terms of workstyle. In response to the COVID-19 outbreak, we have created conditions to facilitate smoother operational processes using staggered work times and ICT-based telework. Our plan for the post-COVID workplace is to realize more diverse working styles tailored to individual needs rather than insisting on a return to pre-pandemic norms.

* Except for some areas of production that rely on shift work

5. Active use of AI and adoption of IT

Since fiscal 2019, we have begun utilizing RPA throughout the company to help improve productivity based on higher process efficiency and lower costs. Fixed process automation and other improvements have so far generated

annual savings of around 10,000 hours.

In addition, we have formed project teams to coordinate the introduction of new DX technologies across Nippon Shinyaku and to lead related activity programs. Through the adoption of AI and advanced IT, we are targeting faster product creation, more efficient processes and productivity gains.

6. Further strengthening of management base

We made steady progress in fiscal 2020 by increasing sales and profits as we work to achieve the performance targets in the 6th Five-Year Medium-term Management Plan.

To achieve sustained growth, we are continuing to strengthen our management base by maintaining a consistent focus on efforts to rebuild management systems, utilize management resources effectively, manage costs, and find ways to improve business profitability.

We are working to strengthen the business foundation to support sustained growth.

At Nippon Shinyaku, we aspire to be an R&D-led drug manufacturer supplying distinctive, high-quality pharmaceuticals. We face a low probability of success: it is said only one in every 30,000 compounds ends up as a new drug. It also requires a long time to develop any medicine. It is vital for us to provide timely disclosures and undertake dialogue so stakeholders gain a clear understanding of our R&D pipeline, the business environment, and our business strategy.

Specific IR initiatives include biannual presentations by top management for the benefit of shareholders and institutional investors in May and November. These give an opportunity for direct dialogue. We also hold conference calls to discuss quarterly results in February and August. Separately, the Corporate Planning Dept. and the R&D Administration Dept. collaborate to respond to IR inquiries and explain our R&D pipeline status, financials, and business strategy. Our IR briefings are increasing year after year. In fiscal 2020, we gave briefings to around 180 companies. Going forward, we plan to hold strategy briefings for R&D and other areas, and to upgrade the information provided via our corporate website. Moreover, as society moves towards an ESG-based investment approach as part of achieving sustainable development goals, we are upgrading our ESG-based management approach.

We have already made progress towards achieving the targets set for fiscal 2021, the third year of the 6th five-year plan. Achieving these targets will help us to continue returning profits to shareholders and investors.

In addition, we are upgrading our internal frameworks to support reliable disclosure and the incorporation of feedback from shareholder and investor dialogues into our business management. The aim is for constructive dialogues with shareholders and investors to translate into sustained growth and increases in corporate value over the medium and long term.

We ask for your continued support and understanding.

Takanori Edamitsu

Director
Head of Business Management



Strategies for Value Creation

Pharmaceuticals

R&D

Fiscal 2020 saw us gain approval for the launch in Japan and the U.S. of Viltespo, a nucleic acid medicine we had developed over many years for treating Duchenne muscular dystrophy (DMD). In fiscal 2021, we will continue to apply the R&D expertise that we have gained in small molecules and nucleic acid medicines, while also focusing on the development of new drug discovery modalities such as gene therapy. The pursuit of innovation will remain the core of our R&D efforts. Besides pipeline development based on a combination of in-house drug discovery, in-licensing and product life cycle management (PLCM), we will continue to work on overseas development.

Kazuchika Takagaki Director, Head of R&D



Strengths Nippon Shinyaku's excellence in R&D has resulted in products such as the small molecule Upravi and the nucleic acid medicine Viltespo. We are also focused on developing the capabilities to create a broad range of medicines based on new modalities such as gene therapy. We aim to continue creating new value via such expertise, focusing on four therapeutic areas (urology, hematology, intractable and rare diseases, and gynecology). At the same time, we are developing our global presence to supply medicines to patients worldwide.



Progress of the 6th Five-Year Medium-term Management Plan

FY2020 Overview

Expanding the pipeline in focus therapeutic areas

In November 2020, we applied to the Japanese Ministry of Health, Labour and Welfare (MHLW) for approval for an additional indication of chronic thromboembolic pulmonary hypertension (CTEPH) for Upravi (code no.: NS-304; generic name: selexipag), a pulmonary arterial hypertension (PAH) treatment launched in 2016. Upravi was designated as an orphan drug for CTEPH by MHLW. In addition, late-stage Phase II clinical trials and early-stage Phase II clinical trials are under way to add arteriosclerosis obliterans and lumbar spinal stenosis, respectively, to the indications for Upravi.

Viltespo (code no.: NS-065/NCNP-01; generic name: viltolarsen), a DMD treatment launched in Japan and the U.S. in 2020, was designated as

an orphan drug by the European Commission in June 2020. Joint international Phase III clinical trials are also under way for Viltespo.

In March 2021, we obtained MHLW domestic approval for an additional indication of acute myeloid leukemia (AML) for Vidaza for Injection 100 mg (generic name: azacitidine), a myelodysplastic syndrome treatment launched in March 2011.

For NS-32, an iron deficiency anemia treatment in-licensed from Pharmacosmos A/S in 2016, we completed Phase III clinical trials in Japan and applied for approval in March 2021.

In March 2021, we also entered into an exclusive license agreement with the Menarini Group (headquarters: Florence, Italy) for the development and commercialization of tagraxofusp, a treatment for blastic plasmacytoid dendritic cell neoplasm (BPDCN), in Japan.

FY2021 Strategies

Aiming to further expand the pipeline and establish a new foundation for growth

We will accelerate the development of our in-house products, including another DMD treatment (exon 44) after Viltespo and a myelofibrosis treatment (NS-018). We also aim to launch in-licensed products—an iron deficiency anemia treatment (NS-32) and an intractable epilepsy treatment (ZX008)—onto the market as early as possible and expand the pipeline by promoting PLCM for Upravi (NS-304).

With recently growing public attention on new drug discovery modalities, such as gene therapy and regenerative medicine, it has been becoming difficult to survive the development competition only with conventional drug discovery approaches. We will broaden our possibilities for drug discovery by readily trying new drug discovery modalities and establish a foundation for growth by further pursuing originality.

Value creation initiatives

–strengthening internal resources to help realize a healthy future

Initiatives to flesh out drug pipeline and create new platform for growth

1. Selecting optimal modalities for drug discovery

In recent years in the field of drug discovery research, advances in nucleic acid therapeutics and molecular biology have led to increased use of new drug discovery modalities. Nippon Shinyaku has focused on the development of both small molecule drugs and nucleic acid therapeutics, bringing examples of each to market, and now is also working on gene therapies. To assist

in our endeavors, we have strengthened ties with academic institutions and other external parties, analyzing the attributes and future potential of various drug discovery modalities, and selecting the modalities we consider optimal for specific diseases and mechanisms. We have also provided employees with education and training in the use of these new drug discovery modalities and conducted strategic planning surrounding drug discovery themes.

2. Promoting PLCM strategies

Due in part to depletion of drug discovery targets, the cost and duration of new

drug development continues to increase, adding to the difficulty of drug discovery each year. The external environment is changing dramatically also, as exemplified by the start of annual revisions to NHI drug prices. Against this backdrop, pharmaceutical companies are finding it ever more important to secure profitability via initiatives to maximize product value. Nippon Shinyaku practices PLCM to enhance the value of existing products such as Upravi by proactively adding new indications and dosage forms. We also engage in strategic PLCM planning for drug candidates still in development, based on these compounds' distinguishing features.

Pipeline (As of August 10, 2021)

Japan

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase			NDA filing	Launch
						I	II	III		
NS-065/NCNP-01 (Viltolarsen)	Launched PIII	Intractable disease/orphan disease	Duchenne muscular dystrophy	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	█	█	█	█	█
NS-304 (Selexipag)	NDA filing		Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Co-development: Janssen Pharmaceutical K.K.	█	█	█	█	█
NS-32 (Ferric derisomaltose)	NDA filing	Gynecology	Iron deficiency anemia	Licensed-in from: Pharmacosmos A/S	Nippon Shinyaku	█	█	█	█	█
ZX008	PIII	Intractable disease/orphan disease	Dravet syndrome/Lennox-Gastaut syndrome	Licensed-in from: Zogenix, Inc.	Zogenix, Inc.	█	█	█	█	█
		Cardiovascular	Arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
NS-304 (Selexipag)	PII	Orthopedics	Lumbar spinal stenosis	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
		Cardiovascular	Pediatric pulmonary arterial hypertension	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
NS-580	PII	Gynecology	Endometriosis	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
NS-87	PI/II	Hematologic malignancies	Secondary acute myeloid leukemia	Licensed-in from: Jazz Pharmaceuticals PLC	Nippon Shinyaku	█	█	█	█	█
NS-229	PI	Inflammatory diseases	Inflammatory diseases	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
NS-917	Preparation for PI	Hematologic malignancies	Relapsed/refractory acute myeloid leukemia	Licensed-in from: Delta-Fly Pharma, Inc.	Nippon Shinyaku	█	█	█	█	█
NS-401 (tagraxofusp)	Preparation for development		Blastic plasmacytoid dendritic cell neoplasm	Licensed-in from: The Menarini Group	Nippon Shinyaku	█	█	█	█	█

Overseas

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase			NDA filing	Launch
						I	II	III		
NS-065/NCNP-01 (Viltolarsen)	Launched PIII	Intractable disease/orphan disease	Duchenne muscular dystrophy	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	█	█	█	█	█
NS-304 (Selexipag)	PIII		Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Licensed-out to: Johnson & Johnson	█	█	█	█	█
NS-018 (ilgicatinib)	Preparation for PII	Hematologic malignancies	Myelofibrosis	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█

Strategies for Value Creation

Sales

The mission of the Sales and Marketing Division is to support patient well-being based on supplying medicines as well as providing medical professionals with high-quality information on appropriate disease treatments.

Rather than being buffeted by changes in the external environment, we are focused on developing human resources to forge our own path. By clarifying the role of each employee and working together as a team, the Sales and Marketing Division aims to maintain the position of Nippon Shinyaku as a trusted partner for medical professionals.

Shouzou Sano Managing Director, Head of Sales and Marketing



Strengths Since introducing our system of internal examinations in 2013, we have developed our Specialist MR corps with advanced detailing expertise in the areas of arterial hypertension and hematology. With more products targeting specialized domains such as cancer and rare diseases, Nippon Shinyaku's MR culture is based firmly on continued education to support detailing activities. To improve quality further, we have a broad range of training programs for our sales and marketing personnel. In other moves aimed at cultivating a good environment within the division, we have instituted a team-based system, and have also created opportunities for employees to share knowledge easily.

Progress of the 6th Five-Year Medium-term Management Plan

FY2020 Overview

Establishing a high-quality detailing system suitable for the new normal

In FY2020, in response to the COVID-19 pandemic, we shifted the focus of our detailing activities from conventional face-to-face communication to online communication, or e-detailing. To conform to this dramatic shift, we built a system to provide the same high-quality communication as in previous years by not only improving our digital content but also devoting efforts to developing the digital capabilities of our human resources. We also established a mechanism for promptly providing information to medical professionals by enhancing communication both through MRs and through digital channels. In the area of pulmonary hypertension, Nippon Shinyaku is the only company in the world that

provides three oral treatments for pulmonary arterial hypertension (PAH) with different mechanisms of action—Upravi, Opsumit, and Adcirca. As a leading company in this area, we contribute to medical treatment and the improvement of healthcare systems.

In the area of pediatrics and neurology, we launched Viltepso, a treatment for Duchenne muscular dystrophy (DMD), in May 2020.

Since there had been no treatment for the disease before Viltepso was launched, we are deeply committed to detailing activities concerning the new treatment so that it will reach patients as soon as possible.

In the areas of hematology and urology as well, our sustained detailing activities have been highly rated by medical professionals, making these areas major pillars of our business performance.

FY2021 Strategies

Contributing to regional healthcare and the well-being of patients by following area marketing plans

In FY2021, we reorganized our academic organization into a Product Marketing Department. This department plays a leading role not only in offering first-class training to MRs and helping them increase their knowledge of the therapeutic areas the Company focuses on, but also in creating and implementing area marketing plans based on objective data. The digital shift in MR activities, represented by e-detailing, has widely expanded the field for the activities of Product Marketing Department staff. Detailing activities through digital channels will become more important in the future, but we place the same level of importance on conducting high-quality real-life detailing activities. This means that we are committed to enhancing the quality of MRs' detailing activities and establishing a system for promptly fulfilling the needs of medical professionals. To achieve this, MRs and Product Marketing Department staff will work together to accomplish their mission in Sales to help patients gain access to proper therapies as quickly as possible.

Value Creation Initiatives

Contributing to the treatment of patients

Nippon Shinyaku is committed to contributing to patients suffering from rare diseases. In the field of pediatric neurology, Viltepso launched in May 2020 upon its NHI price listing as a treatment for Duchenne muscular dystrophy (DMD). Previously, only steroids had demonstrated any effectiveness in slowing the progress of this disease, giving rise to a significant unmet treatment need for DMD.

In the area of pulmonary arterial hypertension (PAH), Nippon Shinyaku offers three oral agents with different mechanisms of action: Upravi, Adcirca, and Opsumit. PAH is a rare disease thought to affect only one or two people in every million, and the prognosis is poor, as without medical intervention the median survival time after diagnosis is 2.8 years. There had been a dearth of treatments for PAH, but in recent years several innovative new drugs have launched, including the three offered by Nippon Shinyaku. As a result, the survival profile of PAH patients looks to be improving.

To ensure that our valuable products assist as many patients as possible and without delay, we think it important that suspected sufferers are identified in a timely fashion so that they can be referred to specialist institutions to receive the appropriate treatment. We have introduced a variety of initiatives to support the well-being of both patients and their families.

Contributing to DMD patients

Nippon Shinyaku is taking steps to raise awareness of this disease and its treatments, not only among specialists in the field of pediatric neurology, but also among non-specialists engaged in daily pediatric practice. By conducting activities to foster awareness among both patients and medical professionals, we aim to ensure the timely delivery of medications to patients battling DMD.

Nippon Shinyaku also disseminates information on DMD to patients and ordinary consumers via "DMD wo Shiru" (Know DMD), a disease awareness website for DMD patients; the "HeIC+ Hospital Search – Duchenne Muscular Dystrophy" website providing information on medical institutions; and "Moshikashite NMD" (Could this be NMD?), a website jointly established by three companies selling medications for neuromuscular diseases. In addition to setting up these websites, Nippon Shinyaku also runs advertisements in newspapers, creating opportunities for conveying the words of specialists to a wide audience of regular consumers, to instill in them a deeper understanding of DMD and its treatments. We believe that promoting broader awareness of the disease, especially among parents with young children, will aid in timely diagnosis, and by extension, appropriate treatment.

Contributing to pulmonary hypertension patients

In order to raise awareness of pulmonary hypertension (PH) among non-specialist physicians, Nippon Shinyaku utilizes an array of digital content such as company websites dedicated to the subject, e-detailing and webinars. To help ensure that patients go on to receive appropriate treatment, we offer lectures around the nation that provide a forum for non-specialist physicians to communicate with those specializing in the PH field.

Among patient-oriented initiatives, we run two dedicated websites, "Pulmonary Hypertension Treatment Support" and "Did You Know That Shortness of Breath and PH are Complications of Scleroderma," providing information on the disease itself and its symptoms, as well as testing, treatment, and assistance schemes. We have also launched a smartphone app, "PAH Care Notebook," that can be used to record daily symptoms and medications, digitizing this information for patients to review in graph and report form and use as a tool for communicating with medical professionals. The app also reminds patients not to forget their medications and can refer patients to the "Pulmonary Hypertension Treatment Support" website if they have concerns, for example about side effects. In this manner, we strive to afford PH patients peace of mind about their treatment.

Strategies for Value Creation

Pharmaceuticals

Resource Procurement, Production & Assurance

In fiscal 2020, we achieved most of the Year 2 targets contained in the 6th Five-Year Medium-term Management Plan. Completion of the global supply chain to support in-house sales of Viltepso in the U.S., including quality assurance systems, was a major step forward as we work to develop other overseas markets in Europe and China going forward.

Separately, we are managing progress toward achieving material improvements in sustainability by 2030. Addressing the specific issues identified in the plan, we see our mission as the development of a global supply chain built on world-class reliability and quality assurance systems to provide high-quality pharmaceuticals for the benefit of patients worldwide.

Hitomi Kimura Director, Head of Resource Procurement, Production & Assurance



Strengths The advent of in-house sales in the U.S. has magnified the importance of overseas markets. We are responding by upgrading EHS^{*1} programs at the Odawara Central Factory as part of efforts to accommodate the shift toward products for specialized domains such as cancer and rare diseases. Within efforts to develop supply and QA capabilities to support our global supply chain, we are also working to ensure our logistics processes for transportation and storage of pharmaceuticals are compliant with GDP^{*2} guidelines.

*1. EHS: Environment, Health & Safety *2. GDP: Good Distribution Practice

Progress of the 6th Five-Year Medium-term Management Plan

FY2020 Overview

Accelerating our efforts to further enhance our global supply system and increase productivity in response to the launch of Viltepso in the U.S.

In FY2020, we established global supply and reliability assurance systems in response to the launch of Viltepso for sale in the U.S.

Specifically, we made various preparations, including validating transportation and packaging and establishing the procedures for operations with various subcontractors, quality assurance in the U.S., change management, and pharmacovigilance.

In addition, we strengthened our system for stable product supply by newly installing refrigerated storage exclusively for the active ingredients of oligonucleotide therapies in the Odawara Central Factory in line with the BCP.^{*3} At the factory, we have also been conducting gap analysis, including mock inspections, in preparation for commencement of global operations. Furthermore, we have begun detailed discussions about new investments related to

oligonucleotide therapies, with a view to other therapies following Viltepso.

In terms of distribution, we established a global supply system and adopted various measures to meet the Good Distribution Practice (GDP) Guidelines for Pharmaceuticals, including establishing an appropriate organizational structure, relocating our distribution warehouses, and producing a procedure manual.

Just as in FY2019, we devoted efforts to strengthening our system for stable product supply and further promoting streamlined operations and low-cost management. For these purposes, we defined new standards for risk assessment in our supply chain and cut the cost of procuring ingredients of our focus products.

*3. BCP: Business continuity plan

FY2021 Strategies

Devoting efforts to strengthening our global supply system and responding to the diversification of specialties and drug modalities

Against the backdrop of the growing importance of expansion into overseas

markets, we are striving to strengthen our global supply system to adapt to European, Chinese, and emerging markets by leveraging as a foothold the supply and reliability assurance systems that we established in preparation for the start of in-house local sales in the U.S.

We are also actively facilitating the use of the Odawara Central Factory to respond to the market shift to specialties and the diversification of drug modalities. Specific measures include utilizing the manufacturing plant for highly active solid formulations in product life cycle management (PLCM) for Upravi (code no.: NS-304; generic name: selexipag), a pulmonary arterial hypertension (PAH) treatment, discussing new investments concerning oligonucleotide therapies, and responding to overseas inspections in preparation for the launch of relevant products. Moreover, we are striving to streamline our manufacturing process in anticipation of a future decline in the working population by robotizing production facilities at our factory and introducing AI and factory automation technologies.

We will also make sustained cost management efforts, including cutting procurement and distribution costs, to contribute to the generation of profits.

Value Creation Initiatives

Quality assurance and supply stability

Ensuring reliability from R&D to manufacturing and marketing

Based on our policy commitment to supply safe, high-quality products, the Regulatory Affairs, Safety Management and Quality Assurance Division leads efforts to ensure the quality, efficacy and safety of the pharmaceuticals we supply.

We file applications for manufacturing and marketing approval using the data gained from the preclinical and clinical studies conducted at the R&D stage. The division audits filing submissions at the appropriate stage to ensure the reliability of data from all R&D studies.

Once manufacturing and marketing approval is gained, work continues to ensure full compliance with the terms of approval via close cooperation between the general marketing supervisor, QA manager and safety manager. We seek to fulfill our responsibilities to the market by ensuring regulatory compliance and the proper maintenance and management of manufacturing and marketing licenses to guarantee product quality and safety.

Quality assurance for pharmaceuticals

R&D stage	
Preclinical studies	Clinical trials
Test data reliability based on GLP and reliability standards	Trial data reliability based on GCP



Manufacturing/ marketing stages		
Quality control	Safety management	Management of approvals/licenses
QC based on GMP/GQP	Safety management based on GVP	Maintenance/ management of manufacturing/ marketing approvals and licenses



Pharmaceutical risk management initiatives

Risk management for Nippon Shinyaku products is based on the use of a Risk Management Plan (RMP)^{*4}. The aim is to ensure pharmaceutical safety at the post-marketing stage by using the RMP to evaluate the benefits and risks across all stages from R&D to post-marketing and institute required safety measures in line with results of analyses. The RMPs are published on the websites of the Pharmaceuticals and Medical Devices Agency (PMDA) and Nippon Shinyaku.

Our Safety Management Department prepares manuals to support those with responsibility for RMP execution. We are also developing systems to enable borderless Group cooperation for RMP processes. To support global development of drugs such as Viltepso, an oligonucleotide drug for the treatment of Duchenne muscular dystrophy, we are also in the process of establishing a pharmacovigilance system based on global standards as part of ensuring the integrated management of safety-related information.

*4. Risk Management Plan: An RMP defines the critical risks for an individual drug at the post-marketing stage and collates measures taken by the company to mitigate such risks

Building pharmaceutical QA systems

Our pharmaceutical QA systems are continually developed by the Quality Assurance Department in compliance with Good Quality Practice (GQP) and Good Manufacturing Practice (GMP). Management reviews are used to help improve quality systems, product quality and resource allocation. Audits are also used to check compliance with GMP and the terms of regulatory approvals. As we develop our global operations, we are building QA infrastructure to meet the local regulatory requirements; investing in English communication skills; and

recruiting and training people with the QA-related knowledge and experience in overseas markets.

Ensuring reliable product supplies

To reinforce the reliability of the entire supply chain, we have instituted criteria to support the dynamic assessment of underlying risks for each product, in line with the international risk management standard ISO 31000. Based on the results of the risk assessment, we prioritize risk mitigation measures according to impact magnitude and consider ways to prevent supply interruptions. On the distribution side, we have set up our logistics based on the Good Distribution Practice (GDP) guidelines for pharmaceuticals. We are also looking at mitigating the risks posed by natural disasters by decentralizing our storage warehouse locations.

We have set up an in-house accreditation system at the Odawara Central Factory for qualifications relating to areas such as management of manufacturing and quality processes. We monitor the skills status of the workforce to ensure critical skills are not lost through retirement, and support multi-skills development by all our employees. The Business Continuity Plan (BCP) supports our preparations for any disaster-related supply issues caused by events such as earthquake, fire, power blackout, flood, or volcanic eruption. We have undertaken seismic reinforcement works and installed fire and flood-proof walls and doors, along with a slanting roof to aid removal of volcanic ash; the site also has its own emergency backup power generation and fuel supply set-up, as well as specially installed emergency exits. Besides investing in hardware, we have also prepared safety manuals and undertake regular emergency training drills. We are also considering making further investments to support reliable supplies of nucleic acid medicines.

Strategies for Value Creation

Functional Food

The Functional Food business aims to help address environmental concerns and societal issues such as food shortages and related waste through our bulk materials and supplement businesses, in the process supplying a stream of new and distinctive products of high quality to help prevent disease and to support improvements in human health.

By cultivating a strong corporate culture to empower individual action, we hope to contribute to lifestyles that are healthier and enriched through food.

Hitoshi Ishizawa Director, Head of Functional Food



Strengths At the Food Development Laboratories, we leverage the advanced expertise that Nippon Shinyaku has built up as a drug maker to develop new commercial foods of high quality and originality. We also benefit from our pharmaceutical heritage in the expertise we can bring to managing materials, production and product quality.

Developing and selling a broad range of products such as health food ingredients, protein preparations and preservatives, Nippon Shinyaku aspires to contribute to healthier lifestyles through food.



Progress of the 6th Five-Year Medium-term Management Plan

FY2020 Overview

Achieving the FY2020 sales target in the face of restrictions on business activities amid the COVID-19 pandemic

In FY2020, our business activities were severely restricted to prevent the spread of COVID-19. Even amid that situation, we continued our efforts to increase our R&D capabilities as a pharmaceutical manufacturer focusing on the development of new products. Specific measures included promoting joint research with academia (academic research institutions, including universities) and developing an AI-assisted R&D platform.

We also strove to strengthen our quality assurance system to become an organization that is trusted by society. Although the COVID-19 pandemic prevented us from visiting ingredient suppliers outside Japan for local inspections, we instead

conducted remote inspections and reviewed and managed the quality control format in cooperation with the suppliers in order to improve our quality assurance system.

