

A New Way of Life

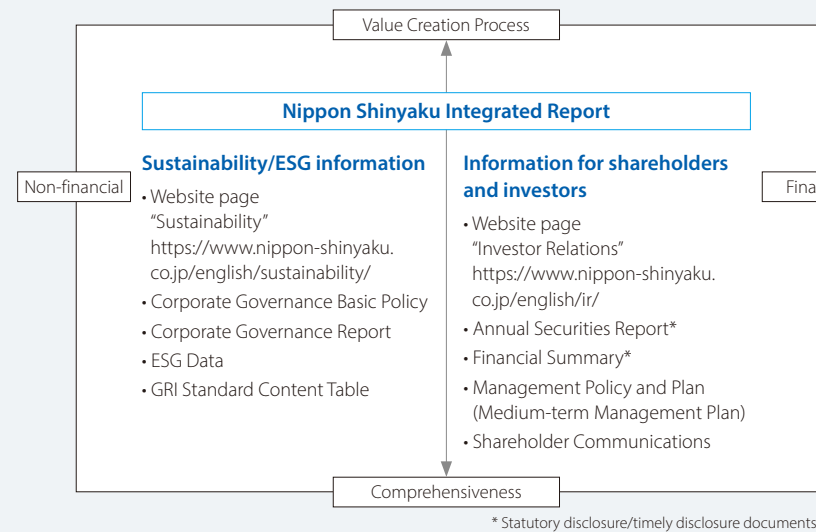
Integrated Report 2023

NIPPON SHINYAKU Co., Ltd.

■ Editorial Policy

This report provides comprehensive coverage of non-financial information, including the environment, society, and governance, in addition to financial information so that all of our stakeholders can understand the corporate value of the Nippon Shinyaku Group.

■ Information Disclosure System



■ Scope of Reporting

Period covered: Fiscal 2022 (April 1, 2022 – March 31, 2023)

* Some sections of the report discuss initiatives from April 2023 onwards.

Companies covered: Nippon Shinyaku Co., Ltd. and its Japanese and overseas group companies

* However, some sections of the report only cover Nippon Shinyaku Co., Ltd.

■ Guidelines Referenced

- Integrated Reporting Framework, International Sustainability Standards Board (ISSB)
- GRI Standards
- ISO 26000/JIS Z 26000
- Guidance for Collaborative Value Creation, Ministry of Economy, Trade and Industry



■ 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.

* As figures presented in this report have been rounded, totals may not exactly equal the sum of their composite figures.

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

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

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We will value dialogue in order to co-create well-being for each employee. ➡ P. 59

Chihiro Katagiri
Well-being Promotion Section
Personnel Department



We will deliver our unique, high-quality pharmaceuticals quickly and stably to patients around the world. ➡ P. 43

Satoshi Asano
SC Management Section
Supply Chain Management Department



I feel that the day is approaching when an intractable disease, previously said to have no treatment, becomes treatable. ➡ P. 35

Tamotsu Takeda
Representative Director
Japan Muscular Dystrophy Association



While studying abroad, I acquired know-how related to cutting-edge gene editing technology, and I now apply the technology I learned to preparing proposals for new drug discovery themes. ➡ P. 38

Tatsuhiko Arakawa
Proposal Strategy Section
Strategic Planning and Research Department

A New Way of Life

The passion for creating original drugs of quality that has been transmitted from one generation of Nippon Shinyaku personnel to the next since the company's very beginning. Nippon Shinyaku will continue contributing to the maintenance and enhancement of people's health.



I will continue to uplift as many patients as possible by conveying the importance of going through treatment and the value of Nippon Shinyaku's products. ➡ P. 47

Erina Kouno
FerrCare Product Marketing Group
Primary Care Product Marketing Department
Sales and Marketing Planning Division
Sales and Marketing Division



We put an emphasis on conveying the efficacy and safety of Viltespo based on solid evidence. ➡ P. 13

Jonathan Cabral
NS Pharma, Inc.
Head of Patient Service



I took advantage of Nippon Shinyaku's well developed childcare leave system and became keenly aware of how difficult it is caring for a child during my month-long leave. ➡ P. 55

Shunya Kaji
Hospital Team
Chuo Sales and Marketing Branch
Tokyo Business Office
Sales and Marketing Division



We have been developing applications, focusing on generation-specific nutritional issues as a