In the supplements business, the cancellation and postponement of sports events in various areas had a serious impact on sales of our sports supplements (the WINZONE series). Nevertheless, our follow-up activities with corporate and university teams led to WINZONE users achieving good results in various sports events.

We also strove to win new customers for our aging care supplements,

Mangostia and *Kioku no Kobako*, through online marketing, resulting in a drastic increase in the number of regular customers.

In the bulk materials business, despite a sharp decline in demand among international tourists to Japan, sales of lacto-protein preparations grew significantly against the background of heightened health awareness among remote workers and a consequent rise in demand for at-home workouts and sports nutrition products, many of which contain lacto-protein.



WINZONE PROTEIN



Mangostia



Kioku no Kobako

FY2021 Strategies

Further accelerating the Functional Food business's shift to greater profitability with both bulk materials and supplements businesses as growth drivers

In the supplements business, we established the Supplement Sales Planning Department in FY2021. In FY2021, with this new organizational structure, we aim to make a giant leap by allocating our management resources to sports supplements, with which we aim to become the most popular brand among athletes, and to aging care supplements, with which we aim to become a pioneer in disease prevention and aging care.

In the bulk materials business, we will further increase our sales by launching new distinctive products according to a well-designed schedule in our main product categories of health food ingredients, preservatives, and protein preparations.

Additionally, we will newly introduce a consumer preference analysis tool and a marketing database to devise more effective sales strategies and maximize the sales of new products as early as possible.

As shown above, we position both supplements and bulk materials businesses as growth drivers for the Functional Food business. We will achieve rapid growth of the supplements business with the aim of further accelerating the Functional Food business's shift to greater profitability.

Value Creation Initiatives

Helping to reduce food waste

With more people living to one hundred years of age, it is important that we can all achieve health and prosperity to enjoy a longer life. Japan's fiscal situation has deteriorated, however, due to lower birth rates and an aging population, and we must look after our own health without relying on public healthcare spending. While pharmaceuticals will continue to play an essential role in treating illness, now is increasingly the time for people to make smart use of functional foods as a way of staying healthy. With many more health-conscious and demand increasing for ways to prevent disease, our aim is to help people to lead a rich and healthy life through food.

The COVID-19 pandemic has brought significant changes to all our lives. The attitudes of consumers towards food is also moving with the times. Recently, we have seen a trend toward thinking about how foods are made and their benefits to health, in addition to taste and nutrition. More consumers want to buy foods with eco-friendly characteristics. There is also a growing desire for consumers to know where and how a product was made, and where the ingredients listed on the label came from. The related concept of 'clean label' foods is a rising worldwide trend. Beyond demanding that foods are safe and healthy, consumers are also showing a strong desire to understand them better. These trends are stimulating the creation and rapid growth of

new global markets for products such as meat alternatives, as well as preservative-free foods with more natural ingredients. At Nippon Shinyaku, we take a forward-looking approach to develop foods that help address societal issues such as environmental protection, global food shortages, and food waste. We aim to identify demand trends before they fully emerge, while leveraging the advanced technical expertise we possess as a pharmaceutical company to create new products that will make a positive contribution to people's health through food.

The population of Japan is in long-term decline, with projections it will fall below the 100 million mark by the middle of the century, reaching 99.13 million in 2048. In line with this trend, we expect the food market in Japan to continue shrinking gradually. Elsewhere in Asia, however, notably in China, Vietnam, Thailand and Indonesia, working populations are growing. Markets in these countries will expand rapidly due to the high rates of economic growth and increased numbers of people in higher income groups.

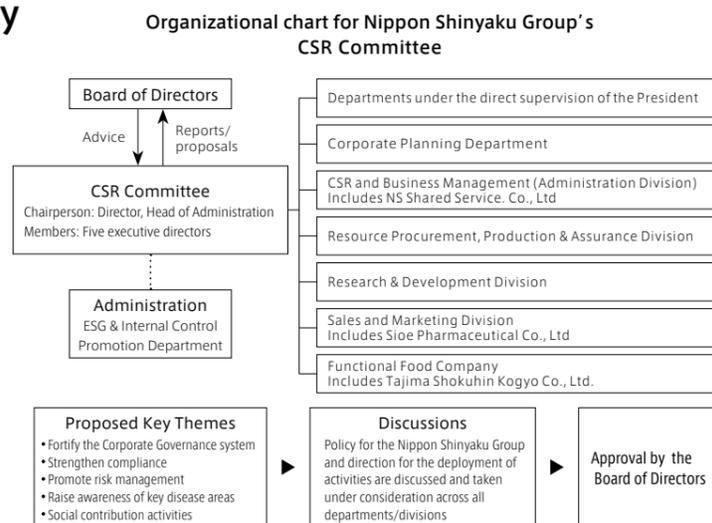
Our overseas sales of functional foods are limited at present because we only have a presence in a few markets such as China, South Korea, and Taiwan. However, we are receiving ever more inquiries from overseas. We aim to develop our global sales set-up so we can supply to people worldwide highly original and valuable healthcare products and materials that we have developed in-house.



How We View Sustainability

CSR Promotion System

The Nippon Shinyaku Group has a CSR committee in place to confirm that its corporate activities meet society's norms and expectations and to orient its various activities so as to expand and enrich the Group's overall CSR initiatives in line with its CSR policy.



Engaging with materiality issues as part of realizing a sustainable world

The global COVID-19 pandemic has led to major changes in our lives while at the same time shifting our values and perspectives. On a positive note, it has made us realize more than ever before the degree to which everyone worldwide is connected and how interdependent we are. In 2015, the United Nations created a goal for the international community of building a sustainable society in which no one is left behind. I believe the time is now ripe for nations, companies and consumers to address this goal seriously.

At Nippon Shinyaku, we announced a list of 19 materiality items in April 2021 following a year of internal consultation. Each of the 19 items is important, but I would place two at the top of the list: first, taking care of the global environment through measures to tackle climate change; second, ensuring the well-being and respecting the diversity of all our employees.

To address climate change, we have pursued measures to reduce environmental impact in line with our Basic Environmental Policy, and have set targets in line with the goals adopted by the government and economic organizations. We are considering adopting significantly more ambitious targets after the commitment made by the government to achieve net-zero emissions by 2050.

In terms of policies to promote diversity and inclusion and to support employee well-being, we concur with the movement spearheaded by Keidanren to increase the representation of women at director level in Japan to at least 30% by 2030 as part of the efforts to eliminate gender disparity in the Japanese workforce. We do not need to be investing large sums to create a company where women, seniors and other employees can work

happily and be fulfilled, but we do need to change the awareness of employees. Changing the so-called unconscious bias is not easy even through repeated training and on-the-job support, and I am taking the lead in trying to get this message across patiently over time. At the same time, we must also seek to trust and empower our colleagues at work. Demonstrating trust in subordinates and using delegation may only have minor short-term effects, but there are major long-term benefits in this approach since it will help develop the most effective workforce. It is also in keeping with the tradition of this company to recruit and develop people who can think for themselves.

A workplace where we are psychologically confident enough to discuss any issue is an essential prerequisite for working together to build a sustainable society. Eliminating harassment, encouraging cross-generational fertilization of ideas, and forging the links that foster innovation: these are one half of our CSR challenge as we also work together to solve the problems caused by disease.



Takashi Takaya
Director,
Head of Administration



Related SDGs



Initiatives for the Environment

Environmental Management

Nippon Shinyaku Basic Environmental Policy

At Nippon Shinyaku, our mission is to help people lead healthier, happier lives. When we seek growth, it should be growth in harmony with the natural environment. That is why we strive to protect, sustain, and improve the environment through eco-considerate business activities.

- 1 We will effectively operate an internal organization responsible for environmental issues and establish clear targets for our collective pursuit of environmental conservation initiatives.
- 2 We will comply with laws, regulations, and internal rules pertaining to the environment, and work at environmental conservation cognizant of our responsibility to society at large.
- 3 We will maintain an accurate awareness of the impact of our business activities on the environment (e.g., global warming, depletion of resources, environmental pollution) and seek to continuously improve our environmental preservation activities and prevent pollution.
- 4 We will train and educate all employees to recognize the importance of environmental conservation and act in a responsible manner.
- 5 We will be considerate of biodiversity when pursuing our business activities, and encourage the sustainable development of our society.
- 6 We will proactively publish information about our environmental preservation activities, and communicate with our local communities and other stakeholders.

Environmental Management Organization

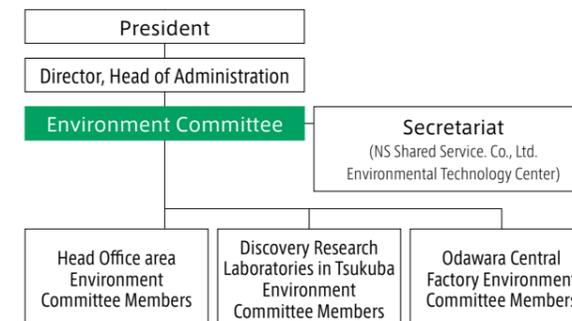
Nippon Shinyaku formulated the Nippon Shinyaku Basic Environmental Policy as a guideline for our environmental conservation activities. The Environment Committee, chaired by the Director, Head of Administration, was established to put this policy into practice and determines the direction and targets of our environmental preservation activities.

The 6th Nippon Shinyaku Environmental Targets Plan (FY2020-2022)

The Nippon Shinyaku Environmental Targets Plan sets specific voluntary targets for the company to carry out to comply with its Basic Environmental Policy.

Under the 6th Nippon Shinyaku Environmental Targets Plan (FY2020-2022), we are striving to reduce our environmental footprint in all aspects of our business operation and enhance corporate value through ESG management.

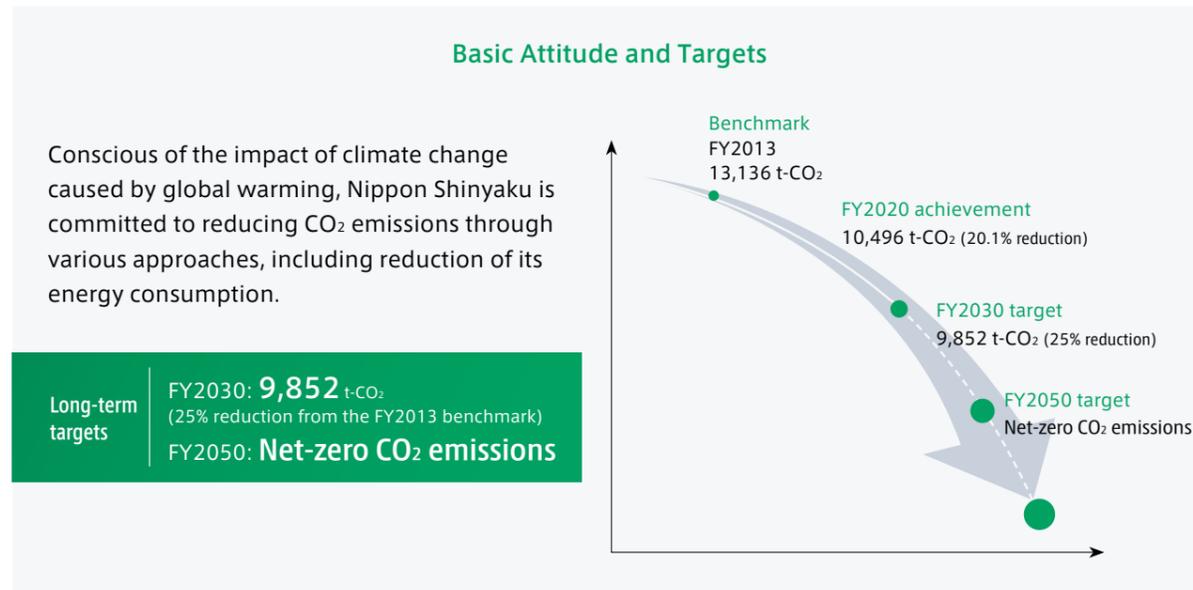
Environmental Management Structure



Item	Targets
Global warming alleviation	Reduce GHG emissions by FY2030 by 25% from the FY2013 benchmark. Reduce GHG emissions by 6% by 2022.
Waste management	Reduce the final amount of landfilled waste by FY2022 by 70% from the FY2005 level. Set the target waste plastic recycling rate for FY2022 at 65%. Set the target waste recycling rate for FY2022 at 55% or above.
Chemical substance management	Promote appropriate management of chemical substances, including those designated under the Pollutant Release and Transfer Register (PRTR) Act, so as to continue reducing their release into the natural environment.
Environmental management	Continue the certification of the environmental management systems (ISO 14001 and KES Step 2) so as to effectively improve environmental performance.
Stakeholders	Actively engage in community service and promote ESG to contribute to the achievement of SDGs. Disclose ESG information appropriately to society. Promote community service related to the conservation of biodiversity.

Initiatives for the Environment

Climate Change Alleviation



Initiatives to reduce CO₂ emissions

1. Reducing energy consumption through equipment improvement

On the occasion of equipment renewal, we renew air-conditioning refrigerators, boilers, and total heat exchangers. We have also been gradually replacing conventional lighting equipment with LED equipment and installing motion detectors on lighting equipment. Through these measures, we aim to reduce CO₂ emissions, thereby contributing to climate change alleviation.

At the Odawara Central Factory, we introduced highly efficient chillers at the time of the renewal of air-conditioning refrigerators. At the Tokyo Office, ice thermal storage equipment* was introduced to level off consumption peaks.

* This shifts daytime power consumption for air conditioning to night time, with the use of ice heat stored in the thermal storage tank during the night.

2. Introducing hybrid vehicles for sales representatives

By introducing hybrid vehicles for our sales activities and also encouraging employees to use public transportation systems while in urban centers, we are promoting measures to better respond to climate change and raising employee awareness.

Nippon Shinyaku's sales vehicles will be entirely replaced by hybrid cars in the four-year period starting from FY2020, except in heavy snowfall areas. In FY2020, hybrid cars already accounted for 43% of the company's fleet of sales vehicles.

3. Energy conservation following the guidelines for saving electricity and energy

We are making company-wide power and energy-saving efforts, following the guidelines for saving electricity and energy drawn up by an in-house committee specifically established to promote conservation initiatives. Concrete company-wide power-saving measures range from appropriate indoor temperature settings to encouraging personnel to turn off all unnecessary lights and use stairways instead of elevators.

4. Expanding initiatives

In addition to equipment renewal, equipment operating hours and temperature settings are also continuously reviewed to improve our energy-saving performance.

From April 2021, we switched to using renewable energy sources to meet roughly 30% of the Head Office area's electricity needs.

Initiatives involving the use of renewable energy, including the installation of solar power generators, will be further examined and implemented.

5. In-house Awareness-raising Education

The importance and necessity of environmental protection are covered in a range of in-house training and educational programs, including intranet-based training programs. These programs contribute to raising and maintaining employees' environmental awareness.

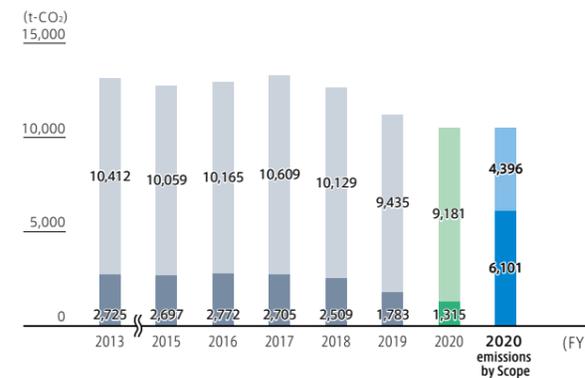
Scope 1, 2, and 3 emissions reduction

Nippon Shinyaku is focusing on expanding the range of emissions calculations with a view to mitigating and adapting to climate change throughout the entire supply chain.

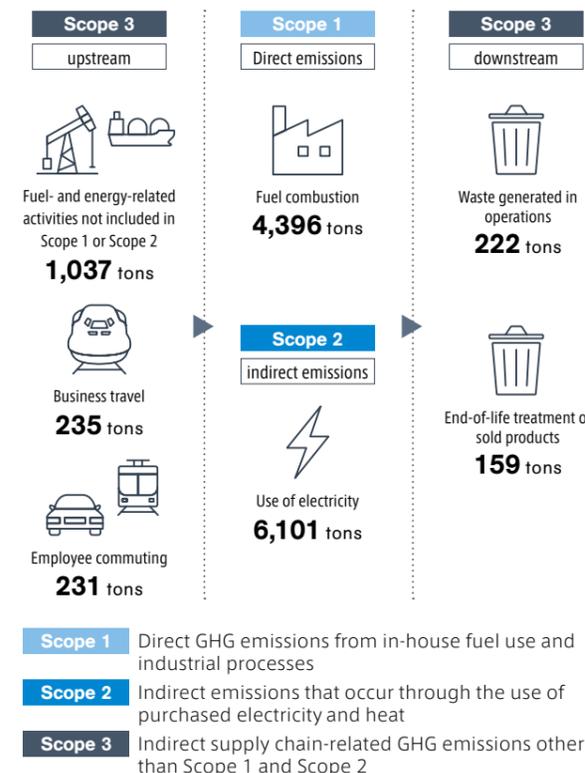
In addition to the Scope 1 and 2 emissions already calculated, from FY2020 the company also has been calculating Scope 3 emissions.

Scope 1 and 2 emissions volume

■ Main business sites: Head Office area, Odawara Central Factory, Discovery Research Laboratories in Tsukuba
■ Sales offices, etc.
■ Scope 1: Direct GHG emissions from owned or controlled sources
■ Scope 2: Indirect emissions that occur through the use of purchased electricity, steam, and heat



Supply chain emissions volume



Promoting the Recycling of Resources

Basic Attitude and Targets

Recognizing the limits of natural resources, we at Nippon Shinyaku are constantly striving to reduce the amounts of resources we use, adopting various methods, including reuse and dual or common use. We are also focusing our efforts on the active use of recycled raw materials to ensure that the waste resulting from our activities is recycled or reused. As general indicators for these efforts, we are working to reduce the quantities of waste generation and waste disposal in landfills. With regard to the use of water, including cooling water at our manufacturing sites, we endeavor to protect and nurture water sources in the environment and regulate the quality of waste water from our facilities in compliance with applicable laws and regulations.

As a long-term target concerning waste plastic, we are aiming to achieve a reuse/recycling rate of 81.1% by FY2030 (in line with the target set by the Federation of Pharmaceutical Manufacturers' Associations of Japan).

Initiatives for Resource Recycling

1. Appropriate treatment and utilization of waste materials

We appropriately treat and manage waste materials, recycle metals, and collect and sort out plastic waste, all in compliance with the Waste Disposal and Public Cleansing Act and applicable Kyoto City ordinances.

In the Head Office area and at the Discovery Research Laboratories in Tsukuba, we have adopted an integrated waste management service (ASP service) capable of appropriate and continuous support to waste management. This enables us to confirm responsible waste treatment and disposal by our service providers. Furthermore, in the Head Office area, we disclose information regarding waste materials from time to time on the in-house intranet based on the KES Environmental Management System Standard.

2. Reduced package waste

By reducing the amount of pharmaceutical package waste, we are trying to reduce the burden on the environment, while ensuring that new packaging will not compromise product quality.

3. Reduced use of office paper

As part of our drive to realize paperless offices, we have been digitizing documents and reducing the volume of office paper purchased year after year. In FY2020, we achieved a 38.7% YoY decrease in office paper purchases. At the same time, we have been continuing the purchase of "green" office paper commensurate with the Act on Promoting Green Purchasing.

Initiatives for the Environment

4. Plastics Smart campaign - a 1.2-ton reduction of PET bottle use

Endorsing its objective of reducing marine plastic litter, Nippon Shinyaku has joined the Plastics Smart campaign launched by the Ministry of the Environment of Japan by registering the Blue Smile Project, our plastic waste reduction initiative. In this project, all employees are provided with their own multiple-use bottles and encouraged to use them in the workplace, while on assignment away from the workplace, and even in their free time. Moreover, the suspension of the sale of drinks in PET bottles from vending machines in the Head Office area resulted in a drop of waste PET bottles from 1.2 tons in FY2019 to zero. This achievement drew great attention and praise from society, and Nippon Shinyaku was featured on the Kyoto City-operated website "Kogomi Net," dedicated to waste reduction and recycling information, as a company proactively engaged in plastic waste reduction.



Reusable bottle distributed to all employees



Web http://kyoto-kogomi.net/recycle_plastic/

Appreciation by External Parties

Recognition by Kyoto City for Excellence in Industrial Waste Disposal and Promotion of 3Rs

Fiscal 2019 marked the first time our Head Office area was commended by Kyoto City as a "Business Recognized for Excellence in Industrial Waste Disposal and Promotion of 3Rs," under a system devised by Kyoto City to evaluate the responsibility of waste generators. In fiscal 2020 we were recognized again.



Sticker recognizing "Excellence in Industrial Waste Disposal and Promotion of 3Rs"



Certificate recognizing "Excellence in Industrial Waste Disposal and Promotion of 3Rs"

Recognition by Kyoto City as Office with Excellent 2R, Sorting and Recycling Activities

In fiscal 2020, our Head Office area was certified by Kyoto City as an Office with Excellent 2R, Sorting and Recycling Activities, mainly in recognition of Nippon Shinyaku's participation in the Plastics Smart campaign and our registered initiative, the Blue Smile Project.



Certificate of an especially excellent business operator for 2R

Promoting Proper Management of Chemical Substances

Basic Attitude and Goals

For a pharmaceutical company that handles a variety of chemical substances, their appropriate management is a vital social responsibility. At Nippon Shinyaku, we ensure responsible management of all chemicals, and a dedicated committee, established in compliance with the company's Basic Regulations on the Management of Chemical Substances, clarifies the company's policy in this regard so that chemicals are managed correctly by all departments. Thanks to our IT system that enables a comprehensive and exhaustive inspection of the status of legal and regulatory compliance concerning chemical substances, we maintain a responsible management mechanism concerning all chemicals handled in-house in conformity with the latest applicable laws and regulations. Furthermore, we regularly assess workplace risks, including those related to chemical substances, from the perspective of occupational health and safety to realize the highest level of workplace safety.

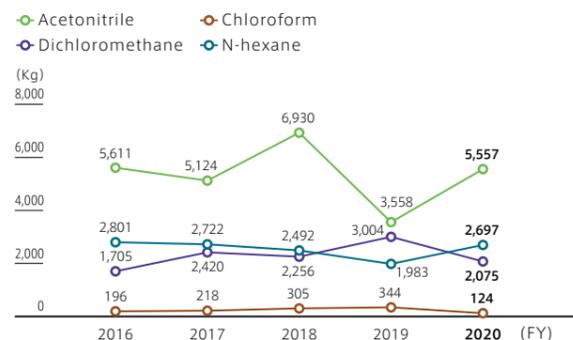
PRTR Method-based Management

In the Pollutant Release and Transfer Register (PRTR) method defined under the Act on Specific Chemical Substances*, business operators that handle one ton or more of any designated Type 1 chemical substances per year are required to notify these chemicals and details of their treatment. The corresponding chemicals we handle are acetonitrile, N-hexane, and dichloromethane in the Head Office area. We file all required reports and notices, demonstrating our appropriate management of all designated chemicals.

The manufacturing plant for highly active solid formulation at the Odawara Central Factory is equipped with the latest triple containment structure. In this structure, highly active chemicals are contained first by equipment, second by air current and chamber pressure, and third by building, thereby preventing leakage into the external environment and taking maximum care for safety, quality, and environmental protection.

* The unabridged title of the law is the Act on Confirmation, etc., of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof.

PRTR-designated Type 1 chemicals (quantities handled)



Conservation of Biodiversity

Basic Attitude

At Nippon Shinyaku, we carry out activities designed to protect internationally recognized endangered plant species and those designated as endangered species by the Ministry of the Environment of Japan. We also organize tour workshops on themes related to these plants.

The Yamashina Botanical Research Institute conserves and cultivates over 3,000 varieties of plants, including more than 160 species that are the botanical origins of herbal medicines recorded in the Japanese Pharmacopoeia, numerous internationally recognized endangered species such as *Welwitschia mirabilis*, and species recognized as being in danger of extinction by the Ministry of the Environment of Japan. We attach great importance to research into cultivation from the perspective of biodiversity conservation. We participate in local activities for the preservation of rare plants native to Kyoto. For example, we are active in the protection and propagation of futaba aoi (*Asarum caulescens*) and kikutani-giku (*Chrysanthemum seticospe*).

Involvement by Yamashina Botanical Research Institute in conservation activity

Raising Awareness of Biodiversity Conservation

In addition to disseminating information via the website (<https://yamashina-botanical.com/>), the Yamashina Botanical Research Institute routinely holds tours by appointment, as well as hosting seminars for professionals, indigo dyeing workshops for elementary school students, public holiday tours, and other events designed to raise awareness of conserving plant diversity.

Cultivating and returning *Chrysanthemum seticospe* to its natural habitat

Conservation activities by Nippon Shinyaku include cultivating and propagating Kyoto City's endangered *Chrysanthemum seticospe* to feature in Kyoto Station's "Green Water Corridor" and Kyoto City's Kikutani Forest of Flowering Chrysanthemums (returning the plant to its natural habitat). We returned 300 shoots of this plant to the natural habitat in fiscal 2020.

Cultivation and dedication of futaba aoi (*Asarum caulescens*)

Nippon Shinyaku participates in the Aoi Project, a campaign launched by a general incorporated association established to preserve futaba aoi (*Asarum caulescens*), which is used in the Aoi Festival, one of the three major traditional festivals of Kyoto. Nippon Shinyaku takes part in the cultivation and ritual dedication of the plant for the festival. The number of futaba aoi growing in Kyoto has been rapidly decreasing in recent years. In July 2020, we dedicated 150 pots of futaba aoi, which we had cultivated from seeds for three years.

Protection of *Welwitschia mirabilis* and other endangered species

Nippon Shinyaku also practices ex situ conservation of endangered species protected by the Washington Convention, such as *Welwitschia mirabilis* and aloes.



Touring Yamashina Botanical Research Institute

Appreciation by External Parties

1. Receipt of Kyoto Environmental Award (Honorable Mention)

Kyoto City established the Kyoto Environmental Award with the aim of raising interest in the environment and further promoting various practical activities that contribute to environmental conservation, such as preventing global warming, creating a recycling-oriented society, and maintaining biodiversity. During the COVID-19 pandemic, the Yamashina Botanical Research Institute held virtual tours in place of real-world tours and received an Honorable Mention in the Kyoto Environmental Award for this initiative.



Virtual tour

2. Recognized as Contributor to Kyoto City's "Kyoto Biological & Cultural Regeneration Project"

In 2019, the Yamashina Botanical Research Institute was officially recognized and registered as a contributor to the Kyoto Biological & Cultural Regeneration Project, run in accordance with the Kyoto City Biodiversity Plan to promote preservation and regeneration of rare animals or plants that have a distinctive place in traditional Kyoto culture.

In contributing to this project, the Yamashina Botanical Research Institute promotes the preservation of plants, such as okera (*Atractylodes ovata*), fuji bakama (*Eupatorium japonicum*), and kikyo (*Platycodon grandiflorus*), which are inseparable from Kyoto's traditional cultural landscape. In addition, the Research Institute actively promotes the preservation of endangered plants registered in Kyoto Prefecture's Red Book and organizes related educational and awareness-raising activities.

3. Kyoto City's Kagayaki Award and Special Kagayaki Award

In 2019, the Yamashina Botanical Research Institute was nominated for commendation by Kyoto City for local companies that make outstanding achievements in specific categories. The company received the Kagayaki Award and Special Kagayaki Award. The commendation system was instituted based on the Kyoto City Ordinance on the Promotion of Sustainable Development by Local Businesses established in April 2019. The awards are presented to local companies recognized as pursuing their business activities while nurturing deep ties with the local communities through contribution to general safety and security, activities leading to the preservation of cultural assets, natural environmental protection, and so forth.

Initiatives for Society

Promoting Employee Health Management and Workplace Safety

Related SDGs



Policy and Objectives

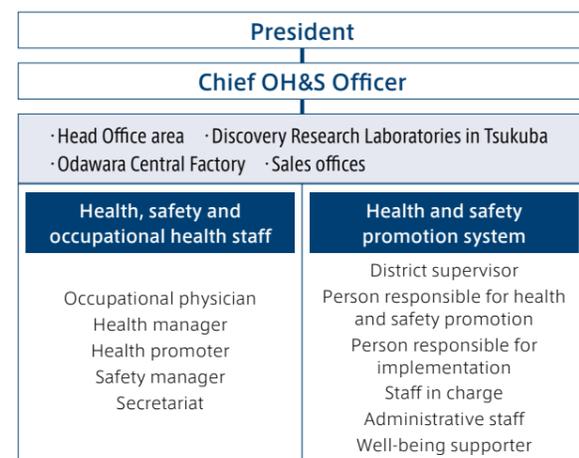
The Health Declaration issued by Nippon Shinyaku in 2018 committed the company to actively maintaining the health of employees while supporting family members, based on a health management-based approach to the workplace environment and related working conditions. The subsequent transformation of the way we live and work by the COVID-19 pandemic prompted a refashioning of this commitment to health management as the Nippon Shinyaku Health Declaration 2020. In an interview conducted at the time as part of efforts to raise internal awareness, then-President and current Chairman Shigenobu Maekawa shared his thoughts on the concept behind the new Health Declaration and his personal approach to maintaining health.

For company-wide health management to progress effectively, health literacy on the part of each and every employee is essential. Heightened individual awareness results in positive change in behavior. Believing that this should also positively influence families and others around these individuals, we are moving toward our goal of health management, well-being for all.



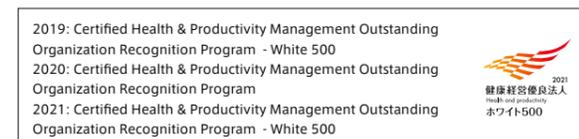
measures for employee health management.

These people are also involved in raising the awareness of health management across the company and in gathering frontline feedback to help develop improved policies.



External Recognition

We have participated in the annual survey on health management practices conducted by the Ministry of Economy, Trade and Industry (METI) since 2018, and been recognized under the program several times.



The growing number of firms taking part in the survey makes it increasingly hard to gain the "White 500" designation, and our success in doing so is testament to the quality of our activities in the health



management area. In February 2021, we were also awarded the "Sports Yell Company" designation by the Japan Sports Agency. This recognizes firms that actively work to promote the health of employees through sports-based initiatives as part of the broader push to promote the social benefits of sport.

Mental Healthcare

In 2003, Nippon Shinyaku was one of the pioneers in Japan of an Employee Assistance Program (EAP) designed to support early detection, prevention and treatment of mental health issues. The program includes annual stress checks for employees. In fiscal 2019, we also began offering an on-site counselling service to help workers

communicate any concerns, while stationing mental health professionals at worksites to provide support. Going forward, we will continue to fine-tune our approach to mental health management.

Specific Health Management Initiatives

To promote the health of individual employees through enhanced awareness, we are providing training and web-based health-related experiences to help people clearly ascertain their health status and any areas where they should try to improve. This approach supports the self-identification of high-risk individuals within the general population.

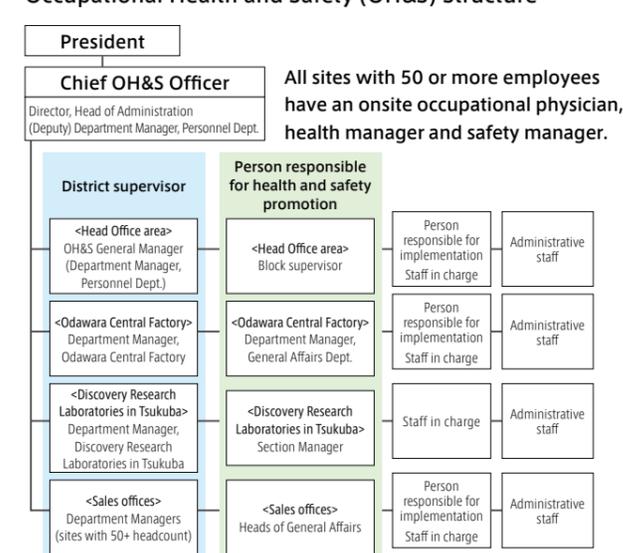
Measure	Description
1 Improving health literacy	
Campaign to undertake "Health Challenge"	To help achieve better health outcomes by altering lifestyle habits in an enjoyable manner, we are enrolling employees in the "Health Challenge" program offered by Tokio Marine & Nichido Medical Service Co., Ltd. * A self-selected 12-part program with challenges such as quitting smoking, drinking less, or walking
Group walking events (organized by Kencom)	These events encourage people to team up with work colleagues, other club members, friends or other fellow workers to compete for 2 kg bags of rice as prizes awarded to each member of teams achieving average daily step counts of at least 8,000.
Introduction of "smart meals"	We introduced "smart meals" at our Head Office canteen to provide more nutritionally well-balanced menu choices for employees interested in adjusting daily dietary habits to their physical condition.
Aging care education events	An event organized with the Functional Food Division entitled, "Creating a Younger Body Using Anti-Glycation Products" included the chance to test blood sugar levels and receive related advice from a health professional.
"Jar of Health"	Twice-monthly column dedicated to improving employees' health literacy.
Seminar on women's health	An in-house seminar focused on the importance of gynecological diagnostic screening for female employees, drawing on lessons from related experiences of the effects on patients and their families of breast cancer and other potentially serious diseases affecting working women. The event discussed women's related concerns.
2 Support for quitting smoking	
Quit smoking support measures	One of our workplace health management goals is to help all employees quit smoking by the end of September 2022. From October 2020, smoking on Nippon Shinyaku premises is completely banned. This has also been reflected in flextime systems. "Today's tabacolumnn" issued on the 2nd and 12th of each month / "Swan Day" initiatives on the 22nd of each month to support quitting ('swan' in Japanese is a homonym for 'non-smoking') Reimburse the full out-of-pocket expenses of outpatient smoking cessation programs for employees trying to quit Held a companywide non-smoking event called the Swan Cup in 2021



Occupational Health and Safety (OH&S)

To ensure workplaces are comfortable and provide conditions that safeguard employee health and safety, we have created systems to prevent workplace accidents and promote OH&S. We have set up OH&S committees throughout the company as part of ongoing efforts to maintain OH&S and to upgrade systems. While the activity mix differs by site, besides basic OH&S programs, every part of Nippon Shinyaku promotes workplace OH&S from a health and productivity management point of view. This means ensuring the physical and mental health and safety of all employees, while also trying to create a rewarding work environment that supports well-being.

Occupational Health and Safety (OH&S) Structure





Initiatives for Society

Achieving a work-life balance and allowing every employee to grow and thrive

Medium-term Management Plan Policy

Amid concerns in Japan of the low birth rate and continued aging causing a decline in the working age population, sustainable growth of enterprises relies on the ability to develop and retain human resources who can play an active role, irrespective of gender, nationality or age. To achieve this goal, companies need to develop systems and cultivate conditions that meet the expectations of employees from various backgrounds. Based on the concept that "unique products come from unique human resources," in accordance with the 6th Five-Year Medium-term Management Plan, Nippon Shinyaku is working to create an organizational climate where every employee can flourish by maintaining respect for diversity and by providing opportunities for individuals to take on challenges and grow.

Measures to support work-life balance

In fiscal 2019, we reformed our long-term care leave system. Whereas we previously allowed carers to take up to a total of 93 days of leave for a single family-care situation, we now have set an upper limit of one year off for caring. We also removed restrictions on the number of times care leave could be taken within that total, to create a system that responds flexibly to individuals' care circumstances.

In fiscal 2020 we adopted the corporate-led babysitter user support scheme instigated by the Cabinet Office. Under this scheme, which is designed to facilitate a balance between work and child-rearing, Japanese workers of all descriptions can use discount coupons issued by the Cabinet Office to lessen their out-of-pocket expenses when making use of babysitter dispatch services. While we already had included financial support for babysitting services in our employee welfare system, by further enhancing support for child-rearing generations we seek to mitigate the mental and physical stress that child-rearing exerts on employees.

In addition, the Nippon Shinyaku Group Mutual Aid Association regularly holds seminars regarding work-life balance support. Large numbers of employees attend these sessions, which include seminars for those balancing work and care, and others for mothers and fathers balancing work with child-rearing. Not only do these seminars provide employees with useful information on work-life balance and on eligibility for company-specific systems, they also provide a forum for employees to share information among themselves.

In this manner we are expanding work-life balance support initiatives with a view to enhancing both the quality of work and QOL and striving for a corporate culture in which every employee is able to achieve an appropriate balance between the two.

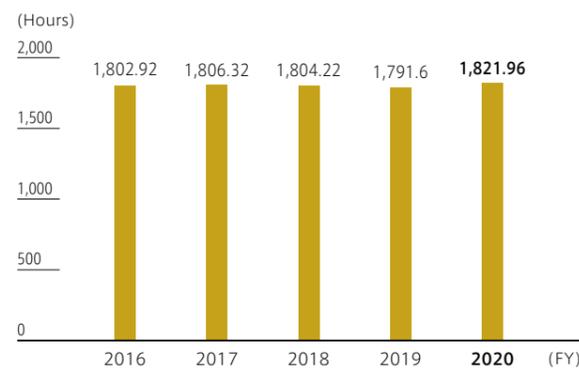
Prevention of long working hours

In January 2018, Nippon Shinyaku became one of the first in the industry to introduce a flexible working hours system for MRs. This system has reduced working hours for MRs by creating a flexible working style. From the outset, no core time was set under this system, allowing individual MRs to adapt break times as well as starting and

ending times to their planned activities. From October 2019, this flextime was expanded across the entire company, except for some divisions including production, and in April 2020 we completely abandoned the concept of core time (a period of the day during which employees are required to be at work).

As a further countermeasure against long working hours, we use e-learning to educate all employees about the Labor Standards Act. Also, when employees are planning daily activities, we have them submit advance applications and follow-up reports for both overtime and telework.

Total annual working hours



Promotion of human resource development efforts to foster an organizational culture in which everyone can play an active role

• **Career Support System, CASA (CAreer Support Academy)**
At Nippon Shinyaku, we think that if every employee thinks and acts for themselves and operates proactively, they will not only grow as a person but also contribute to the company's growth. To foster this approach, we have established a CAreer Support Academy (CASA) comprising three levels of training: "Basic," "Skill Up," and "Challenge." Rather than having every employee participate in the same program, we encourage employees to reflect upon their own strengths and weaknesses, and select their own subjects accordingly from within a broad curriculum.

• Training the Next Generation of Leaders

With a view to nurturing the next generation of leaders, in fiscal 2007 we launched the Next-Generation Leader Development Program, targeted at manager-level employees around 40 years of age. In fiscal 2012 we went on to launch our Next-Generation Leader Challenge Program, geared toward employees around 30 years of age. These programs are respectively held every other year.

In fiscal 2020, we held the 6th Next-Generation Leader Challenge Program. We sought nominations from within the company and selected 13 participants from several departments. Between September 2020 and February 2021 these employees undertook group training as well as attending external education programs. This initiative actively supports the growth of young employees aspiring to be independent leaders capable of spearheading the organization, by providing original ways to learn and gain management experience outside daily work.

• Developing global human resources

To further Nippon Shinyaku's global development, we offer support and training designed to nurture global human resources. To help employees hone their skills in foreign languages, we offer Foreign Language Learning Support courses to all who apply. The program involves online English conversation lessons with a native speaker, and applicants can participate for a period of between 3 and 12 months as they like. In fiscal 2020, we also held an online Business English Practical

Training Program targeted at employees displaying a certain level of language proficiency. Designed to take participants from "learning English" to "using English," this program offers employees opportunities to enhance their skills via practical training in the use of English in meetings, discussions, and so forth.



Business English Practical Training Program, held online

• Support for Overseas Study

We provide support for employees to study at overseas universities and research institutions. This system not only helps employees acquire knowledge and build networks in specialized fields, but also helps them to experience life in other countries and cultures as part of the development of a globally capable workforce equipped to meet modern business challenges. To date, three employees have used this system to study at overseas research institutions of their choice. In fiscal 2019, we widened the scheme to enable employees to apply to study at company-selected research institutions. Each participant is responsible for organizing their own overseas study schedules and related visa requirements. In this way, the program helps to build global skills and personal initiative.

TOPICS

Nippon Shinyaku New Work Style Basic Policy

In July 2020, we devised a New Work Style Basic Policy. As part of this new work style, we adopted initiatives to enable employees to continue working remotely. In fact, we recommended that telework continue even after the COVID-19 pandemic is contained.

Over the past year we have taken steps to build an environment conducive to telework, including installation of digital and communications equipment and security upgrades. To heighten understanding of the telework system and ensure its practical and appropriate use, we offer training to employees via e-learning.

When working remotely, it is difficult to communicate in the same manner as when face to face. We recommend that employees remain conscious of the need for communication, and to that end we have introduced communication tools available companywide as a measure to ensure employees' psychological wellness. Nippon Shinyaku intends to continue promoting a new work style with a view to further enhancing employees' sense of well-being.





Initiatives for Society

Promoting Diversity and Inclusion

Basic Idea

Nippon Shinyaku is striving to build a diverse workforce by hiring a variety of people regardless of gender, age, nationality, and individual traits. We also pursue various initiatives to ensure that every employee can thrive, as alluded to both in our Management Policy (under the heading, "Employees: Develop Each Employee") and the 6th Five-year Medium-term Management Plan (in the goal of cultivating an organizational culture that enables individual employees to fully develop their potential). We are also working to create conditions that foster a workplace climate where every single employee—each with diverse values—can flourish and be independent, enabling the company to generate innovation and realize sustainable growth.

Improving Workplace Climate to Improve Retention

Nippon Shinyaku seeks to offer employees a positively challenging environment that simultaneously supports diverse work styles and is conducive to personal growth. To that end, we have been overhauling our personnel systems and their management.

We have taken a variety of steps to improve employees' working conditions, including expansion of our paid leave system and replacement of unpaid leave with partial paid leave. Other measures to aid in child-rearing have included shorter working hours, staggered commuting, a flextime system, and a telework system.

In July 2020, we launched a New Work Style Basic Policy, with an eye to adapting flexibly to societal change in the manner that we believe is expected of Nippon Shinyaku. We continue to abide by this policy and remain committed to creating an environment enabling each individual to re-imagine their work-life balance and thrive both in and out of the workplace.

More Active Roles by Women

Nippon Shinyaku has long since defined encouraging women to take up more active roles as one of the company's important missions, implementing various initiatives to this end. To give the necessary nudge to women who might be hesitating for various reasons to take their career to the next level, the company has been improving the corporate environment, offering female employees with opportunities for further personal growth.

Nippon Shinyaku aims to help female employees grow by providing opportunities to improve their motivation and skill sets and form external networks. To that end, in fiscal 2020 we sought applicants from throughout the company for a training program held by an external organization supporting women who aspire to management roles. There were many applicants, which is testament to the large number of career-minded female employees. As participants have reported learning a good deal and feeling highly stimulated, we regard this program as an effective means of further boosting female employee's motivation and fulfillment.

Promoting Women to Directorial and Managerial Roles

In fiscal 2019 we devised a General Employer Action Plan based on the Act on Promotion of Women's Participation and Advancement in the Workplace, setting the goal of having 15% or more of female employees in management positions. That goal was met in fiscal 2020, when 15.1% of female employees held management positions. The number of women in management/executive positions is increasing every year, and we seek to further elevate women to managerial, executive, and eventually directorial positions by actively recruiting career-minded women who are not satisfied with their current lot.

"#Here We Go 203030" Initiative

Nippon Shinyaku supports the "#Here We Go 203030" initiative announced by the Japan Business Federation (Keidanren), which has set the aspirational target of increasing the proportion of female directors in Japan to more than 30% by 2030. Keidanren came up with the "#Here We Go 203030" initiative to create a movement to achieve this target, and provide a driving force for accelerating promotion of "active participation in the workforce by diverse people" as a means of achieving inclusion and co-creation of diverse value.



Mid-career Recruitment

Corporate competition is intensifying due to ongoing globalization and other factors. For companies' lasting growth, responsiveness to change, speedy execution, fresh viewpoints, and new ways of thinking are becoming ever more important. To obtain such qualities together with high levels of expertise, leadership skills, broad perspectives, and a breath of fresh air, Nippon Shinyaku actively turns to mid-career hires in the hope that they will lead to organizational cultural reform and corporate value enhancement. The company's number of mid-career hires has been increasing year after year, with positive results in all job types and fields.

Supporting Senior Employees Remaining Active

Nippon Shinyaku has adopted a continued employment (rehiring) system that in principle enables employees who wish to work past the legally prescribed retirement age of 60 to do so up to the age of 65, in a position organized by the company in the community where they plan to live once retired.

Under this system, treatment for the following year and a second, point-based severance payment is determined via fair appraisal of the achievement of personal goals set by rehired senior employees, affording them greater motivation to continue working.

Nippon Shinyaku will continue to support workforce participation by senior employees by devising new work styles that further heighten rehired employees' appetite for work and productivity.

Employees with Disabilities

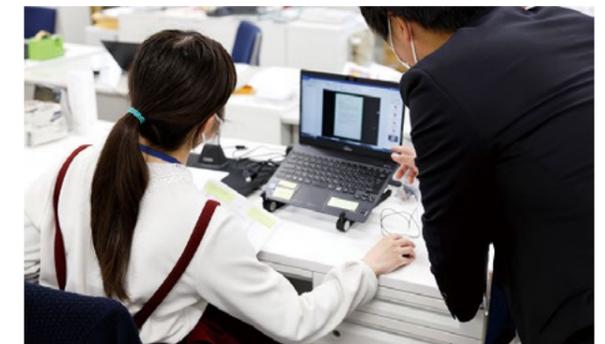
Based on the principle of inclusion, Nippon Shinyaku is working toward expanding employment and creating new job opportunities for persons with disabilities.

To expand employment, we have been collaborating with a special-needs support school since fiscal 2007, offering a dual system of learning while working*. In terms of creating new job opportunities, we have made efforts to simplify and standardize various routine tasks, with a view to shifting employees with disabilities into roles that they can undertake and enabling work-sharing. Furthermore, several consultants are stationed in the workplace to promote an environment where those with disabilities can work productively side by side with others. This is one example of how we are working to create comfortable work environments.

In addition to the above, we have taken steps to eliminate obstacles to persons with disabilities in the workplace, in line with provisions in the Act on the Elimination of Discrimination against Persons with Disabilities and Revised Act on Employment Promotion, etc., of Persons with Disabilities (both enacted in April 2016), that explicitly require businesses to provide reasonable accommodation to employees with disabilities.

When employing such persons, we conduct short-term practical training to ascertain each individual's daily rhythm and the nature of their disability, before progressively moving on to long-term practical training aimed at familiarizing employees with specific tasks. In this manner, we seek to provide disabled persons with greater motivation to work, and to identify or create suitable positions.

* A training system that combines education at a special-needs support school and vocational training within a company



A disabled employee at work

TOPICS

Human Rights Policy

The Nippon Shinyaku Group has established its Human Rights Policy to fulfill its corporate responsibility of respecting human rights. The Human Rights Policy complements the Nippon Shinyaku Group Charter of Business Conduct, which has been established as operational standards of action that all Nippon Shinyaku Group directors and employees must adopt in their corporate activities to meet society's expectations and win society's trust.

Basic idea	The Nippon Shinyaku Group advocates the Ten Principles of the United Nations Global Compact in four areas (one of which is human rights) as its signatory company, respects internationally recognized human rights norms, such as the Universal Declaration of Human Rights and the UN Guiding Principles on Business and Human Rights, and adheres to the World Medical Association's Declaration of Helsinki with regard to pharmaceutical research. We respect the human rights and dignity of all individuals, strive to prevent harassment and treasure diversity, and act with high ethical values to form relationships of trust with society while naturally maintaining a safe and secure workplace environment.
Policy applicability	The Human Rights Policy is applicable to all Nippon Shinyaku Group directors and employees (including fixed-term contractual, re-hired, temporary, and part-time employees), personnel dispatched by temporary staff agencies, personnel on loan from other organizations, employees of subcontractors and service providers, and all persons engaged in the Nippon Shinyaku Group's operations.
Due diligence	In conformity with the United Nations Guiding Principles on Business and Human Rights, the Nippon Shinyaku Group strives to act with due diligence to prevent and mitigate possible negative impacts resulting from the Group's business activities. We fulfill our corporate responsibility of respecting human rights by observing the laws and regulations of the countries and regions in which we operate, avoiding infringement of human rights, and not letting others infringe on human rights.
Relief	In the event that the Nippon Shinyaku Group's business activities are found to have compromised or caused any negative impacts on human rights, the Group will take relief measures or act otherwise for the relief of the victims in collaboration with other parties concerned and undergo appropriate procedures to prevent recurrence.



Initiatives for Society

Community Life

Basic Concepts

Besides its core mission of supplying the world with high-quality medicines as a manufacturer of pharmaceuticals, Nippon Shinyaku is committed to fulfilling its role as a corporate citizen to help local and regional communities. Activities to enrich community life include providing educational support for the children who will lead the next generation, and opening our botanical research institute and other company facilities to the public. We also hold public lectures nationwide with the aim of disseminating the latest information and promoting correct understanding of diseases. In addition, we fund public research grants in a bid to foster scientific developments in the fields of medicine and pharmacology.

Contributing to Communities and Culture

Nippon Shinyaku Children's Literary Awards

Designed to commemorate our 90th anniversary, the Nippon Shinyaku Children's Literary Awards were established in 2009 with the support of the Japan Juvenile Writers Association and the City of Kyoto as a way of inspiring the dreams and nurturing the spirits of children through picture books. Awards are made in the two categories of stories and artwork, and the two first-prize winners collaborate to produce a picture book with a print run of 20,000 copies. The books are distributed to children nationwide through medical institutions and via public facilities such as libraries.

The 12th Nippon Shinyaku Children's Literary Awards ceremony was held online, in view of rising COVID-19 cases. "Nezuo Mouse," the main character in this year's picture book, "A Zodiac Animal's Job is Never Done," made an impression at the awards by leaping out of the book and playing host. The ceremony included a book-reading and guest singing performances, all streamed live on YouTube. While it was very different from previous occasions, the ceremony had features that could only be provided online.

Visitors to our newly updated (Japanese-only) special website (<http://kodomo-bungaku.jp/>) are able

to see electronic versions of past and present books and hear them read aloud as they browse the pages.

Nippon Shinyaku Sparkling Future Mobile Library

We began the Nippon Shinyaku Sparkling Future Mobile Library in 2019 as part of our centenary celebrations to bring exciting library experiences to children. The library van carries around 1,000 picture books, including the Nippon Shinyaku Children's Literary Award-winning titles, a range of universal design titles (such as Braille and audio books), and digital books. Staff take the mobile library to visit local kindergartens.

Going forward, we hope to contribute to both the physical and mental health of children by giving them various opportunities to be touched by the wonder of books.



Nippon Shinyaku Sparkling Future Mobile Library



Group photograph from 12th Nippon Shinyaku Children's Literary Awards online ceremony

Nippon Shinyaku & Seitaro Kuroda Smiles Art Project

In 2013 we launched the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project, a nationwide campaign spearheaded by illustrator Seitaro Kuroda that visits communities around Japan and encourages locals to band together and create art on the walls of hospitals and nursing facilities.

In March 2021, we held the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project online, by organizing a link between Mr. Kuroda's studio, the Kyoto Municipal Narutaki Comprehensive Support School, and children receiving care at Utano Hospital. We managed to host a new style of event dubbed Smiles Collabo Art, combining pictures already colored in by the children with a live painting session by Mr. Kuroda.

Through this project, we hope to continue strengthening bonds and generating smiles by visiting local hospitals and drawing pictures together with people from all walks of life, including physicians, patients, senior citizens, children, and students.



Live painting session during Smiles Collabo Art event

Public Research Grant Scheme

As part of our centenary celebrations, Nippon Shinyaku initiated a "Public Research Grant Scheme" to contribute to the advancement of science in medical and pharmacological fields in which the company is active. Under the scheme, we aim to support young researchers by offering grants to successful applicants. With the third round of grants, offered in fiscal 2021, we sought applicants to perform fundamental research in two fields: hematopoietic tumors and hereditary muscular disorders such as muscular dystrophy. After rigorous examination by an external review committee, we awarded grants to six projects in the field of hematopoietic tumors and four in the field of muscular dystrophy and other hereditary muscular disorders.



Contributing to the Culture of Kyoto

As a company headquartered in Kyoto, Nippon Shinyaku engages in activities to preserve and maintain the culture of Kyoto. For more than half a century, each year Nippon Shinyaku has produced calendars that feature pictures of Kyoto's seasonal scenery, customs, and historical events, and are made using traditional stencil-dyeing and wax-dyeing techniques. In November 2020, we relaunched our Kyo Gallery website (<https://www.nippon-shinyaku.co.jp/english/kyo-gallery/>), displaying more than 300 works included over the years in the calendars.



We also publish a quarterly PR magazine entitled "Kyo" to showcase the huge appeal of Kyoto—from the city's many shrines, temples and other cultural assets to its cuisine and local produce.

Educational Support and Community Interaction through Sports

Working with governments at the municipal and local level and baseball associations, the Nippon Shinyaku amateur baseball team offers baseball clinics for elementary, junior and senior high school students in places including Kyoto (head office), Odawara (factory) and Kushimoto, Wakayama Prefecture (training facility). These events improve the baseball skills and strength of children while fostering interaction with local communities. Representing the City of Kyoto at the Intercity Baseball Tournament, in 2020 the Nippon Shinyaku Baseball Club brought smiles to the faces of local citizens, achieving the wonderful result of third place and winning the Kyoto City Sports Honor Award.

Due to the COVID-19 pandemic, the Intercity Baseball Tournament was not held in fiscal 2020. Instead, the Nippon Shinyaku Baseball Club engaged in cleanup activity including litter collection in the area around the company, also participating in the Citrus Ribbon Project with the slogan "Citrus Ribbon Project x Nippon Shinyaku = Supplement for the Mind," with a view to awareness-raising and elimination of bias against medical workers and people infected with COVID-19.



"Supplement for the Mind" activity



Initiatives for Society

Responsible Procurement

Basic Rationale

Recently it has been widely recognized that companies have much greater responsibilities than simply providing products to consumers. Corporate social responsibility requires that a company protect human rights, comply fully with laws and regulations, and protect the environment throughout the supply chain.

Maintaining public trust is a major tenet of Nippon Shinyaku's management policies. We have formulated the Responsible Procurement Guidelines to promote this, based on the five areas of legal compliance, confidentiality, equitable business practices, rational selection of suppliers, and environmental consideration. Based on this thinking, we are dedicated to implementing responsible procurement policies across all these areas in partnership with our suppliers to ensure that we maintain public trust.

Responsible Procurement Guidelines

Stringent legal compliance	Nippon Shinyaku complies with all relevant legislation (Antimonopoly Act, Subcontract Act, Unfair Competition Prevention Act, etc.) and industry and internal rules, also refraining from making unreasonable demands or taking unfair advantage.
Confidentiality	We take thoroughgoing measures to prevent leaks of confidential information concerning business partners, also eschewing fraudulent transactions.
Equitable business practices	In our dealings with all business partners, Nippon Shinyaku offers transparent, fair, and equitable transactions based on free competition principles.
Rational selection of suppliers	Nippon Shinyaku chooses its suppliers by taking comprehensive account of factors including management stability, the quality and prices that they offer, their development prowess, their social credibility, and their concern for the environment.
Consideration for the environment	We comply with laws and regulations pertaining to the environment and undertake environmentally friendly procurement in adherence to our Basic Environmental Policy.

Main Activities

As part of our responsible procurement program, Nippon Shinyaku conducts a Responsible Procurement Survey of major domestic and overseas suppliers on a biannual basis.

Besides compliance status and consideration for the environment, the survey covers procurement reliability issues such as supply continuity preparedness, adherence to product quality and delivery standards, production capacity, and mechanisms in place to prevent forced labor, child labor, and discrimination.

The survey response rate is consistently over 90%, and the survey is used to confirm that suppliers are implementing a range of responsible procurement initiatives, including measures to safeguard continuity of supply.

We will continue to conduct regular surveys and reinforce efforts to undertake follow-up initiatives as required to ensure that we and our suppliers fulfill our corporate social responsibilities.



GOVERNANCE

Corporate Governance

Related SDGs



Basic Concepts

At Nippon Shinyaku, we recognize that one of management's most important tasks is to fulfill accountability to all stakeholders by ensuring management transparency, in order to raise our corporate value through social contributions. To that end, it is essential that our corporate governance functions effectively, and, in line with four clearly defined basic concepts that are posted on our website, we are working tirelessly to enhance corporate governance as a means of driving sustainable growth and increasing the value of our public presence, as well as bolstering our corporate value over the medium and long term.

The Corporate Governance Basic Policy was instituted on December 15, 2015, and sets forth our basic concepts of corporate governance. The Policy was revised on June 29, 2021.



The following items are posted on our website.

https://www.nippon-shinyaku.co.jp/english/ir/esg_management/governance.php

- Corporate Governance Report
- Corporate Governance Basic Policy

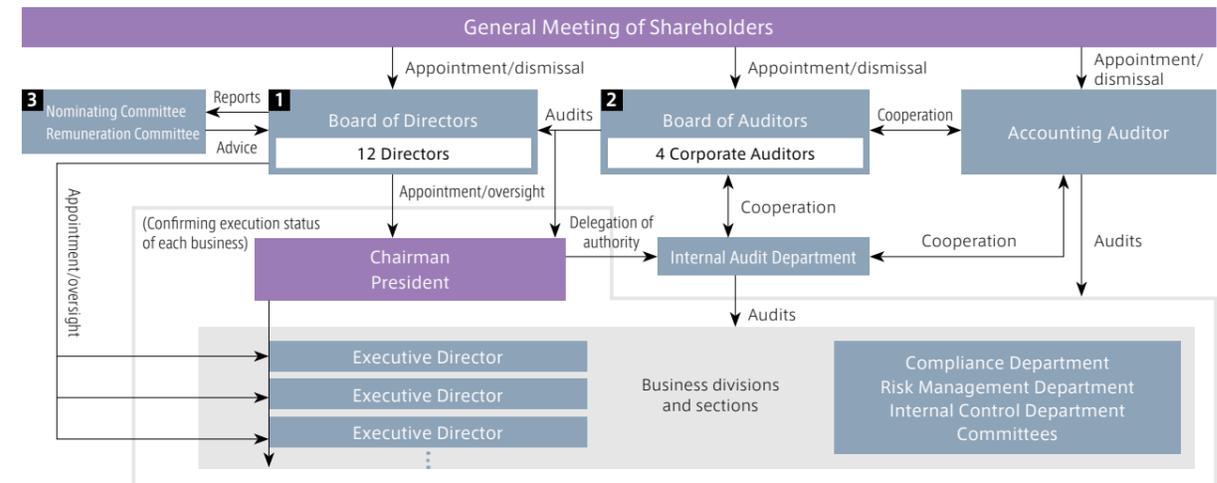


Steps taken to strengthen corporate governance (number of directors is as of conclusion of each year's Annual General Meeting of Shareholders)

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Number of directors	7	9	9	9	9	10	10	10	12	12
(of whom, inside)	7	7	7	7	7	7	7	7	8	8
(of whom, external)			2	2	2	3	3	3	4	4
(of whom, female)							1	1	1	3
Number of auditors					4	4	4	4	4	4
(of whom, standing)					2	2	2	2	2	2
(of whom, external)					2	2	2	2	2	2
Committees						Existence of Nominating Committee			Existence of Remuneration Committee	

Organization for Corporate Governance

Headed by the company chairman and consisting of 12 members including four external directors, the Board of Directors holds a meeting once a month in principle and resolves and reports on material business matters.

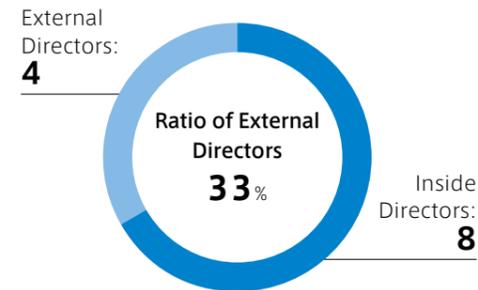




GOVERNANCE

1 Board of Directors

Role	<ul style="list-style-type: none"> Ensures business fairness and transparency through general management oversight. Makes decisions in the best interests of the Company by (1) setting policies governing the appointment/dismissal of directors and auditors using procedures that are objective, timely and transparent, based on findings of the Nominating Committee; (2) evaluating the serious risks facing the Company and formulating related countermeasures; and (3) making important business decisions.
Meeting frequency	Monthly; extraordinary sessions if required 14 meetings held in fiscal 2020
Attendees	All directors and auditors



External Directors: Appointment Rationale and Main Activities

Name	Reasons for Appointment	Attendance at Board of Directors meetings (Fiscal 2020: meetings attended / meetings held)
Yukio Sugiura	Appointed because he offers advice to management from a practical perspective, based on his expertise and insight from an independent standpoint as a pharmacologist.	(14/14)
Miyuki Sakurai	Appointed because she offers advice to management from a practical perspective, based on her expertise and insight from an independent standpoint as a lawyer.	(14/14)
Yoshinao Wada	Appointed because he offers advice to management from a practical perspective, based on his expertise and insight from an independent standpoint as a physician.	(14/14)
Yukari Kobayashi <small>Newly appointed</small>	Appointed on the premise that she can offer advice to management from a practical perspective and from an independent standpoint, based on her wealth of experience and broad insight gained from engagement in various businesses and corporate management for many years, mainly at foreign IT companies.	—

Analysis/evaluation of effectiveness of the Board of Directors

Frequency	Annual
Methodology	Self-evaluation survey completed by all directors
Content	The Board's effectiveness in discussing and deciding issues was determined by asking each director if they actively voice their opinion; if discussions are conducted based on multi-faceted, wide-ranging perspectives; if debate is free and constructive; and if the discussions support appropriate decisions by management.
Results of fiscal 2020 evaluation	As previously, the survey confirmed that all Board members believe that meetings provide the opportunity to actively voice opinions; to engage in free, constructive debate based on multi-faceted, wide-ranging perspectives; and that the discussions support appropriate management decisions. This result indicates the Board of Directors is broadly effective.

2 Board of Auditors

Role	<ul style="list-style-type: none"> Provides corporate oversight in coordination with the Board of Directors, supporting the corporate governance system by supervising the actions of the Board as an independent entity accountable to shareholders. Based on its specialized knowledge and vast experience, the Board of Auditors actively expresses opinions to the Board of Directors and management.
Meeting frequency	Monthly; extraordinary sessions if required 16 meetings held in fiscal 2020
Attendees	All auditors

Cooperation with Accounting Auditor

- The accounting auditor provides reports on outline audit plans and the implementation status of interim audits at regular meetings with the Board of Auditors.
- Mutual efforts are made to improve audit effectiveness and efficiency based on close cooperation, including witnessing of audits.

Cooperation with Internal Audit Department

- The close cooperation between the Board of Auditors and the Internal Audit Department based on regular meetings and other means as required involves two-way reporting on audit plans and findings, as well as related discussions and exchanges of opinions.
- After submitting internal audit reports to the President, the department sends reports to the Board of Auditors and provides auditors with related oral presentations.

External Auditors: Appointment Rationale and Main Activities

Name	Reasons for Appointment	Attendance at Board of Directors meetings (Fiscal 2020: meetings attended / meetings held)
Tsuyoshi Kondo	Appointed because he offers advice that will enhance management soundness and transparency while also improving compliance, based on his expertise and insight from an independent standpoint as a lawyer.	(14/14)
Sumitaka Maruyama	Appointed because he offers advice that will enhance management soundness and transparency while also improving compliance, based on his expertise and insight from an independent standpoint as a licensed tax accountant.	(14/14)

3 Nominating Committee and Remuneration Committee

Composition	Committees are composed of at least three members, including at least two independent external directors, one of whom acts as chair.
Role	Members report to the Board of Directors about deliberations of important matters relating to the appointment and dismissal of directors and auditors (Nominating Committee) and related remuneration issues (Remuneration Committee).

Committee Composition

	Committee Name	All Committee Members	Full-time Members	Inside Directors	External Directors	Outside Experts	Other	Chairperson
Committee Corresponding to Nomination Committee	Nominating Committee	3	0	1	2	0	0	External Director
Committee Corresponding to Remuneration Committee	Remuneration Committee	3	0	1	2	0	0	External Director

Training for Directors and Auditors

Nippon Shinyaku holds training and debriefing sessions attended by all directors (including candidates), in order to convey information that is essential for directors on legal responsibilities, corporate governance, etc., and to share information on the important operations performed by each division. Auditors also are able to attend these sessions. New directors and new corporate auditors receive new officer training offered internally upon their assumption of office. In this manner, Nippon Shinyaku provides the necessary training opportunities for directors and corporate auditors, covering any expenses incurred.

Officers' Remuneration

Policy on Determining Remuneration Amounts and Calculation Methods

At Nippon Shinyaku, policy on officers' remuneration amount and calculation method is decided by the Board of Directors, and the amount is set within the limits decided by resolution of the General Meeting of Shareholders. The Board of Directors bases this policy on recommendations by the Remuneration Committee, over half of whose members are external directors, with an external director acting as chairperson, and also references survey data from specialized external institutions as an objective benchmark.

GOVERNANCE

Remuneration of (non-external) directors	<ul style="list-style-type: none"> Comprises monthly salary and bonuses. Monthly salary is set according to directorial role (excluding external directors) as well as performance appraisal. Performance-linked bonuses for (non-external) directors are also set by multiplying annual operating income by a fixed percentage based on directorial role. Individual remuneration amounts including salary and bonuses are set after consultation with the Remuneration Committee. If the Board of Directors delegates authority to the President, the latter can determine individual remuneration for (non-external) directors using Board-approved methods and director performance appraisals, in line with the findings of the Remuneration Committee.
Remuneration of external directors	<ul style="list-style-type: none"> Remuneration only has a fixed component to ensure proper management oversight. Individual remuneration amounts are set after consultation with the Remuneration Committee. If the Board of Directors delegates authority to the President, the latter can determine individual remuneration amounts in line with the findings of the Remuneration Committee.
Remuneration of auditors	<ul style="list-style-type: none"> Remuneration only has a fixed component to ensure proper management oversight and auditing functions. Individual remuneration amounts are based on discussions with auditors.

Total remuneration for each officer category with subtotals for each type of remuneration and numbers of recipients

As of March 31, 2021

Officer category	Total remuneration (millions of yen)	Subtotals for each type of remuneration (millions of yen)		Number of recipients
		Fixed basic remuneration	Performance-linked remuneration	
Directors (excl. External Directors)	398	201	196	8
Auditors (excl. External Auditors)	34	34	—	3
External Directors/Auditors	60	60	—	6

* Includes directors who were in office between July 2019 and June 2020

Internal Control System

Pursuant to the Japanese Companies Act, we have resolved a basic policy on the establishment of an internal control system through our Board of Directors, establishing a framework to ensure the proper execution of business by ensuring regulatory compliance and raising business effectiveness and efficiency. Moreover, we comply with the internal control reporting requirements

applied from fiscal 2008 under the Financial Instruments and Exchange Act, operate under a framework we have developed for ensuring proper financial reporting, and, through the Internal Audit Department positioned directly under the President, evaluate the state of internal controls for financial reporting.

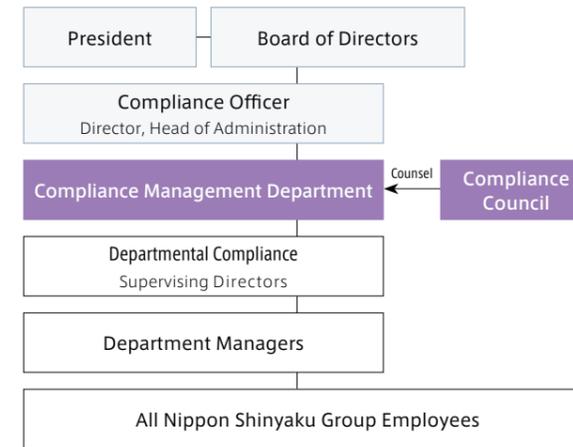
Accounting auditor	<ul style="list-style-type: none"> Deloitte Touche Tohmatsu LLC is contracted to audit financial reporting and internal controls to ensure proper accounting procedures and management transparency.
Internal Audit Department	<ul style="list-style-type: none"> Department has 9-person team and reports directly to President. Department conducts internal audits of all processes supporting risk management, control and governance of Nippon Shinyaku Group; results are reported to the President and shared with the Board of Directors.

Compliance

Framework for Compliance

The Nippon Shinyaku Group has in place Compliance Operating Rules, with the Director, Head of Administration acting as a compliance officer and a dedicated department to oversee compliance initiatives. The supervising director for each department is responsible for departmental compliance initiatives, which are carried out by the managers in each department.

Compliance Framework Chart



Compliance Initiatives

The Compliance Management Department plans and formulates group-wide compliance initiatives based on advice from the Compliance Council.

Compliance Training in Fiscal 2020

Type of Training	Description
Departmental compliance training (monthly)	Departmental training incorporating company-wide content and department-specific content, for all group employees
Training for new employees (April)	Training that focuses on teaching regular new employees about compliance concepts and approaches, and stressing the importance of compliance.
Training for midcareer recruits (as and when required)	Training covers compliance concepts and approaches for mid-career recruits.
Training for newly promoted managers (March, October)	Training that focuses on teaching compliance to newly promoted managers.
Training for employees in their second year at the company (June -October)	Conducted monthly e-learning concerning compliance for employees in their second year at the company.
Training on the Charter of Business Conduct for new employees (as and when required)	Enhancing understanding of and compliance with the Charter of Business Conduct.

Messages from the President in April 2020 and October 2020 stressed the importance of raising compliance standards even higher.

We revised the key points of our Charter of Business Conduct to reflect changes in the environment surrounding the Nippon Shinyaku Group. In view also of altered working conditions due to the increase in telework, we digitized our Charter of Business Conduct booklet to make it accessible at any time on notebook computers and smartphones loaned to all employees.

Internal Compliance Reporting (Whistleblowing Hotline)

Nippon Shinyaku maintains an internal compliance reporting system based on a set of regulations as a self-policing means to handle legal or regulatory violations. All Nippon Shinyaku Group company employees can report violations, perceived or real, and seek advice with regard to compliance issues via whistleblowing hotlines set up both within and outside the Group companies that can be reached through a dedicated phone number or e-mail address.

The regulations on internal compliance reporting stipulate necessary measures to be taken for the protection of whistleblowers' privacy and the duty of confidentiality, and they guarantee that whistleblowers will not be subjected to unfair treatment as a result of their reporting.

Information on the internal compliance reporting system is provided to all Group employees from time to time to make it known throughout the Nippon Shinyaku Group.

Education Initiatives

- A competition to create compliance slogans was held and the best entries were chosen via an internal review and vote by all Group employees. Compliance education posters based on the winning slogans were then made for display across all departments.
- Created compliance cards outlining business philosophy and management policy, for all Group employees to keep on their person



Compliance cards

Compliance education posters

GOVERNANCE

Risk Management

Risk Management Framework

The Nippon Shinyaku Group has in place Basic Risk Management Rules for identifying underlying risks and aiding the departments responsible for each risk in formulating preventive policies as well as measures for responding when such situations arise.

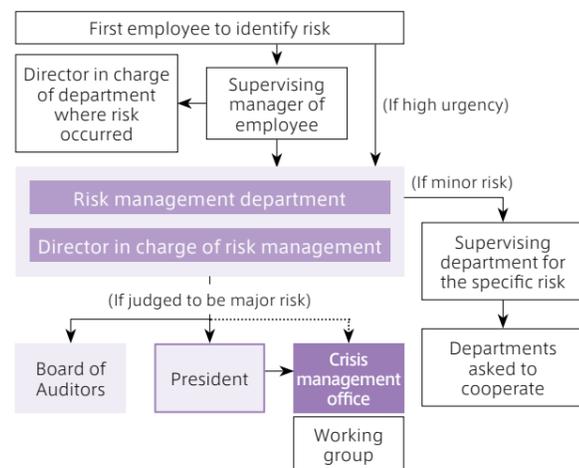
Additionally, each year we identify highly critical risks and set risk management goals and action plans for the year. In fiscal 2020, these included "cyberattacks," "information leakage," "disasters," "harassment," and "breaches of labor laws," which led us to strengthen controls and raise awareness.

Furthermore, every year we conduct a self-check survey of all group employees for the purpose of verifying each individual's risk awareness.

When an incident does occur, the director in charge of risk management receives a report from the risk management department, and then determines the effect the incident will exert on business operations.

If the effect is considered minor, the supervising department for the specific risk will be directed to respond. If, on the other hand, it is deemed that the incident will have a serious effect on business operations, the President will be immediately notified, while a temporary crisis management office will be established to respond to the incident in a timely manner. Once the incident is dealt with, measures are devised to prevent recurrence, and these are put in place by the relevant departments.

Path of Risk Notification



Initiatives to Prevent Workplace Harassment

At Nippon Shinyaku, we treat harassment as a serious issue that disrespects individuals and infringes upon their human rights. We have formulated the Group Harassment Prevention Rules to help prevent workplace harassment of any kind and maintain a good working environment. We have also set up a dedicated hotline to receive any harassment complaints, provide related advice, and

conduct internal fact-finding investigations. Other activities to prevent harassment and support compliance in this area include compliance and manager training programs and the distribution of anti-harassment policy pamphlets and portable awareness cards.

Protecting and Respecting Intellectual Property Rights

The Nippon Shinyaku Group recognizes the importance of the intellectual property (IP) created at all stages of a product's life from early research to post-launch marketing. Our Patent Strategy Committee formulates global IP strategy, examines IP-related issues, and oversees the Group's response to these issues. Patents, trademarks and other IP rights related to pharmaceuticals, functional foods and other products developed in-house are managed appropriately to support the maximum degree of commercial freedom in business activities.

Based on our fundamental IP stance that pays equal respect to third-party intellectual rights, we take a thorough approach to managing IP risks, including ownership investigations.

Supply Chain Risk Management

Upgraded systems to ensure supply reliability

In fiscal 2020, the impact of the COVID-19 pandemic on the pharmaceutical industry in Japan focused attention on weaknesses in the supply chains for drugs. At Nippon Shinyaku, we ensured a reliable supply of our products by taking steps to maintain drug inventories based on our Business Continuity Plan (BCP) and good communications with suppliers.

Upgrading our systems to ensure reliability of supply using a risk management approach is one of the goals of the current medium-term management plan. To accommodate greater supply chain diversity and evolving business conditions, we have been working to prevent supply interruptions by making supply chains more resilient. In fiscal 2020, we also created a new set-up to manage supply chain risks via a risk-based approach, based on assessing the underlying supply risks and related potential market and frontline medical impacts.

The underlying risks are assessed in relation to various frameworks. Quality assurance is the first and most critical factor in ensuring the efficacy and safety of pharmaceuticals. Next, we strictly monitor the production and quality management processes at our in-house manufacturing sites and those of affiliates to ensure full compliance with the relevant laws and regulations of Japan and other countries, as well as with Good Manufacturing Practice (GMP).

We have also formulated our own unique set of multifaceted criteria to enable the advanced assessment and management of supply chain risks that differ by product, based on other frameworks such as transportation

and logistics systems, maintenance of alternative supplier networks, and inherent difficulties in accurate demand forecasting.

By creating an integrated risk management system to formulate countermeasures based on established priorities and outcomes of risk assessments, we have made rapid and steady progress in developing a more resilient supply chain.

The BCP formulated for the Odawara Central Factory aims to maintain uninterrupted supply by preparing for major incidents such as an earthquake or flood. We are helping suppliers and external manufacturing sites to upgrade the status of their BCPs to a similar level.

Going forward, we will continue to promote these activities, keeping in mind that constant improvement is required due to the dynamic nature of risk.

Initiatives on Information Security

Nippon Shinyaku has instituted a policy and basic rules relating to information security. Based on this policy, the ISMS*1 Committee has been created to oversee the operation of the Group's information security management system and to promote related improvements.

Protecting the security of information assets is a top priority for us since our research attracts global attention. We also strive to keep our information security as advanced as possible because social conditions, business processes and information technology are changing on an almost daily basis.

In fiscal 2018, we created a dedicated internal set-up (NS-CSIRT*2) to respond quickly to any cyberattacks or other incidents that threaten the Group's information security. NS-CSIRT has since run regular cyberattack simulations and drills to test and modify each division's response procedures and to improve the way our

information security systems operate. We have introduced systems for restricting the memory of USB devices that can connect to office PCs as a way of preventing malware infections and data leaks. In fiscal 2019, we also established the SOC*3 to undertake 24/7 surveillance of the Group's networks and computer systems. Besides monitoring for any suspicious activity, the SOC can work with external information security experts to respond rapidly in the event of any serious information security breach, thus helping to minimize the related impact.

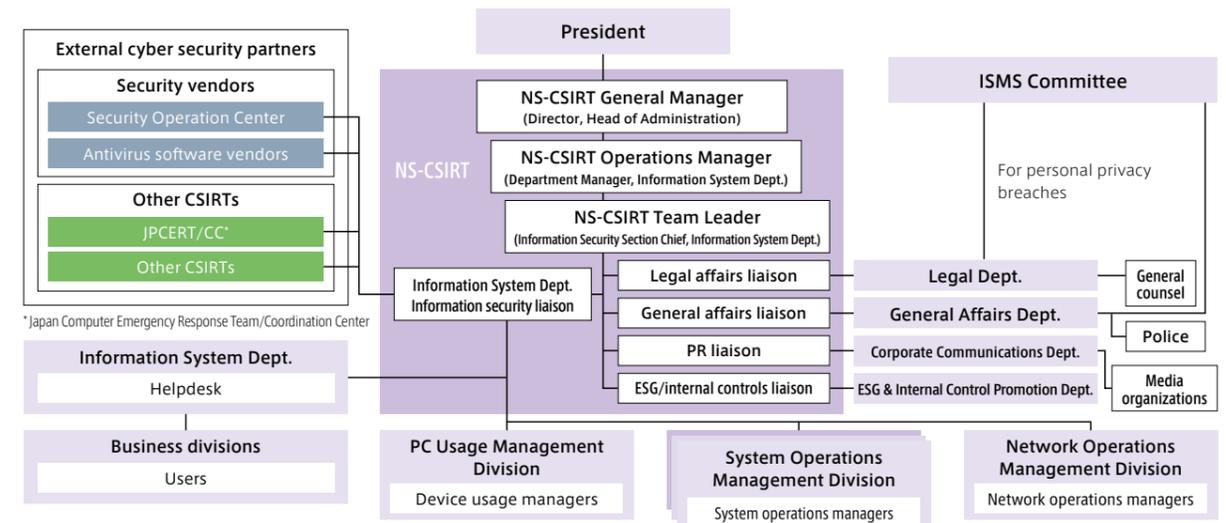
In fiscal 2020, we introduced cloud storage service to our internal network to help boost efficiency while significantly improving the ability to manage data and prevent any leaks.

While implementing these various measures, given that human error is the ultimate cause of most information security breaches, we are also taking steps to mitigate people-related information security risks. To ensure high levels of employee awareness about the need for strong information security, we provide training on information security to all new recruits (including graduates, mid-career hires and people seconded to the Group), as well as continuing online education courses to keep awareness levels high. Amid a growing threat from email phishing attacks in recent years, we conduct regular training sessions on how to deal with suspicious emails. The aim is not only to build awareness of the threat posed by such emails, but also to develop capabilities over time by building on previous training sessions as part of a PDCA cycle-approach to improving information security.

Going forward, we plan to further upgrade our information security risk countermeasures for protecting the Group's information assets in partnership with external organizations.

*1 ISMS: Information Security Management System
 *2 NS-CSIRT: NS-Computer Security Incident Response Team
 *3 SOC: Security Operation Center

NS-CSIRT framework



GOVERNANCE

Messages from External Directors



Yukio Sugiura
External Director

Continuous in-house development of innovative drugs to create a seamless, full pipeline of next-generation products

Recent years have been momentous for Nippon Shinyaku. Having celebrated its centennial in 2019, the company is now focused on the global development of Upravi and Viltepso. We have also had a leadership transition. The Nominating Committee debated the qualities that the incoming President would need, ranging from vision and leadership to the ability to respond to change and build diversity. We evaluated candidates and reported our findings to the Board, who made the final decision on who to appoint. The Japanese pharmaceuticals market shrank in 2020, creating harsh conditions for drug manufacturers. I will be looking to President Nakai to set out a long-term vision and new lifestyle-based business model as part of showing the necessary problem-solving and leadership qualities to help get us through these tough times.

I believe the path Nippon Shinyaku must take is continuous in-house development of innovative drugs to create a seamless, full pipeline of next-generation products. The essential factors will be the powerful motivation of our research teams, a forward-looking strategy, and a passion for improving the lives of patients. To this end, I want to see us invest further in our abilities to discover drugs and create highly innovative medicines based on our advanced clinical development expertise. As an external director, I will apply my specialist knowledge and experience with objectivity and independence, along with a commitment to diversity, to ensure we develop innovative medicines and build a stronger business.



Miyuki Sakurai
External Director

Formulating strategies and addressing vital issues in ways that lead to financial results and new innovations

President Nakai has been appointed to lead Nippon Shinyaku into this era of the so-called 'new normal,' responding to huge societal changes caused by digital transformation while further expanding the business. I believe he can display the strong leadership needed to secure future growth for Nippon Shinyaku and guide the company to a successful strategy in overseas markets, especially in Europe and Asia.

Nippon Shinyaku regards sustainability and diversity as critical issues in working to realize sustained growth and enhance the management platform, and we have prioritized related measures. To promote greater sustainability, we have created separate CSR working groups reporting to the Board to oversee the implementation of specific programs that address the three component elements of ESG. I also think it is excellent how we are trying to raise internal awareness of these efforts and to share related information. Amid increasingly long-term impacts due to the COVID-19 pandemic, our ability to revise the BCP from various angles while introducing reforms such as remote working support to allow more diverse work styles demonstrates our success in grasping these opportunities for positive change. As we move ahead step by step, I expect us to formulate strategies and to address vital issues in ways that lead to financial results and new innovations.



Yoshinao Wada
External Director

Building a position as a leading player in Japan and worldwide

Nippon Shinyaku has worked to enhance transparency and objectivity and promote debate by instituting the Nominating and Remuneration Committees, which are both chaired by an external director, and ensuring the four external directors have a strong voice on the Board of Directors. I think the level of governance at Nippon Shinyaku is broadly satisfactory. The recent moves to separate oversight and executive roles between the Chairman and the President, with the latter given the clear chief executive role, have also strengthened governance, in my opinion. However, external directors do not have access to sufficient information prior to items being placed on the Board meeting agenda to evaluate the full picture. A clearer and deeper analysis of items that should be debated by the Board could be facilitated through enhanced sharing of information. For example, prior to Board meetings, this could be achieved through advance briefings on the assessment of business risks or access to supplementary briefing materials.

Nippon Shinyaku is acknowledged widely as a "company with a meaningful existence in the healthcare field" because it has sought to build on its strengths in traditional domains to develop a presence in the challenging field of intractable and rare diseases. I would like to pay homage to the collective efforts of all employees, which have now translated into several years of sales and profits in this difficult field. By developing a strong pipeline and building a presence in rare diseases, I expect Nippon Shinyaku to be regarded as a leading player, not only in Japan but worldwide as well.



Yukari Kobayashi
External Director

The increasing importance of doing as much as possible to provide proper and accurate information about products

As a recently appointed external director of Nippon Shinyaku, I see it as my duty to utilize my experience of implementing reforms in a global enterprise, including internal reorganization programs, M&A, and business model transformation. I will be supporting efforts to gain rapid results from reform projects aimed at promoting global development. I also hope to give a different perspective to industry insiders when debating Nippon Shinyaku's role in helping more people lead healthier lives.

Today, the COVID-19 pandemic has led to heightened interest in healthcare and medicines. The problem is that many are confused about whether the information they receive from various media sources is accurate or is misinformation. In this situation, I think it is vital that Nippon Shinyaku does all it can to supply proper and accurate information about products so that users can feel confident they are making the best choice. In addition, from the perspective of providing preventive healthcare to help extend healthy life expectancy, by providing information correctly as a pharmaceutical maker, I hope Nippon Shinyaku can be of benefit to society by helping more people to manage their health based on the correct health-related knowledge.

GOVERNANCE

Board of Directors, Corporate Officers and Corporate Auditors



Shigenobu Maekawa
Chairman

1976 Joined the Company
1992 Transfer to Japan Federation of Employers' Associations
2002 Department Manager, Corporate Planning Department, Corporate Strategy Office
2004 Corporate Officer
2005 Director
2005 Corporate Planning, Finance & Accounting, and Information system, and Department Manager, Corporate Planning Department
2006 Managing Director
2007 General Manager, Corporate Planning, Finance & Accounting, and Information system
2007 President
2021 Chairman (current position)

Attendance at board meetings (FY2020): 14/14



Toru Nakai
President

1995 Joined the Company
2016 Department Manager, Business Planning Department
2018 Acting General Manager, Corporate Planning (NS Pharma, Inc.)
2019 General Manager, Global Business Division, Attached to Global Business Division (NS Pharma, Inc.)
2019 Director
2019 General Manager, Global Business; Head of Global Business Division
2021 President (current position)

Attendance at board meetings (FY2020): 14/14



Shouzou Sano
General Manager, Sales and Marketing Div.

1984 Joined the Company
2008 Department Manager, Saitama Branch Office, Sales and Marketing
2010 Corporate Officer, Department Manager, Osaka Branch Office, Sales Promotion Division, Sales and Marketing
2013 Corporate Officer, Head of Tokyo Area Division, Sales and Marketing
2015 Corporate Officer, Head of Sales and Marketing
2015 Director
2015 General Manager, Sales and Marketing; Head of Sales and Marketing Division (current position)
2019 Managing Director (current position)

Attendance at board meetings (FY2020): 14/14



Miyuki Sakurai
External Director

1992 Completed training program at Legal Training and Research Institute of Japan
1992 Registered with Osaka Bar Association
1992 Joined Nishimura Law and Accounting Office
2003 Joint Owner, Hanamizuki Law Office (current position)
2015 Auditor, Nissay Life Foundation (current position)
2016 Auditor, Osaka University (current position)
2017 External Director (current position)
2020 Member of the Board, NIPPON SHOKUBAI CO., LTD. (current position)

Attendance at board meetings (FY2020): 14/14



Yoshinao Wada
External Director

1975 Joined Osaka University Hospital
1981 Department of Maternal Medicine, Osaka Medical Center for Maternal and Child Health
1991 Department Manager, Department of Molecular Medicine, Research Institute, Osaka Medical Center for Maternal and Child Health
1995 Guest Professor, Osaka University (concurrent position)
1998 Director, Research Institute, Osaka Medical Center for Maternal and Child Health
2006 Member, Science Council of Japan (concurrent position)
2011 Department Manager, Department of Maternal Medicine; Director, Research Institute; Osaka Medical Center for Maternal and Child Health
2014 Chief Department Manager, Department of Maternal Medicine; Director, Research Institute; Osaka Medical Center for Maternal and Child Health
2016 Part-time physician, Department of Maternal Medicine, Osaka Medical Center for Maternal and Child Health (current position)
2019 External Director (current position)

Attendance at board meetings (FY2020): 14/14



Yukari Kobayashi
External Director

1987 Joined IBM Japan, Ltd.
2002 General Manager, Overall Management, IBM Japan, Ltd.
2007 Executive Director, IBM Japan, Ltd.
2007 Executive Officer, IBM Business Consulting Services KK
2016 Joined Mercer Japan Ltd.
2016 In charge of Growth Strategy; General Manager, President's Office, Mercer Japan Ltd.
2018 Director, Mercer Investment Solutions Ltd.
2018 COO, Mercer Japan Ltd.
2018 Joined Microsoft Japan Co., Ltd.
2018 Corporate Officer; General Manager, Corporate Strategy Management Division; General Manager, President's Office, Microsoft Japan Co., Ltd.
2020 Representative Partner, Amanda Life Consulting LLC. (current position)
2021 External Director (current position)

Attendance at board meetings (FY2020): —



Takashi Takaya
General Manager, Administration Div.

1984 Joined the Company
2005 Department Manager, Marketing Department, Sales and Marketing
2009 Department Manager, Marketing Department, Sales and Marketing Planning Division, Sales and Marketing
2010 Department Manager, Marketing and Planning Department, Sales and Marketing Planning Division, Sales and Marketing
2011 Head of Sales and Marketing Planning Division, Sales and Marketing
2012 Corporate Officer; Head of Sales and Marketing Planning Division, Sales and Marketing
2018 Director (current position)
2018 General Manager, Administration (current position)

Attendance at board meetings (FY2020): 14/14



Takanori Edamitsu
General Manager, Business Management

1989 Joined the Company
2011 Department Manager, Corporate Planning Department
2013 Corporate Officer; Department Manager, Corporate Planning Department
2018 Director (current position)
2018 General Manager, Business Management (current position)

Attendance at board meetings (FY2020): 14/14



Kazuchika Takagaki
General Manager, Research and Development Div.

1986 Joined the Company
2014 Department Manager, Discovery Research Laboratories in Tsukuba, Discovery Research Labs., Research & Development
2016 Department Manager, Discovery Research Labs., Research & Development
2017 Corporate Officer; Department Manager, Discovery Research Labs., Research & Development
2021 Director (current position)
2021 Director, Research and Development; Head of Research & Development Division (current position)

Attendance at board meetings (FY2020): —



Morio Matsuura
Standing Corporate Auditor

1983 Joined the Company
2013 Department Manager, Keiji/Hokuriku Business Office Kinki Tokai Div., Sales and Marketing
2015 Department Manager, Osaka Business Office Nishinoh Div., Sales and Marketing
2017 Department Manager, Kitakanto/Koshin-etsu Business Office Sales and Marketing
2019 Associate Department Manager, Sales and Marketing Planning Div., Sales and Marketing
2019 Standing Corporate Auditor (current position)

Attendance at board meetings (FY2020): 14/14



Kenji Kuwabara
Standing Corporate Auditor

1983 Joined the Company
2004 Department Manager, Biological Research Dept., Discovery Research Labs., R&D
2008 Department Manager, Nucleic Acid Business Promotion Dept., Nucleic Acid Business Div., R&D
2010 Department Manager, Discovery Research Laboratories in Tsukuba, Discovery Research Labs., R&D
2012 Department Manager, Alliance & Business Planning Dept., Business Development Div., R&D
2016 General Manager, Beijing Representative Office
2019 General Manager, Beijing Representative Office, Global Business Div.
2019 General Manager, Beijing Representative Office, Global Business
2020 Deputy Head, Global Business
2020 Standing Corporate Auditor (current position)

Attendance at board meetings (FY2020): 12/12



Hitoshi Ishizawa
General Manager, Functional Food Div.

1985 Joined the Company
2013 Department Manager, Kita-Kanto Branch Office, Northern Japan Division, Sales and Marketing
2014 Department Manager, Chugoku Branch Office, Western Japan Division, Sales and Marketing
2015 Department Manager, Tokyo Branch Office, Eastern Japan Division, Sales and Marketing
2017 Department Manager, Osaka Branch Office, Sales and Marketing
2018 Corporate Officer; Department Manager, Osaka Branch Office, Sales and Marketing
2021 Corporate Officer; Department Manager, Kansai Branch Office, Sales and Marketing
2021 Director (current position)
2021 General Manager, Functional Food Div. (current position)

Attendance at board meetings (FY2020): —



Hitomi Kimura
Director

General Manager, Resource Procurement, Production & Assurance Div.

1984 Joined the Company
2015 Department Manager, Regulatory Affairs Department, Regulatory Affairs, Safety Quality Assurance Division
2020 Head of Regulatory Affairs, Safety Quality Assurance Division (Marketing Supervisor-General)
2021 Corporate Officer, Head of Regulatory Affairs, Safety Quality Assurance Division (Marketing Supervisor-General)
2021 Director (current position)
2021 General Manager, Resource Procurement, Production & Assurance Div. (current position)

Attendance at board meetings (FY2020): —



Yukio Sugiura
External Director

1988 Professor, Institute for Chemical Research, Kyoto University
1998 Guest professor, Pharmaceutical Department, The University of Manchester
1998 Director, Institute for Chemical Research, Kyoto University
2005 Emeritus professor, Kyoto University (current position)
2005 President, The Pharmaceutical Society of Japan
2007 Specially appointed professor, Faculty of Pharmaceutical Sciences, Doshisha Women's College of Liberal Arts
2013 External Director (current position)

Attendance at board meetings (FY2020): 14/14



Tsuyoshi Kondo
External Auditor

1993 Completed legal training at The Legal Training and Research Institute of Japan
1993 Qualified as a lawyer
1993 Worked for Kondo Chiaki & Tsuyoshi Law Office
2001 President of Kondo Law Office (current position)
2003 Registered as a patent attorney
2010 Specially appointed professor, Graduate School of Law, Kansai University (current position)
2016 Company Auditor (current position)
2018 Outside Director, Senshu Electric Co., Ltd. (current position)

Attendance at board meetings (FY2020): 14/14



Sumitaka Maruyama
External Auditor

1974 Assigned to Osaka Regional Taxation Bureau
2008 District Director, Nishinari Tax Office
2009 Director, Second Human Resources Div., Management & Coordination Dept., Osaka Regional Taxation Bureau
2014 Deputy Assistant Regional Commissioner, First Taxation Dept., Osaka Regional Taxation Bureau
2015 Assistant Regional Commissioner, First Taxation Dept., Osaka Regional Taxation Bureau
2016 Registered as Licensed Tax Accountant
2019 Company Auditor (current position)
2019 Outside Auditor, UNITIKA LTD. (current position)

Attendance at board meetings (FY2020): 14/14

Corporate Officers

Hirokata Harada
Head of Medical Supervisory Div.

Koji Honma
General Manager, Personnel Dept.

Hideki Sasaki
Department Manager, Odawara Central Factory

Hiromu Nakajima
Chief Medical Officer

Hayato Wada
Department Manager, Tokyo Business Office

Masaya Toda
Head of Licensing & Alliance Div.

Kazuyuki Yamate
General Manager, Business Management Dept.

Masafumi Taira
Head of Clinical Development Div.

Mitsuharu Koizumi
Head of Sales and Marketing Planning Div.

Current as of June 29, 2021

Ten-Year Financial Data

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

(FY)

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2020
For the year										Millions of Yen	Thousands of U.S. Dollars
Net sales	67,304	69,941	76,517	79,991	84,209	98,781	101,448	114,716	116,637	121,885	1,108,045
Pharmaceuticals	55,746	58,318	63,345	66,340	70,489	85,315	87,416	100,223	101,643	106,478	967,981
Functional Food	11,558	11,622	13,172	13,651	13,720	13,466	14,031	14,492	14,994	15,406	140,054
Cost of sales	32,702	34,776	39,033	41,226	44,016	44,835	46,929	50,952	53,155	49,954	454,127
Gross profit	34,601	35,165	37,483	38,764	40,192	53,946	54,519	63,764	63,481	71,931	653,918
Total selling, general and administrative expenses	28,588	28,263	29,445	30,202	31,643	38,666	37,439	43,119	41,813	45,796	416,327
Selling, general and administrative expenses	19,174	19,214	19,914	21,233	21,904	23,762	24,217	26,418	27,819	29,692	269,927
R&D expenses	9,414	9,049	9,530	8,968	9,739	14,903	13,221	16,701	13,994	16,104	146,400
Operating income	6,012	6,901	8,038	8,562	8,549	15,280	17,079	20,644	21,668	26,134	237,581
Net income attributable to owners of the parent	3,715	4,647	5,750	5,882	6,340	11,749	12,953	16,302	16,866	20,702	188,200
Depreciation and amortization	2,948	2,759	2,704	2,665	2,452	2,648	2,773	3,418	3,468	3,550	32,272
Capital investment	967	1,332	1,072	1,239	3,554	3,949	2,811	1,242	2,500	2,583	23,481
Cash flows from operating activities	3,658	3,767	6,015	6,113	8,915	18,916	6,719	15,310	12,737	21,388	194,436
Cash flows from investing activities	(759)	(2,026)	(3,357)	(3,718)	(3,978)	(5,750)	(11,342)	511	(2,339)	(1,564)	(14,218)
Cash flows from financing activities	(1,341)	(1,413)	(1,606)	(1,773)	(1,907)	(2,193)	(3,787)	(3,708)	(5,660)	(6,199)	(56,354)
End of the year										Millions of Yen	Thousands of U.S. Dollars
Total assets	106,304	113,730	118,188	129,757	135,370	150,905	155,887	168,763	175,017	197,028	1,791,163
Interest-bearing debt	75	35	—	—	—	—	—	—	—	—	—
Net assets	84,566	89,529	93,186	101,207	102,762	114,316	125,689	135,190	145,760	162,543	1,477,663
Financial information per share										Yen	U.S. Dollars
Earnings per share	55.04	68.87	85.25	87.26	94.10	174.42	192.31	242.04	250.42	307.37	2.79
Net assets per share	1,250.11	1,323.87	1,378.93	1,498.88	1,522.33	1,693.81	1,862.54	2,003.39	2,160.11	2,409.01	21.9
Dividend per share	19	21	23	25	28	48	52	70	86	99	0.90
Principal financial indicators										%	%
Operating income to net sales	8.9	9.9	10.5	10.7	10.2	15.5	16.8	18.0	18.6	21.4	—
Equity ratio	79.4	78.5	78.7	77.8	75.8	75.6	80.5	80.0	83.1	82.4	—
Return on assets	5.8	6.3	6.9	7.0	6.5	10.8	11.2	12.7	12.6	14.0	—
Return on equity	4.5	5.4	6.3	6.1	6.2	10.8	10.8	12.5	12.0	13.5	—
Payout ratio	34.5	30.5	27.0	28.7	29.8	27.5	27.0	28.9	34.3	32.2	—

Non-Financial Data

For further details, see https://www.nippon-shinyaku.co.jp/english/sustainability/esg/esg_data.php



Environment

Material Flow Data (FY)

INPUT	Classification	2018	2019	2020	
Materials	Raw materials (t)	311	267	225	
	Packaging materials (t)	267	272	232	
	Energy	Electricity ¹ (1,000 kWh)	15,058	14,987	15,251
		Heavy oil (kL)	0	0	0
		Kerosene (kL)	3	3	4
		City gas (1,000 m ³)	1,640	1,629	1,549
		LPG (m ³)	336	374	1
		Gasoline (kL)	899	600	389
		Diesel (kL)	1	2	2
	Water consumption	Tap water (1,000 m ³)	66	59	59
Well water (1,000 m ³)		138	123	101	
Products	Shipped products (t)	524	484	461	
	Transported products (10,000 t-km)	15	16	13	
Gas & Water emissions	CO ₂ emissions ² (Scope 1,2)(t-CO ₂)	12,638	11,218	10,496	
	Wastewater (1,000 m ³)	204	182	161	
Waste substances	Amount generated (t)	522	482	428	
	Final amount of landfilled waste (t)	1.5	3.01	3.93	
Container and package recycling ³	Waste containers and packages (Amount contracted out as post-consumer recovered waste) (t)	201	201	195	
	Class I Designated Chemical Substances handled ⁴	Acetonitrile (kg)	6,930	3,558	5,557
Chloroform (kg)		305	344	124	
Dichloromethane (kg)		2,256	3,004	2,075	
N-hexane (kg)		2,492	1,983	2,697	

*1 Electricity consumption increased due to a switch from a gas absorption-type air-conditioning system to an electric one at the Odawara Central Factory.
 *2 Despite the overall power consumption increase, CO₂ emissions decreased from the previous year as a result of the reduced use of other energy sources.
 *3 Waste containers and packaging (FY2019 entrusted amount for recycling)
 *4 Amount of Class I Designated Chemical Substances handled based on the transfer register system under PRTR law

Putting Environmental Management System Certification into Action

Office name	Acquired certifications	Date of certification acquisition	Last 3rd-party review
Odawara Central Factory	ISO 14001	August 2004	February 2021 (Periodic review)
Head Office area business office	KES Step2 ⁵	June 2012	August 2020 (Review for renewal)

*5 KES: Abbreviation for Kyoto Environmental management system Standard

Environmental Accounting (FY)

Environmental conservation costs (excluding our sales offices)	Costs	2019		2020	
		Investments	Expenses	Investments	Expenses
	Costs within our business areas (Thousands of yen)	182,129	231,657	209,596	241,856
	-Pollution prevention costs ⁷ (Thousands of yen)	30,700	25,384	19,000	53,301
	-Global environmental conservation costs ⁸ (Thousands of yen)	151,429	141,062	190,596	132,483
	-Resource recycling costs ⁹ (Thousands of yen)	0	65,211	0	56,072
	Upstream & downstream costs ¹⁰ (Thousands of yen)	0	4,768	0	4,845
	Management activity costs ¹¹ (Thousands of yen)	19,049	78,362	0	79,246
	R&D costs (Thousands of yen)	0	0	0	0
	Social activity costs ¹² (Thousands of yen)	0	1,995	0	1,173
	Environmental remediation costs (Thousands of yen)	0	84	0	164
	Total (Thousands of yen)	201,178	316,866	209,596	327,284

Environmental conservation benefits ¹³	Benefit verification	2019	2020	Year on year change	Year on year rate
		CO ₂ emissions (t-CO ₂)	11,218	10,496	-722
	-Electricity usage (1,000 kWh)	14,987	15,251	264	101.8%
	-Heavy oil & kerosene usage (kL)	3	4	1	142.1%
	-City gas & LPG usage (1,000 m ³)	1,629	1,549	-80	95.1%
	-Gasoline & diesel usage (kL)	602	391	-211	64.9%
	Water consumption (main business locations) (1,000 m ³)	182	161	-21	88.2%
	Waste substances generated (main business locations) (t)	482	428	-54	88.8%
	Final amount of landfilled waste (main business locations) (t)	3.0	3.9	0.9	130.6%

*6 Costs aimed at reducing the environmental impact caused by business activities. We compiled them based on "Environmental Accounting Guidelines 2005" published by the Ministry of the Environment
 *7 Costs related to environmental damage prevention due to pollution such as water pollution, soil pollution, air pollution, etc.
 *8 Costs related to global warming prevention, energy-saving activities, etc.
 *9 Costs related to proper disposal of waste, recycling etc.
 *10 Consignment fee for recycling of containers and packaging (costs for collection and recycling of packaging containers for pharmaceuticals, etc. in Nippon Shinyaku), etc.
 *11 Costs related to maintenance and operation of EMS (Environmental Management System) and environmental education of employees
 *12 Costs related to offering classes to elementary schools in Kyoto city, greening in the workplace, regional cleanup activities, etc.
 *13 Corresponding to an increase or decrease in factors impacting the environment from the reference year: the decreased gasoline and diesel usage due to reduced external sales activities and increased internal work due to the COVID-19 pandemic.

(FY)

	2016	2017	2018	2019	2020
CO₂ emissions (t-CO₂)					
Main business locations ¹⁴	10,165	10,609	10,129	9,435	9,181
Sales offices, etc.	2,772	2,705	2,509	1,783	1,315
Supply chain emissions by scope (t-CO₂)					
Scope 1: Direct greenhouse gas (GHG) emissions from owned or controlled sources	—	—	—	5,063	4,396
Scope 2: Indirect emissions that occur through the use of purchased electricity, steam, and heat	—	—	—	6,155	6,101
Scope 3: Fuel- and energy-related activities not included in Scope 1 or Scope 2	—	—	—	1,019	1,037
Scope 3: Waste generated in operations	—	—	—	—	222
Scope 3: Business travel	—	—	—	—	235
Scope 3: Employee commuting	—	—	—	—	231
Scope 3: End-of-life treatment of sold products	—	—	—	160	159
Total energy consumption (Thousands of GJ)					
Main business locations ¹⁴	199	209	212	211	210
Sales offices, etc.	43	43	40	30	23
Electricity (1,000 kWh)					
Main business locations ¹⁴	13,039	13,980	14,180	14,109	14,305
Sales offices, etc.	974	969	878	878	946
City gas (1,000 m³)					
Main business locations ¹⁴	1,586	1,619	1,639	1,627	1,546
Sales offices, etc.	3	3	2	2	2
Water (1,000 m³)					
Main business locations ¹⁴	266	275	204	182	161
Waste substances generated (t)					
Head Office area	258	229	184.9	177	198
Odawara Central Factory	135.2	246	315.3	282	213
Discovery Research Laboratories in Tsukuba	31.3	31.9	21.5	23	18
Handling amount of PRTR-regulated Class I Designated Chemical Substances (kg)					
Acetonitrile	5,611	5,124	6,930	3,558	5,557
Chloroform	196	218	305	344	204
Dichloromethane	1,705	2,420	2,256	3,004	2,075
N-hexane	2,801	2,722	2,492	1,983	2,697

*14 Main business locations: Head Office area, Odawara Central Factory, Discovery Research Laboratories in Tsukuba

Social

(FY)

	2016	2017	2018	2019	2020
Employees & Promoting Women in the Workplace (persons)					
Number of employees (parent company)	1,727	1,753	1,761	1,793	1,806
Number of female employees	478	488	494	516	529
Ratio of female employees (%)	27.7	27.8	28.1	28.8	29.3
Number of executives	555	566	555	554	555
Number of female executives	65	69	72	78	84
Ratio of female executives (%)	11.7	12.2	13.0	14.1	15.1
Number of managers	285	319	321	329	331
Number of female managers	14	17	25	32	34
Ratio of female managers (%)	4.9	5.3	7.8	9.7	10.3
Number of recruits	68	74	72	79	76
Number of female recruits	24	22	25	28	33
Ratio of female recruits (%)	35.3	29.7	34.7	35.4	43.4
Average number of years of service of female employees (years)	17.3	17.4	17.3	18.1	16.7
Average number of years of service of male employees (years)	17.4	17.6	17.5	17.7	17.6
Number of employees taking parental leave for childcare	2	0	0	7	14
Male	2	0	0	7	14
Female	13	28	18	22	19
Paid annual leave acquisition rate (%)	62.7	64.2	70.6	71.3	63.5
Total annual working hours (hours)	1802.92	1806.32	1804.22	1791.6	1821.96
Human Resources Development (times)					
Training for new employees	1	1	1	1	1
Training for newly promoted managers	2	2	2	2	2

Governance

(FY)

	2016	2017	2018	2019	2020
Number of directors (persons)	9	10	12	12	12
Number of external directors	2	3	4	4	4
Number of female directors	0	1	1	1	3
Ratio of female directors (%)	0	10	8	8	25
Number of auditors (persons)	4	4	4	4	4
Number of external auditors	2	2	2	2	2
Ratio of external auditors (%)	50	50	50	50	50

Management's Discussion and Analysis

1. Overview of Performance

In fiscal 2020, both society and the economy were significantly impacted worldwide as countries still struggled to contain the COVID-19 pandemic. The Japanese economy similarly was affected by a decelerating global economy and ongoing effects from the COVID-19 pandemic, and there remains a lack of visibility over the economic outlook both for Japan and the remainder of the world.

Conditions for the Nippon Shinyaku Group and broader pharmaceutical industry stayed harsh due to various measures to restrict healthcare spending in Japan, including the promotion of greater use of generics and annual NHI price revisions, as well as effects from the COVID-19 pandemic.

In the functional food business, there was strong demand for functional foods due to increased health consciousness. However, conditions remained challenging due to factors including low growth in spending by thrifty households, and the cancellation of sporting events and downturn in inbound demand caused by the COVID-19 pandemic.

Under such conditions, the Nippon Shinyaku Group focused on building public trust by honing its reputation as an essential supplier in the healthcare field with a meaningful role to play in society.

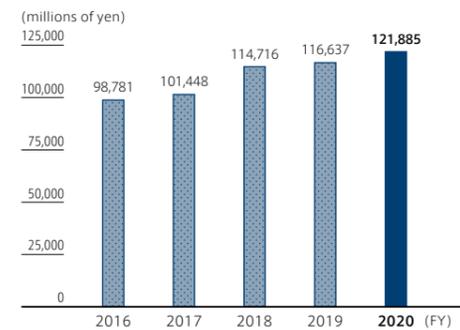
Net sales grew 4.5% to ¥121,885 million, as although the prescription pharmaceuticals business in Japan and functional food business both were affected by the COVID-19 pandemic, there were contributions from royalties on overseas sales of our original pulmonary arterial hypertension (PAH) treatment Upravi, as well as milestone payments for Upravi and higher sales of new prescription pharmaceuticals in Japan. In terms of profits, operating income increased 20.6% to ¥26,134 million as higher sales and an improved product mix led to a decline in the cost-of-sales ratio, while ordinary income increased 19.2% to ¥26,760 million, and net income attributable to owners of the parent increased 22.7% to ¥20,702 million.

2. Overview by Segment

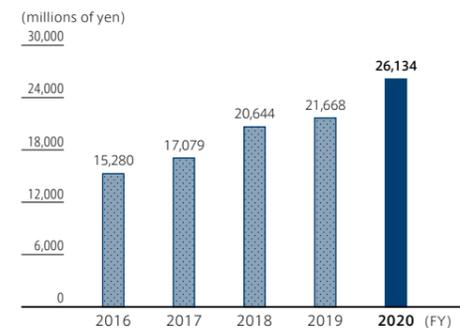
1 Pharmaceuticals

In fiscal 2020, the prescription pharmaceuticals business posted royalties on overseas sales of Upravi, higher sales for new products including Defitelio, a treatment for sinusoidal obstruction syndrome (hepatic veno-occlusive disease), Gazyva (CD20-positive follicular lymphoma treatment), and Upravi, and growth in co-promotion revenues. There were further contributions from milestone revenues for Upravi, and from Viltepso, the Duchenne muscular dystrophy (DMD) treatment launched in Japan in May 2020 and the U.S. that August. As a result, net sales increased 4.8% year on year to ¥106,478 million.

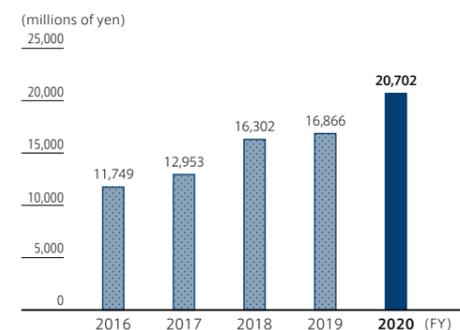
Net sales



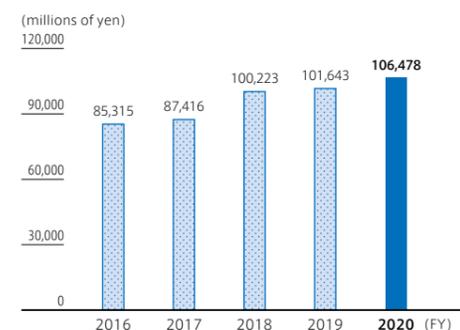
Operating income



Net income attributable to owners of the parent



Pharmaceuticals



2 Functional Food

Net sales increased 2.8% year on year to ¥15,406 million, due to increased sales of protein preparations, preservatives and other products.

3. Financial Condition

(Assets)

Current assets totaled ¥139,090 million at the fiscal year-end, due to an increase in cash and cash equivalents and in inventories compared to the previous fiscal year-end, more than offsetting a reduction in notes and accounts receivable. Fixed assets increased to ¥57,937 million, mainly due to an increase in investment securities and long-term prepaid expenses. As a result, total assets increased by ¥22,011 million compared to the previous fiscal year-end, to ¥197,028 million.

(Liabilities)

Current liabilities totaled ¥31,514 million due to an increase in income taxes payable and other payables, despite a decrease in notes and accounts payable compared to the previous fiscal year-end. Long-term liabilities totaled ¥2,970 million, due to a decrease in liability for retirement benefits.

As a result, total liabilities increased by ¥5,228 million compared to the previous fiscal year-end, to ¥34,485 million.

(Equity)

Equity increased by ¥14,502 million compared to the previous fiscal year-end, to ¥154,535 million. Accumulated other comprehensive income increased by ¥2,261 million to ¥7,719 million. As a result, total equity increased by ¥16,782 million to ¥162,543 million.

Cash Flows

Cash and cash equivalents as of March 31, 2021 increased by ¥13,584 million compared to the previous fiscal year-end, to ¥57,883 million.

(Cash flows from operating activities)

Net cash provided by operating activities amounted to ¥21,388 million. The main cash inflows were ¥28,759 million from income before income taxes; depreciation and amortization of ¥3,550 million; and an increase of ¥1,523 million in other current liabilities. The main cash outflows were an increase in inventories of ¥5,629 million and income tax payments of ¥4,304 million.

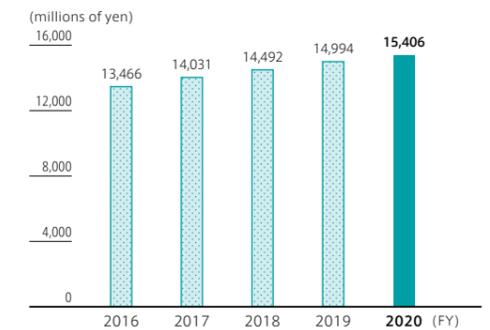
(Cash flows from investing activities)

Net cash used in investing activities amounted to ¥1,564 million. The main components of net cash outflow were expenditures of ¥2,168 million for property, plant and equipment and of ¥694 million for long-term prepaid expenses.

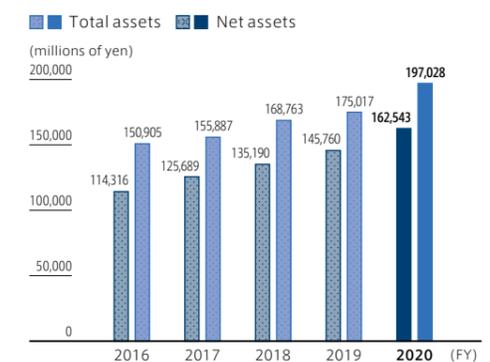
(Cash flows from financing activities)

Net cash used in financing activities amounted to ¥6,199 million, primarily comprising cash dividends paid.

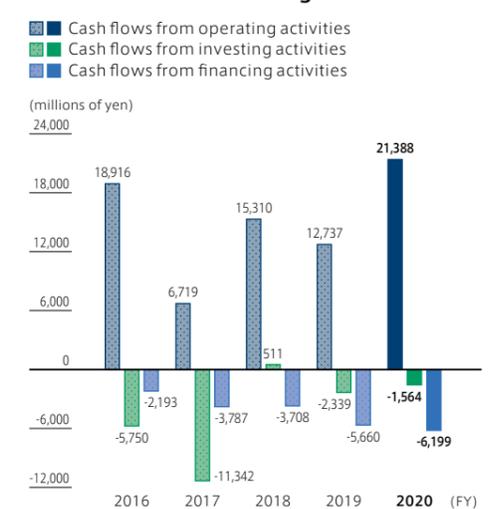
Functional Food



Total assets / Net assets



Cash flows from operating activities / Cash flows from investing activities / Cash flows from financing activities



Consolidated Financial Statements

Consolidated Balance Sheet

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
March 31, 2021

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2021	2020	2021
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents (Note 10)	¥ 57,963	¥ 44,298	\$ 509,663
Time deposits (Note 10)	807	807	7,336
Marketable securities (Notes 3 and 10)	2,029	2,010	35,718
Notes and accounts receivables (Note 10):			
Trade notes	530	599	4,818
Trade accounts	39,267	40,923	356,972
Other	487	890	4,427
Total notes and accounts receivables	40,285	42,412	366,227
Inventories (Note 4)	35,524	29,894	322,945
Other current assets	2,481	2,502	22,554
Total current assets	139,090	121,925	1,264,454
PROPERTY, PLANT, AND EQUIPMENT:			
Land	7,430	7,459	67,545
Buildings and structures	28,287	27,792	257,154
Machinery, equipment, and vehicles	12,811	12,444	116,463
Tools, furniture, and fixtures	9,408	8,955	85,527
Construction in progress	451	305	4,100
Total	58,390	56,957	530,818
Accumulated depreciation	(37,083)	(36,012)	(337,118)
Net property, plant, and equipment	21,306	20,944	193,690
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 3 and 10)	22,113	18,909	201,027
Long-term prepaid expenses	9,390	8,631	85,363
Deferred tax assets (Note 9)	1,518	1,726	13,800
Other assets	3,608	2,878	32,800
Total investments and other assets	36,631	32,146	333,009
TOTAL	¥197,028	¥175,017	\$1,791,163

See notes to consolidated financial statements.

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2021	2020	2021
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Notes and accounts payables (Note 10):			
Trade notes	¥ 1,787	¥ 1,777	\$ 16,245
Trade accounts	7,755	9,435	70,500
Other	7,071	4,831	64,281
Total notes and accounts payables	16,615	16,045	151,045
Income taxes payable (Note 10)	6,679	2,081	60,718
Accrued expenses	4,463	4,492	40,572
Deposits from customers	211	209	1,918
Other current liabilities	3,544	2,137	32,218
Total current liabilities	31,514	24,965	286,490
LONG-TERM LIABILITIES:			
Liability for retirement benefits (Note 5)	2,646	3,956	24,054
Deferred tax liabilities (Note 9)		9	
Other long-term liabilities	324	324	2,945
Total long-term liabilities	2,970	4,290	27,000
EQUITY (Notes 6 and 13):			
Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares	5,174	5,174	47,036
Capital surplus	4,445	4,445	40,409
Retained earnings	147,391	132,886	1,339,918
Treasury stock – at cost, 2,898,183 shares in 2021 and 2,897,768 shares in 2020	(2,476)	(2,473)	(22,509)
Accumulated other comprehensive income:			
Unrealized gain on available-for-sale securities	8,911	6,929	81,009
Deferred gain on derivatives under hedge accounting	11	7	100
Foreign currency translation adjustments	(96)	(3)	(872)
Defined retirement benefit plans	(1,107)	(1,475)	(10,063)
Total	162,254	145,491	1,475,036
Noncontrolling interests	288	269	2,618
Total equity	162,543	145,760	1,477,663
TOTAL	¥197,028	¥175,017	\$1,791,163

Consolidated Financial Statements

Consolidated Statement of Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2021

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2021	2020	2021
NET SALES (Note 14)	¥ 121,885	¥ 116,637	\$ 1,108,045
COST AND EXPENSES:			
Cost of sales	49,954	53,155	454,127
Selling, general, and administrative expenses (Notes 7 and 8)	45,796	41,813	416,327
Total	95,750	94,969	870,454
Operating income (Note 14)	26,134	21,668	237,581
OTHER INCOME (EXPENSES):			
Interest and dividend income	531	574	4,827
Interest expense	(2)	(2)	(18)
Other—net	2,095	202	19,045
Other income—net	2,624	774	23,854
INCOME BEFORE INCOME TAXES	28,759	22,442	261,445
INCOME TAXES (Note 9):			
Current	8,821	4,732	80,190
Deferred	(783)	821	(7,118)
Total income taxes	8,038	5,553	73,072
NET INCOME	20,721	16,888	188,372
NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTERESTS	18	22	163
NET INCOME ATTRIBUTABLE TO OWNERS OF THE PARENT	¥ 20,702	¥ 16,866	\$ 188,200
	Yen		U.S. Dollars
PER SHARE OF COMMON STOCK (Notes 2.p and 12):			
Basic net income	¥ 307.37	¥ 250.42	\$ 2.79
Cash dividends applicable to the year	99.00	86.00	0.90

See notes to consolidated financial statements.

Consolidated Statement of Comprehensive Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2021

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2021	2020	2021
NET INCOME	¥ 20,721	¥ 16,888	\$ 188,372
OTHER COMPREHENSIVE INCOME (LOSS) (Note 11):			
Unrealized gain (loss) on available-for-sale securities	1,982	(2,510)	18,018
Deferred gains on derivatives under hedge accounting	4	12	36
Foreign currency translation adjustments	(92)	(3)	(836)
Defined retirement benefit plans	367	1,851	3,336
Total other comprehensive income (loss)	2,261	(650)	20,554
COMPREHENSIVE INCOME (LOSS)	¥ 22,982	¥ 16,237	\$ 208,927
TOTAL COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO:			
Owners of the parent	¥ 22,963	¥ 16,215	\$ 208,754
Noncontrolling interests	18	22	163

See notes to consolidated financial statements.

Consolidated Statement of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2021

	Thousands		Millions of Yen								Non-controlling Interest	Total Equity	
	Outstanding Number of Shares of Common Stock	Common Stock	Accumulated Other Comprehensive Income						Total				
			Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available-for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments		Defined Retirement Benefit Plans			
BALANCE, APRIL 1, 2019	67,354	¥ 5,174	¥ 4,445	¥ 121,677	¥ (2,469)	¥ 9,440	¥ (5)	¥ (3,326)	¥ 134,936	¥ 253	¥ 135,190		
Net income attributable to owners of the parent				16,866					16,866		16,866		
Cash dividends, ¥84.00 per share				(5,657)					(5,657)		(5,657)		
Purchase of treasury stock						(3)			(3)		(3)		
Net change during the year							(2,510)	12	¥(3)	1,851	(650)	16	(634)
BALANCE, MARCH 31, 2020	67,354	5,174	4,445	132,886	(2,473)	6,929	7	(3)	(1,475)	145,491	269	145,760	
Net income attributable to owners of the parent				20,702					20,702		20,702		
Cash dividends, ¥92.00 per share				(6,196)					(6,196)		(6,196)		
Purchase of treasury stock						(3)			(3)		(3)		
Net change during the year							1,982	4	(92)	367	2,261	18	2,280
BALANCE, MARCH 31, 2021	67,354	¥ 5,174	¥ 4,445	¥ 147,391	¥ (2,476)	¥ 8,911	¥ 11	¥ (96)	¥ (1,107)	¥ 162,254	¥ 288	¥ 162,543	

	Thousands of U.S. Dollars (Note 1)		Millions of Yen								Non-controlling Interest	Total Equity
	Common Stock	Capital Surplus	Accumulated Other Comprehensive Income						Total			
			Retained Earnings	Treasury Stock	Unrealized Gain on Available-for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Defined Retirement Benefit Plans				
BALANCE, MARCH 31, 2020	\$47,036	\$40,409	\$1,208,054	\$(22,481)	\$62,990	\$ 63	\$(27)	\$(13,409)	\$1,322,645	\$2,445	\$1,325,090	
Net income attributable to owners of the parent			188,200						188,200		188,200	
Cash dividends, \$0.83 per share			(56,327)						(56,327)		(56,327)	
Purchase of treasury stock				(27)					(27)		(27)	
Net change during the year					18,018	36	(836)	3,336	20,554	163	20,727	
BALANCE, MARCH 31, 2021	\$47,036	\$40,409	\$1,339,918	\$(22,509)	\$81,009	\$100	\$(872)	\$(10,063)	\$1,475,036	\$2,618	\$1,477,663	

See notes to consolidated financial statements.

Consolidated Financial Statements

Consolidated Statement of Cash Flows

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2021

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2021	2020	2021
OPERATING ACTIVITIES:			
Income before income taxes	¥28,759	¥22,442	\$261,445
Adjustments for:			
Income taxes—paid	(4,304)	(6,235)	(39,127)
Depreciation and amortization	3,550	3,468	32,272
Changes in assets and liabilities:			
Decrease in trade notes and trade accounts receivables	1,724	5,033	15,672
Increase in inventories	(5,629)	(10,521)	(51,172)
Decrease (increase) in other current assets	21	(442)	190
(Decrease) increase in trade notes and trade accounts payables	(1,669)	3,227	(15,172)
Increase (decrease) in other current liabilities	1,003	(116)	9,118
Increase in asset for retirement benefits	(1,858)		(16,890)
Increase (decrease) in liability for retirement benefits	457	(1,222)	4,154
Other—net	(665)	(2,895)	(6,045)
Total adjustments	(7,370)	(9,704)	(67,000)
Net cash provided by (used in) operating activities	21,388	12,737	194,436
INVESTING ACTIVITIES:			
Purchase of property, plant, and equipment	(2,168)	(1,817)	(19,709)
Purchases of investment securities	(1,102)	(62)	(10,018)
Purchases of software	(310)	(319)	(2,818)
Purchase of long-term prepaid expenses	(694)	(1,315)	(6,309)
Other—net	2,711	1,176	24,645
Net cash provided by (used in) investing activities	(1,564)	(2,339)	(14,218)
FINANCING ACTIVITIES:			
Cash dividends paid	(6,196)	(5,651)	(56,327)
Increase in treasury stock	(3)	(3)	(27)
Other—net		(5)	
Net cash provided by (used in) financing activities	(6,199)	(5,660)	(56,354)
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS	(40)	(72)	(363)
NET INCREASE IN CASH AND CASH EQUIVALENTS	13,584	4,665	123,490
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	44,298	39,632	402,709
CASH AND CASH EQUIVALENTS, END OF YEAR	¥57,883	¥44,298	\$526,209

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

1. BASIS OF PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations and in accordance with accounting principles generally accepted in Japan, which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards.

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form that is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2020 consolidated financial statements to conform to the classifications used in 2021.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Nippon Shinyaku Co., Ltd. (the "Company") is incorporated and operates. Japanese yen figures of less than one million yen are rounded down to the nearest million, except for per share data. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥110 to \$1, the approximate rate of exchange at March 31, 2021. U.S. dollar figures of less than one thousand dollars are rounded down to the nearest thousand, except for per share data. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. **Consolidation** - The consolidated financial statements as of March 31, 2021 and 2020, include the accounts of the Company and its three domestic subsidiaries and one overseas subsidiary (collectively, the "Companies").

Under the control and influence concepts, those companies in which the Company, directly or indirectly, is able to exercise control over operations are fully consolidated, and those companies over which the Companies have the ability to exercise significant influence are accounted for by the equity method.

All significant intercompany balances and transactions have been eliminated in consolidation. All material unrealized profit included in assets resulting from transactions within the Companies is eliminated.

Among the consolidated subsidiaries, NS Pharma, Inc. has a fiscal year ending on December 31, and consolidated financial statements were previously prepared using the financial statement of this company as of that fiscal year-end date. Adjustments were previously made to the consolidated accounts to account for significant transactions involving the company that occur between the end of the company's fiscal year-end date and the end of the consolidated fiscal year. As the external sales started recording from the current fiscal year, NS Pharma, Inc. changed the method to a provisional settlement method on the consolidated closing date from the current fiscal year in order to grasp management information and to disclose the consolidated financial statements in more appropriate manners. As a result of this change, the

subsidiary's operating results for the 15-month period from January 1, 2020 to March 31, 2021 were included in the consolidated statement of income. The subsidiary's net sales from January 1, 2020 to March 31, 2020 were ¥612 million, operating income was ¥50 million, and income before income taxes was ¥50 million in the stand-alone financial statements.

- b. **Cash Equivalents** - Cash equivalents are short-term investments that are readily convertible into cash and exposed to insignificant risk of changes in value. Cash equivalents include time deposits, certificates of deposit, and commercial paper, all of which mature or become due within three months of the date of acquisition.
- c. **Marketable and Investment Securities** - Marketable and investment securities are classified and accounted for, depending on management's intent, as follows: i) held-to-maturity debt securities, for which management has the positive intent and ability to hold to maturity, are reported at amortized cost and ii) available-for-sale securities that are not classified as held-to-maturity securities, except for nonmarketable available-for-sale securities, are reported at fair value, with unrealized gains and losses, net of applicable taxes, reported in a separate component of equity. Realized gains and losses on available-for-sale securities are included in earnings and are calculated by using the moving-average method to determine the cost of securities sold. Nonmarketable available-for-sale securities are stated at cost determined principally by the moving-average method. Write-downs are recorded in earnings for securities with a significant decline in value that is considered to be other than temporary.
- d. **Inventories** - Inventories held for sale in the ordinary course of business are measured at the lower of cost, determined mainly by the average cost method, or net selling value, which is defined as the selling price, less additional estimated manufacturing costs and estimated direct selling expenses. The replacement cost may be used in place of the net selling value, if appropriate.
- e. **Property, Plant, and Equipment** - Property, plant, and equipment are stated at cost. Depreciation of property, plant, and equipment of the Companies is computed by the straight-line method based on the estimated useful lives of the assets. The range of useful lives is principally from 10 to 50 years for buildings and structures, from 8 to 10 years for machinery, equipment, and vehicles, and from 4 to 6 years for tools, furniture, and fixtures.
- f. **Long-term Prepaid Expenses** - Long-term prepaid expenses are amortized by the straight-line method principally over 5 to 20 years, based on the term of validity of contracts.
- g. **Long-Lived Assets** - The Companies review their long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss would be measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from the continued use and eventual disposition of the asset or the net selling price at disposition.

Notes to Consolidated Financial Statements

- h. Retirement and Pension Plans** - The Company has contributory funded defined benefit pension plans, unfunded retirement benefit plans and a defined contribution pension plan for employees. Certain subsidiaries use a simplified method for calculating pension liabilities.
- The Company accounts for the liability for retirement benefits based on the projected benefit obligations and plan assets at the balance sheet date. The projected benefit obligations are attributed to periods on a benefit formula basis. Actuarial gains and losses and past service costs that are yet to be recognized in profit or loss are recognized within equity (accumulated other comprehensive income), after adjusting for tax effects and are recognized in profit or loss over 15 years within the average remaining service period of the employees. The discount rate is determined using a single weighted-average discount rate reflecting the estimated timing and amount of benefit payment.
- i. Allowance for Doubtful Accounts** - The allowance for doubtful accounts is stated at an amount considered to be appropriate based on the Companies' past credit loss experience and an evaluation of potential losses in receivables outstanding.
- j. Leases** - Finance lease transactions are capitalized by recognizing lease assets and lease obligations in the consolidated balance sheet. All other leases are accounted for as operating leases.
- k. Allowance for Bonuses** - To prepare for the payment of employee bonuses, an amount corresponding to the current portion of estimated bonus payments to employees is recorded.
- l. Income Taxes** - The provision for income taxes is computed based on the pretax income included in the consolidated statement of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted income tax rates to the temporary differences.
- m. Foreign Currency Transactions** - All short- and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statement of income to the extent that they are not hedged by forward exchange contracts.
- n. Foreign Currency Financial Statements** - The balance sheet accounts of the consolidated foreign subsidiary are translated into Japanese yen at the current exchange rate as of the consolidated balance sheet date except for equity, which is translated at the historical rate. Differences arising from such translation are shown as "Foreign currency translation adjustments" under accumulated other comprehensive income in a separate component of equity. Revenue and expense accounts of the consolidated foreign subsidiary are translated into yen at the average exchange rate.

- o. Derivative Financial Instruments** - The Company uses foreign currency forward contracts as a means of hedging exposure to foreign currency exchange risks related to the procurement of merchandise from overseas suppliers. The Company does not enter into derivatives for trading or speculative purposes. Derivative financial instruments and foreign currency transactions are classified and accounted for as follows: a) all derivatives are recognized as either assets or liabilities and measured at fair value, and gains or losses on derivative transactions are recognized in the consolidated statement of income, and b) for derivatives used for hedging purposes, if such derivatives qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are deferred until maturity of the hedged transactions. The foreign currency forward contracts are utilized to hedge foreign currency exposures in procurement of raw materials from overseas suppliers. Trade payables denominated in foreign currencies are translated at the contracted rates if the forward contracts qualify for hedge accounting.
- p. Per Share Information** - Basic net income per share (EPS) is computed by dividing net income attributable to common shareholders by the weighted-average number of common shares outstanding for the period.
- Cash dividends per share presented in the accompanying consolidated statement of income are dividends applicable to the respective fiscal years, including dividends to be paid after the end of the year.
- q. Accounting Changes and Error Corrections** - Under Accounting Standards Board of Japan ("ASBJ") Statement No. 24, "Accounting Standard for Accounting Changes and Error Corrections," and ASBJ Guidance No. 24, "Guidance on Accounting Standard for Accounting Changes and Error Corrections," accounting treatments are required as follows: (1) Changes in Accounting Policies—When a new accounting policy is applied following revision of an accounting standard, the new policy is applied retrospectively unless the revised accounting standard includes specific transitional provisions, in which case the entity shall comply with the specific transitional provisions. (2) Changes in Presentation—When the presentation of financial statements is changed, prior-period financial statements are reclassified in accordance with the new presentation. (3) Changes in Accounting Estimates—A change in an accounting estimate is accounted for in the period of the change if the change affects that period only, and is accounted for prospectively if the change affects both the period of the change and future periods. (4) Corrections of Prior-Period Errors—When an error in prior-period financial statements is discovered, those statements are restated.

- r. New Accounting Pronouncements** - On March 30, 2018, the ASBJ issued ASBJ Statement No. 29, "Accounting Standard for Revenue Recognition," and ASBJ Guidance No. 30, "Implementation Guidance on Accounting Standard for Revenue Recognition." The core principle of the standard and guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity should recognize revenue in accordance with that core principle by applying the following steps: Step 1: Identify the contract(s) with a customer Step 2: Identify the performance obligations in the contract Step 3: Determine the transaction price Step 4: Allocate the transaction price to the performance obligations in the contract Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation
- The accounting standard and guidance are effective for annual periods beginning on or after April 1, 2021. Earlier application is permitted for annual periods beginning on or after April 1, 2018.
- The Company expects to apply the accounting standard and guidance for annual periods beginning on April 1, 2021, and the application is expected to have an immaterial impact on the consolidated financial statements.
- On July 4, 2019, the ASBJ issued ASBJ Statement No. 30, "Accounting Standard for Fair Value Measurement" and ASBJ Guidance No. 31, "Implementation Guidance on Accounting Standard for Fair Value Measurement," and revised related ASBJ Statements and ASBJ Guidance (the "New Accounting Standards"). Under the New Accounting Standards, nonmarketable available-for-sale equity securities are stated at cost, while under the current accounting standards, nonmarketable available-for-sale securities are stated at cost. The New Accounting Standards are effective for the annual periods beginning on or after April 1, 2021. Earlier application is permitted for annual periods beginning on or after April 1, 2020, or annual periods ending on or after March 31, 2020.
- The Company expects to apply the accounting standard and guidance for annual periods beginning on April 1, 2021, and the application is expected to have an immaterial impact on the consolidated financial statements.
- s. Accounting Estimates of the Impact of COVID-19** - Although there are uncertain factors regarding the impact of COVID-19, the Companies assume that the impact on business performance of the Companies is limited and that the impact on accounting estimates will not be significant.

3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2021 and 2020, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Current:			
Equity securities			
Government and corporate bonds	¥ 2,000	¥ 2,010	\$ 18,181
Other	29		263
Total	¥ 2,029	¥ 2,010	\$ 18,445
Noncurrent:			
Equity securities	¥ 21,451	¥ 18,317	\$ 195,009
Government and corporate bonds	662	562	6,018
Other		29	
Total	¥ 22,113	¥ 18,909	\$ 201,027

The costs and aggregate fair values of marketable and investment securities at March 31, 2021 and 2020, were as follows:

March 31, 2021	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	¥ 8,909	¥ 12,542		¥ 21,451
Held-to-maturity	2,692		¥ 4	2,687

March 31, 2020	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	8,576	9,741		18,317
Held-to-maturity	2,602		4	2,598

March 31, 2021	Thousands of U.S. Dollars			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	\$ 80,990	\$ 114,018		\$ 195,009
Held-to-maturity	24,472		\$ 36	24,427

4. INVENTORIES

Inventories at March 31, 2021 and 2020, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Finished products and merchandise	¥ 18,292	¥ 15,179	\$ 166,290
Work in process	6,940	4,618	63,090
Raw materials and supplies	10,291	10,096	93,554
Total	¥ 35,524	¥ 29,894	\$ 322,945

Notes to Consolidated Financial Statements

5. RETIREMENT AND PENSION PLANS

To provide for the payment of employee retirement allowances, the Company has adopted a defined contribution pension plan. Under most circumstances, employees terminating their employment are entitled to retirement benefits determined based on the rate of pay at the time of termination, years of service and certain other factors. Such retirement benefits are made in the form of a lump-sum severance payment from the Company or from certain consolidated subsidiaries and annuity payments from a trustee. Employees are entitled to larger payments if the termination is involuntary, by retirement at the mandatory retirement age, by death, or by voluntary retirement at certain specific ages prior to the mandatory retirement age.

1. Defined Benefit Pension Plan

(1) The changes in defined benefit obligation for the years ended March 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Balance at beginning of year	¥ 25,567	¥ 29,601	\$ 232,427
Current service cost	1,053	1,141	9,572
Interest cost	142	164	1,290
Actuarial (gains) losses	82	(3,659)	745
Benefits paid	(1,611)	(1,680)	(14,645)
Balance at end of year	¥ 25,233	¥ 25,567	\$ 229,390

(2) The changes in plan assets for the years ended March 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Balance at beginning of year	¥ 21,610	¥ 21,758	\$ 196,454
Expected return on plan assets	864	870	7,854
Actuarial (gains) losses	344	(1,452)	3,127
Contributions from the employer	1,989	2,112	18,081
Benefits paid	(1,601)	(1,677)	(14,554)
Balance at end of year	¥ 23,207	¥ 21,610	\$ 210,972

(3) Reconciliation between the liability recorded in the consolidated balance sheet and the balances of defined benefit obligation and plan assets was as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Defined benefit obligation	¥ 22,586	¥ 23,075	\$ 205,327
Plan assets	(23,207)	(21,610)	(210,972)
	(621)	1,465	(5,645)
Unfunded defined benefit obligation	2,646	2,491	24,054
Net liability arising from defined benefit obligation	¥ 2,025	¥ 3,956	\$ 18,409

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Defined benefit asset	¥ (621)		\$ (5,645)
Liability for retirement benefits	2,646	¥ 3,956	24,054
Net liability arising from defined benefit obligation	¥ 2,025	¥ 3,956	\$ 18,409

(4) The components of net periodic benefit costs for the years ended March 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Service cost	¥ 1,053	¥ 1,141	\$ 9,572
Interest cost	142	164	1,290
Expected return on plan assets	(864)	(870)	(7,854)
Amortization of prior service cost	267	456	2,427
Others	46	58	418
Net periodic benefit costs	¥ 645	¥ 950	\$ 5,863

(5) Amounts recognized in other comprehensive income (before income tax effect) in respect of defined retirement benefit plans for the years ended March 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Actuarial (gains) losses	¥ (529)	¥ (2,663)	\$ (4,809)
Total	¥ (529)	¥ (2,663)	\$ (4,809)

(6) Amounts recognized in accumulated other comprehensive income (before income tax effect) in respect of defined retirement benefit plans as of March 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Unrecognized actuarial losses	¥ 1,593	¥ 2,122	\$ 14,481
Total	¥ 1,593	¥ 2,122	\$ 14,481

(7) Plan assets

a. Components of plan assets
Plan assets as of March 31, 2021 and 2020, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Domestic bonds	9.4%	14.5%	
Domestic stocks	8.3	8.0	
Foreign bonds	12.4	13.1	
Foreign stocks	5.7	5.7	
General accounts	42.1	37.8	
Alternative	17.0	13.9	
Others	5.1	7.0	
Total	100.0%	100.0%	

b. Method of determining the expected rate of return on plan assets

The expected rate of return on plan assets is determined considering the long-term rates of return that are expected currently and in the future from the various components of the plan assets.

(8) Assumptions used for the years ended March 31, 2021 and 2020, are set forth as follows:

	2021	2020
Discount rate	0.2-0.6%	0.2-0.6%
Expected rate of return on plan assets	4.0	4.0

2. Defined Contribution Pension Plan

Premiums for the defined contribution pension plan were ¥103 million (\$936 thousand) and ¥89 million for the years ended March 31, 2021 and 2020, respectively.

6. EQUITY

Japanese companies are subject to the Companies Act of Japan (the "Companies Act"). The significant provisions in the Companies Act that affect financial and accounting matters are summarized below:

(a) Dividends

Under the Companies Act, companies can pay dividends at any time during the fiscal year in addition to the year-end dividends upon resolution at the shareholders meeting. Additionally, for companies that meet certain criteria, including (1) having a Board of Directors, (2) having independent auditors, (3) having an Audit and Supervisory Board, and (4) the term of service of the directors being prescribed as one year rather than the normal two-year term by its articles of incorporation, the Board of Directors may declare dividends (except for dividends-in-kind) at any time during the fiscal year if the Company has prescribed so in its articles of incorporation. However, the Company does not meet all the above criteria.

The Companies Act permits companies to distribute dividends-in-kind (non-cash assets) to shareholders subject to a certain limitation and additional requirements.

Semiannual interim dividends may also be paid once a year upon resolution by the Board of Directors if the articles of incorporation of the company so stipulate. The Companies Act provides certain limitations on the amounts available for dividends or the purchase of treasury stock. The limitation is defined as the amount available for distribution to the shareholders, but the amount of net assets after dividends must be maintained at no less than ¥3 million.

(b) Increases/decreases and transfer of common stock, reserve, and surplus

The Companies Act requires that an amount equal to 10% of dividends must be appropriated as a legal reserve (a component of retained earnings) or as additional paid-in capital (a component of capital surplus), depending on the equity account charged upon the payment of such dividends, until the aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock. Under the Companies Act, the total amount of additional paid-in capital and legal reserve may be reversed without limitation. The Companies Act also provides that common stock, legal reserve, additional paid-in capital, other capital surplus, and retained earnings can be transferred among the accounts with equity under certain conditions upon resolution of the shareholders.

(c) Treasury stock and treasury stock acquisition rights

The Companies Act also provides for companies to purchase treasury stock and dispose of such treasury stock by resolution of the Board of Directors. The amount of treasury stock purchased cannot exceed the amount available for distribution to the shareholders, which is determined by a specific formula. Under the Companies Act, stock acquisition rights are presented as a separate component of equity. The Companies Act also provides that companies can purchase both treasury stock acquisition rights and treasury stock. Such treasury stock acquisition rights are presented as a separate component of equity or deducted directly from stock acquisition rights.

7. RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥16,104 million (\$145,408 thousand) and ¥13,994 million for the years ended March 31, 2021 and 2020, respectively.

8. LEASES

The Companies lease certain machinery, computer equipment, office space and other assets.

Total rental expenses including lease payments under finance leases for the years ended March 31, 2021 and 2020, were ¥1,309 million (\$11,906 thousand) and ¥1,289 million, respectively.

Future minimum payments under noncancelable operating leases were as follows:

	Operating Leases	
	2021	
	Millions of Yen	Thousands of U.S. Dollars
Due within one year	¥ 34	\$ 309
Due after one year	41	373
Total	¥ 76	\$ 691

Notes to Consolidated Financial Statements

9. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in the aggregate, resulted in a normal effective statutory tax rate of approximately 30.5% for the years ended March 31, 2021 and 2020.

The tax effects of significant temporary differences and tax loss carryforwards which resulted in deferred tax assets and liabilities at March 31, 2021 and 2020, are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Deferred tax assets:			
Liability for retirement benefits	¥1,189	¥ 1,210	\$10,809
Accrued expenses	1,155	1,117	10,500
Property, plant, and equipment	30	30	272
Supplies	1,964	1,505	17,854
License	1,257	1,272	11,427
Sales recognition for tax purposes	409		3,718
Tax loss carryforwards	558		5,072
Other	982	673	8,927
Total of tax loss carryforwards and temporary differences	7,547	5,810	68,609
Less valuation allowance for temporary differences	(294)	(295)	(2,672)
Less valuation allowance for tax loss carryforwards	(558)		(5,072)
Total valuation allowance	(853)	(295)	(7,754)
Deferred tax assets	6,127	5,514	55,700
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	3,630	2,811	33,000
Deferred gains on sales of property	956	961	8,690
Defined benefit asset	566		5,145
Other	22	24	200
Deferred tax liabilities	5,176	3,797	47,054
Net deferred tax assets	¥1,518	¥ 1,717	\$13,800

Note: Valuation allowance has increased by ¥557 million. This increase was mainly due to an increase in the valuation allowance for tax loss carryforwards of consolidated subsidiaries.

The expiration of tax loss carryforwards, the related valuation allowances and the resulting net deferred tax assets as of March 31, 2021, were as follows:

	Millions of Yen						
	1 Year or Less	After 1 Year through 2 Years	After 2 Years through 3 Years	After 3 Years through 4 Years	After 4 Years through 5 Years	After 5 Years	Total
March 31, 2021							
Deferred tax assets relating to tax loss carryforwards						¥ 558	¥ 558
Less valuation allowances for tax loss carryforwards						(558)	(558)
Net deferred tax assets relating to tax loss carryforwards							

	Thousands of U.S. Dollars						
	1 Year or Less	After 1 Year through 2 Years	After 2 Years through 3 Years	After 3 Years through 4 Years	After 4 Years through 5 Years	After 5 Years	Total
March 31, 2021							
Deferred tax assets relating to tax loss carryforwards						\$ 5,072	\$ 5,072
Less valuation allowances for tax loss carryforwards						(5,072)	(5,072)
Net deferred tax assets relating to tax loss carryforwards							

A reconciliation between the normal effective statutory tax rates and the actual effective tax rates reflected in the accompanying consolidated statement of income for the year ended March 31, 2021, with the corresponding figures for 2020, is as follows:

	2021	2020
Normal effective statutory tax rate	30.5%	30.5%
Expenses not deductible for income tax purposes	0.2	0.5
Income not taxable for income tax purposes	(0.4)	(0.5)
Tax credits for research and development costs	(5.5)	(5.7)
Inhabitant tax on per capita basis	0.2	0.3
Increase (decrease) in valuation allowance	1.9	(0.1)
Other—net	1.0	(0.3)
Actual effective tax rate	27.9%	24.7%

10. FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

(1) Group policy for financial instruments

Cash surpluses, if any, are invested in low-risk financial assets. Derivatives are not used, for speculative purposes, but to manage exposure to financial risks as described in (2) below.

(2) Nature and extent of risks arising from financial instruments

Receivables, such as trade notes and trade accounts, are exposed to customer credit risk. Marketable securities, mainly certificates of deposit, are exposed to little or no risk of market price fluctuations. Investment securities, mainly equity instruments, are exposed to the risk of market price fluctuations. Marketable and investment securities, mainly held-to-maturity securities of customers and suppliers of the Companies, are exposed to the issuer's credit risk.

Payment terms of payables, such as trade notes, trade accounts, other payables and income taxes payable, are less than one year. Payables in foreign currencies are exposed to the risk of fluctuation in foreign currency exchange rates.

The Company's derivative transactions are comprised of specific foreign exchange forward contracts. The Company has entered into foreign exchange forward contracts, as requested by customers

or based on the judgment of the purchasing department, to hedge foreign currency exchange risk specifically associated with imported merchandise. Such derivative transactions are entered into to hedge foreign currency exposures occurring within the Company's business.

(3) Risk management for financial instruments

Credit risk management

Credit risk is the risk of economic loss arising from a counterparty's failure to repay or service debt according to the contractual terms. The Companies manage their credit risk from receivables based on internal guidelines, which include monitoring payment terms and balances of major customers by the business administration and finance and accounting departments to identify the default risk of customers in advance. With respect to held-to-maturity financial investments, the Companies manage their exposure to credit risk by limiting their funding to high credit rating bonds in accordance with their internal guidelines.

Because the counterparties to derivatives are limited to major financial institutions, the Company does not anticipate any losses from credit risk.

Market risk management (foreign currency exchange risk and interest rate risk)

Foreign currency trade payables are exposed to market risk resulting from fluctuations in foreign currency exchange rates. Such foreign currency exchange risk is hedged principally by forward foreign currency contracts. The Companies have internal policies that restrict the use of derivatives only for the purpose of reducing market risks.

Marketable and investment securities are managed by monitoring market values and the financial position of issuers on a regular basis.

Liquidity risk management

Liquidity risk includes the risk that the Companies cannot meet their contractual obligations in full on maturity dates. The Companies manage their liquidity risk by holding adequate volumes of liquid assets along with adequate financial planning by the finance and accounting department.

(4) Fair values of financial instruments

Fair values of financial instruments are based on quoted prices in active markets. If quoted prices are not available, other rational valuation techniques are used instead.

(a) Fair value of financial instruments

	Millions of Yen		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
March 31, 2021			
Cash and cash equivalents	¥ 57,963	¥ 57,963	
Time deposits	807	807	
Notes and accounts receivables	40,285	40,285	
Marketable and investment securities	22,885	22,881	¥ (4)
Total	¥121,941	¥121,936	¥ (4)
Notes and accounts payables	¥ 16,615	¥ 16,615	
Income taxes payable	6,679	6,679	
Total	¥ 23,294	¥ 23,294	

	Millions of Yen		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
March 31, 2020			
Cash and cash equivalents	¥ 44,298	¥ 44,298	
Time deposits	807	807	
Notes and accounts receivables	42,412	42,412	
Marketable and investment securities	20,590	20,586	¥ (4)
Total	¥ 108,108	¥ 108,104	¥ (4)
Notes and accounts payables	¥ 16,045	¥ 16,045	
Income taxes payable	2,081	2,081	
Total	¥ 18,126	¥ 18,126	

	Thousands of U.S. Dollars		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
March 31, 2021			
Cash and cash equivalents	\$ 526,936	\$ 526,936	
Time deposits	7,336	7,336	
Notes and accounts receivables	366,227	366,227	
Marketable and investment securities	208,045	208,009	\$ (36)
Total	\$1,108,554	\$1,108,509	\$ (36)
Notes and accounts payables	\$ 151,045	\$ 151,045	
Income taxes payable	60,718	60,718	
Total	\$ 211,763	\$ 211,763	

Cash and Cash Equivalents

The carrying values of cash and cash equivalents, time deposits, notes and accounts receivables approximate fair value because of their short maturities.

Marketable and Investment Securities

The fair values of marketable and investment securities are measured at the quoted market price of the stock exchange for the equity instruments, and at the quoted price obtained from the financial institution for certain debt instruments. Fair value information for marketable and investment securities by classification is included in Note 3.

Notes and Accounts Payables and Income Taxes Payable

The carrying values of notes and accounts payables and income taxes payable approximate fair value because of their short maturities.

Derivatives

Fair value information for derivatives is omitted because fair values and unrealized gains were immaterial for the years ended March 31, 2021 and 2020.

(b) Carrying amounts of financial instruments whose fair value cannot be reliably determined

	Carrying Amount		
	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Investments in equity instruments that do not have a quoted market price in an active market	¥1,258	¥329	\$11,436

Notes to Consolidated Financial Statements

(5) Maturity Analysis for Financial Assets and Securities with Contractual Maturities

March 31, 2021	Millions of Yen			
	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years	Due after 10 Years
Cash and cash equivalents	¥ 57,963			
Time deposits	807			
Notes and accounts receivables	40,285			
Marketable and investment securities:				
Held-to-maturity securities	2,030	¥ 360	¥ 300	
Total	¥101,085	¥ 360	¥ 300	

March 31, 2020	Millions of Yen			
	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years	Due after 10 Years
Cash and cash equivalents	¥ 44,298			
Time deposits	807			
Notes and accounts receivables	42,412			
Marketable and investment securities:				
Held-to-maturity securities	2,010	¥ 290	¥ 300	
Total	¥ 89,528	¥ 290	¥ 300	

March 31, 2021	Thousands of U.S. Dollars			
	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years	Due after 10 Years
Cash and cash equivalents	\$ 526,936			
Time deposits	7,336			
Notes and accounts receivables	366,227			
Marketable and investment securities:				
Held-to-maturity securities	18,454	\$ 3,272	\$ 2,727	
Total	\$ 918,954	\$ 3,272	\$ 2,727	

11. OTHER COMPREHENSIVE INCOME (LOSS)

The components of other comprehensive income (loss) for the years ended March 31, 2021 and 2020, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Unrealized gain (loss) on available-for-sale securities:			
Gain (loss) arising during the year	¥4,737	¥(3,261)	\$ 43,063
Reclassification adjustments to profit or loss	(1,936)	(277)	(17,600)
Amount before income tax effect	2,801	(3,539)	25,463
Income tax effect	(819)	1,028	(7,445)
Total	¥1,982	¥(2,510)	\$ 18,018

	Millions of Yen		Thousands of U.S. Dollars
	2021	2020	2021
Deferred gain (loss) on derivatives under hedge accounting:			
Gains arising during the year	¥ 6	¥ 17	\$ 54
Total	¥ 4	¥ 12	\$ 36
Foreign currency translation adjustments:			
Adjustments arising during the year	¥ (92)	¥ (3)	\$ (836)
Total	¥ (92)	¥ (3)	\$ (836)
Defined retirement benefit plan(s):			
Adjustments arising during the year	¥ 262	¥ 2,207	\$ 2,381
Reclassification adjustments to profit or loss	267	456	2,427
Amount before income tax effect	529	2,663	4,809
Income tax effect	(161)	(812)	(1,463)
Total	¥ 367	¥ 1,851	\$ 3,336
Total other comprehensive income (loss)	¥2,261	¥ (650)	\$ 20,554

12. NET INCOME PER SHARE

Reconciliation of the differences between basic and diluted net income per share ("EPS") for the years ended March 31, 2021 and 2020, is as follows:

	Millions of Yen	Thousands of Shares	Yen	Dollars
	Net Income Attributable to Owners of the Parent	Weighted-Average Shares		EPS
For the year ended March 31, 2021-				
Basic EPS				
Net income available to common shareholders	¥20,702	67,353	¥307.37	\$ 2.79
For the year ended March 31, 2020-				
Basic EPS				
Net income available to common shareholders	¥16,866	67,353	¥ 250.42	

13. SUBSEQUENT EVENTS

At the general shareholders meeting held on June 28, 2021, the Company's shareholders approved the payment of a year-end cash dividend of ¥50 (\$0.45) per share to holders of record at March 31, 2021, for a total of ¥3,367 million (\$30,609 thousand).

14. SEGMENT INFORMATION

Under ASBJ Statement No. 17, "Accounting Standard for Segment Information Disclosures," and ASBJ Guidance No. 20, "Guidance on Accounting Standard for Segment Information Disclosures," an entity is required to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. Operating segments are components of an entity about which separate financial information is available and for which such information is evaluated regularly by the chief operating decision-maker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments.

1. Description of Reportable Segments

The Companies' reportable segments are those for which separate financial information is available and regular evaluation by the Company's management is performed in

order to decide how resources are allocated among the Companies. As such, the Companies' reportable segments consist of the 'Pharmaceuticals' industry and the 'Functional Food' industry. The 'Pharmaceuticals' industry consists of the manufacturing and sale of drugs for urological diseases, inflammation and allergies, hematologic malignancies, cardiovascular and metabolic diseases, gastrointestinal disorders, and other diseases. The 'Functional Food' industry consists of the manufacturing and sale of health food ingredients, preservatives, protein preparations, nutritional ingredients, seasonings and spices, sterilization cleaning agents, and others.

2. Methods of Measurement for the Amounts of Sales, Profit (Loss), Assets, Liabilities and Other Items for Each Reportable Segment

The accounting policies of each reportable segment are consistent with those disclosed in Note 2, "Summary of Significant Accounting Policies."

3. Information about Sales, Profit (Loss), Assets, Liabilities and Other Items

	Millions of Yen				
	2021				
	Reportable Segments			Reconciliations	Consolidated
	Pharmaceuticals	Functional Food	Total		
Sales:					
Sales to external customers	¥ 106,478	¥ 15,406	¥ 121,885		¥ 121,885
Total	¥ 106,478	¥ 15,406	¥ 121,885		¥ 121,885
Segment profit	¥ 25,360	¥ 774	¥ 26,134		¥ 26,134
Segment assets	105,503	11,031	116,534	¥ 80,494	197,028
Other:					
Depreciation	3,393	126	3,520	30	3,550
Increase in property, plant, and equipment and intangible assets	2,458	124	2,582		2,583

	Millions of Yen				
	2020				
	Reportable Segments			Reconciliations	Consolidated
	Pharmaceuticals	Functional Food	Total		
Sales:					
Sales to external customers	¥ 101,643	¥ 14,994	¥ 116,637		¥ 116,637
Total	¥ 101,643	¥ 14,994	¥ 116,637		¥ 116,637
Segment profit	¥ 20,686	¥ 982	¥ 21,668		¥ 21,668
Segment assets	98,808	11,218	110,026	¥ 65,175	175,202
Other:					
Depreciation	3,313	118	3,431	37	3,468
Increase in property, plant, and equipment and intangible assets	2,340	157	2,498	2	2,500

	Thousands of U.S. Dollars				
	2021				
	Reportable Segments			Reconciliations	Consolidated
	Pharmaceuticals	Functional Food	Total		
Sales:					
Sales to external customers	\$ 967,981	\$ 140,054	\$ 1,108,045		\$ 1,108,045
Total	\$ 967,981	\$ 140,054	\$ 1,108,045		\$ 1,108,045
Segment profit	\$ 230,545	\$ 7,036	\$ 237,581		\$ 237,581
Segment assets	959,118	100,281	1,059,400	\$ 731,763	1,791,163
Other:					
Depreciation	30,845	1,145	32,000	272	32,272
Increase in property, plant, and equipment and intangible assets	22,345	1,127	23,472		23,481

Note: Unallocated corporate assets included in "Reconciliations" for 2021 and 2020 are ¥80,494 million (\$731,763 thousand) and ¥65,175 million, respectively, and consisted primarily of funds, such as cash equivalents, investment securities, assets for administrative functions, and deferred tax assets.

Notes to Consolidated Financial Statements

Related Information

1. Information about Products and Services

Millions of Yen			
2021			
	Pharmaceuticals	Functional Food	Total
Sales to external customers	¥106,478	¥15,406	¥121,885

Millions of Yen			
2020			
	Pharmaceuticals	Functional Food	Total
Sales to external customers	¥101,643	¥14,994	¥116,637

Thousands of U.S. Dollars			
2021			
	Pharmaceuticals	Functional Food	Total
Sales to external customers	\$967,981	\$140,054	\$1,108,045

2. Information about Geographical Areas

(1) Sales

Millions of Yen					
2021					
Europe					Total
Japan	Switzerland	Other	Other		
¥90,144	¥28,795	¥342	¥2,603		¥121,885

Millions of Yen					
2020					
Europe					Total
Japan	Switzerland	Other	Other		
¥94,473	¥21,584	¥317	¥262		¥116,637

Thousands of U.S. Dollars					
2021					
Europe					Total
Japan	Switzerland	Other	Other		
\$819,490	\$261,772	\$3,109	\$23,663		\$1,108,045

Note: Sales are classified by country or region based on the location of customers.

(2) Property, Plant, and Equipment

Information about geographical areas is omitted, as property, plant, and equipment located in Japan accounted for more than 90% of property, plant, and equipment presented in the consolidated balance sheet as of March 31, 2021 and 2020.

(3) Information about Major Customers

Millions of Yen			
2021			
Name of Customer	Sales		Related Segment Name
	Millions of Yen	Thousands of U.S. Dollars	
Actelion Pharmaceuticals Ltd.	¥28,795	\$261,772	Pharmaceuticals
Alfresa Corporation	16,029	145,718	Pharmaceuticals
MEDICEO CORPORATION	15,957	145,063	Pharmaceuticals
Suzuken Co., Ltd.	15,097	137,245	Pharmaceuticals

2020			
Name of Customer	Sales		Related Segment Name
	Millions of Yen	Thousands of U.S. Dollars	
Actelion Pharmaceuticals Ltd.	¥21,584		Pharmaceuticals
Alfresa Corporation	18,580		Pharmaceuticals
MEDICEO CORPORATION	17,526		Pharmaceuticals
Suzuken Co., Ltd.	17,326		Pharmaceuticals

Independent Auditor's Report

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INDEPENDENT AUDITOR'S REPORT

To the Board of Directors of Nippon Shinyaku Co., Ltd.:

Opinion

We have audited the consolidated financial statements of Nippon Shinyaku Co., Ltd. and its subsidiaries (the "Group"), which comprise the consolidated balance sheet as of March 31, 2021, and the consolidated statement of income, consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies, all expressed in Japanese yen.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Group as of March 31, 2021, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

Convenience Translation

Our audit also comprehended the translation of Japanese yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made in accordance with the basis stated in Note 1 to the consolidated financial statements. Such U.S. dollar amounts are presented solely for the convenience of readers outside Japan.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in Japan. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are independent of the Group in accordance with the provisions of the Code of Professional Ethics in Japan, and we have fulfilled our other ethical responsibilities as auditors. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Member of
 Deloitte Touche Tohmatsu Limited

Independent Auditor's Report

Appropriateness of revenue recognition of milestone and royalty income	
Key Audit Matter Description	How the Key Audit Matter Was Addressed in the Audit
<p>As described in Note 14, "Segment information" to the consolidated financial statements, total consolidated sales of ¥121,885 million for the year ended March 31, 2021 included sales of ¥106,478 million for the Pharmaceuticals segment, or approximately 87% of the total consolidated sales, of which ¥24,338 million were related to revenues from industrial property rights.</p> <p>Nippon Shinyaku Co., Ltd. (the "Company") licenses out the technology for certain in-house developed products to contracting partners. The Company receives from contracting partners milestone income arising from the progress of development or when a certain amount of sales is reached. Royalty income is calculated by multiplying sales by a fixed rate, both of which represents a large portion of revenues from industrial property rights.</p> <p>While sales of merchandise and finished goods to pharmaceutical wholesalers are recorded automatically by transferring the order and shipping data generated on Japan Drug NETwork (JD-NET), which is a data exchange platform commonly used in the pharmaceutical industry, and the sales management system to the accounting system, milestone income is recorded in the accounting system manually based on reports from contracting partners when milestones are achieved. Royalty income is recorded in the accounting system manually based on reports from contracting partners related to net sales for the quarterly accounting period.</p> <p>Therefore, we considered milestone and royalty income to be of higher significance in our audit.</p> <p>Milestone and royalty income also have significant financial impact on the Pharmaceuticals segment's profit and could significantly affect investors' and shareholders' judgment of the Group's financial performance. For these reasons, we identified the appropriateness of revenue recognition of milestone and royalty income as a key audit matter.</p>	<p>Our audit procedures related to revenue recognition of milestone and royalty income from out-licensing of the technology for in-house developed products included the following, among others:</p> <ul style="list-style-type: none"> We tested the design and operating effectiveness of controls related to revenue recognition of milestone and royalty income. We inspected contracts on the technology licensing to obtain an understanding of the underlying transactions as well as the rights and obligations of the parties involved in the contracts. We evaluated the reliability of the reports reflecting the progress of development reported from the contracting partners, which is the basis for determining milestone income, by comparing it with related external evidence. We compared the sales of the Group's in-house developed products disclosed in the financial report on the contracting partner's website with those reported from the contract partners, which are the basis for determining both milestone income arising when a certain amount of sales is reached and royalty income calculated by multiplying sales by a fixed rate. We compared the amount of milestone and royalty income to the bank statement. For recorded milestone and royalty income, we tested the accuracy of amounts denominated in foreign currencies by agreeing them to reports from contracting partners and testing the mathematical accuracy by translating those amounts into Japanese yen.

Recoverability of long-term prepaid expenses related to in-licensing contracts for pharmaceuticals	
Key Audit Matter Description	How the Key Audit Matter Was Addressed in the Audit
<p>Among the lump sum payments and milestone expenditures relating to in-licensing contracts for pharmaceuticals, those that will generate probable future revenues are recorded as long-term prepaid expenses and account for a large portion of the long-term prepaid expenses of ¥9,390 million on the consolidated balance sheet as of March 31, 2021.</p> <p>The Company has entered into in-licensing contracts with pharmaceutical manufacturers. Among the expenditures related to the in-licensing contracts for products launched and substances that are new drug candidates, those determined to generate probable future revenues and expected to be highly recoverable are recorded as long-term prepaid expenses and are amortized using the straight-line method over the contract period.</p> <p>For long-term prepaid expenses related to the in-licensing contracts that were newly recorded on the consolidated balance sheet during the current year, management determined that they would generate probable future revenues based on their assessment of the profitability of the relevant pharmaceuticals. Significant assumptions used in management's assessment of the profitability are marketability and future revenue forecasts for the drug, which are based on the drug price and the number of potential patients for pharmaceuticals to be licensed in. Management predicted the number of potential patients based on external information and estimated the drug price based on relevant prices in other countries and the ratio of prices of similar drugs in Japan against those in other countries.</p> <p>As described above, estimates of the drug price and the number of potential patients, on which assessments of in-licensing contract profitability are based, depend on forecasting the future and involve judgments made by management. For this reason, we determined that the recoverability of long-term prepaid expenses for pharmaceutical in-licensing contracts is a key audit matter.</p>	<p>Our audit procedures on the recoverability of long-term prepaid expenses for in-licensing contracts included the following, among others:</p> <ul style="list-style-type: none"> We tested the design and operating effectiveness of controls over recording long-term prepaid expenses related to in-licensing contracts, including those controls related to the estimate of drug prices and potential patient numbers that provide the basis of the assessment of pharmaceutical in-licensing contract profitability. We inspected pharmaceutical in-licensing contracts to obtain an understanding of the underlying transactions as well as the rights and obligations of the parties involved in the contracts. We assessed the future drug marketability by considering the actual launch records in foreign markets. We also evaluated the progress of the drug development by inspecting the list of drug development approved by the Board of Directors and making inquiries of the company personnel responsible for the development to identify any suspension of the development. We evaluated the reasonableness of the estimated number of potential patients for the in-licensed drug, which is a significant assumption in the assessment of drug profitability, by performing an inquiry of management about their estimation method and rationale, and inspecting the underlying external data such as the number of patients for certain diseases used by management to estimate the potential patient numbers. We compared the drug price in other countries as well as the ratio of prices of similar drugs in Japan against those in other countries, both of which were the basis for estimating the drug price in Japan, with external public data. We considered whether an indication of management bias existed when management estimated future revenues, which are the basis of profitability, by comparing management's projected revenues for previous in-licensing contracts with actual results.

Independent Auditor's Report

Responsibilities of Management and Audit & Supervisory Board Members and the Audit & Supervisory Board for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern in accordance with accounting principles generally accepted in Japan and using the going concern basis of accounting unless management either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Audit & Supervisory Board members and the Audit & Supervisory Board are responsible for overseeing the Directors' execution of duties relating to the design and operating effectiveness of the controls over the Group's financial reporting process.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with auditing standards generally accepted in Japan will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with auditing standards generally accepted in Japan, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks. The procedures selected depend on the auditor's judgment. In addition, we obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain, when performing risk assessment procedures, an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate whether the overall presentation and disclosures of the consolidated financial statements are in accordance with accounting principles generally accepted in Japan, as well as the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

- 4 -

- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with Audit & Supervisory Board members and the Audit & Supervisory Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide Audit & Supervisory Board members and the Audit & Supervisory Board with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with Audit & Supervisory Board members and the Audit & Supervisory Board, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Interest Required to Be Disclosed by the Certified Public Accountants Act of Japan

Our firm and its designated engagement partners do not have any interest in the Group which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan.

Deloitte Touche Tohmatsu LLC
June 29, 2021

- 5 -

Corporate Data / Investor Information As of March 31, 2021

Corporate Data

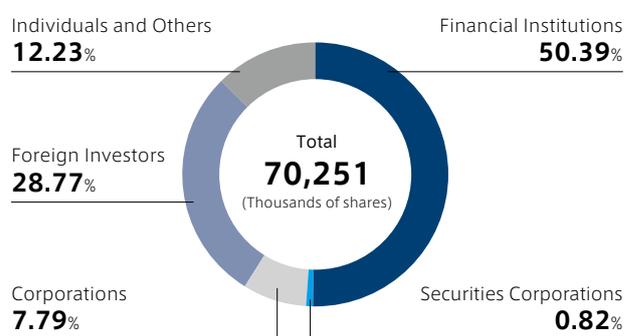
Corporate Name	Nippon Shinyaku Co., Ltd.	Representative Directors	Shigenobu Maekawa, Chairman Toru Nakai, President As of June 29, 2021
Founded	November 20, 1911	Independent and Certified Public Accountants	Deloitte Touche Tohmatsu Shijokarasuma FT Square 20, Naginataboko-cho, Shijo-dori Karasuma-higashiiru, Shimogyo-ku, Kyoto 600-8008, Japan
Date of Incorporation	October 1, 1919	Issued and Outstanding Number of Shares	70,251,484
Head Office	14, Nishinosho-Monguchi-cho, Kissshoin, Minami-ku, Kyoto 601-8550, Japan Phone: +81-75-321-1111 Facsimile: +81-75-321-0678 http://www.nippon-shinyaku.co.jp/english/	Number of Shareholders	6,252
Paid-in Capital	¥5.2 billion (Listed on the First Section of the Tokyo Stock Exchange)	Share Registrar	Mitsubishi UFJ Trust and Banking Corporation 6-3, Fushimimachi 3-chome, Chuo-ku, Osaka 541-0044, Japan



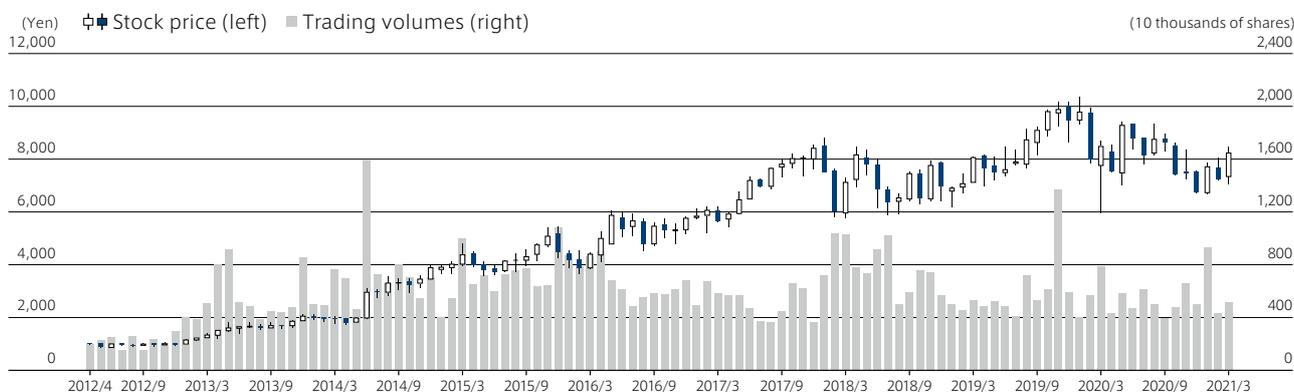
Major Shareholders

The Master Trust Bank of Japan, Ltd. (Trust account)
Meiji Yasuda Life Insurance Company
Custody Bank of Japan (Trust account)
MUFG Bank, Ltd.
The Bank of Kyoto, Ltd.
STATE STREET BANK AND TRUST COMPANY 505001
Nippon Life Insurance Company
GOVERNMENT OF NORWAY
Tokio Marine & Nichido Fire Insurance Co., Ltd.
Custody Bank of Japan (Trust account 9)

Distribution of Shares Issued



Stock Price and Trading Volumes



Network As of April 1, 2021

Main Offices

Tokyo Office	Business Offices	Sapporo, Tohoku, Kanetsu, Tokyo, Chiba/Saitama, Yokohama, Nagoya, Kansai, Keiji/Hokuriku, Chushikoku, Kyushu
	Business Branches	Asahikawa, Fukushima, Kitatohoku, Tochigi, Ibaraki, Niigata, Koshin, Josai, Jonan, Tama, Chiba, Atsugi, Shizuoka, Kobe, Himeji, Hokuriku, Okayama, Shikoku, Kitakyushu, Nishikyushu, Okinawa, Kumamoto, Minamikyushu, and others
Discovery Research Laboratories, Discovery Research Laboratories in Tsukuba, Food Development Laboratories, Yamashina Botanical Research Institute, Odawara Central Factory, East Logistic Center, West Logistic Center		

Domestic Subsidiaries

Soie Pharmaceutical Co., Ltd., Tajima Shokuhin Kogyo Co., Ltd., NS Shared Service. Co., Ltd.

Overseas Offices and Subsidiary

NS Pharma, Inc., Beijing Representative Office, London Office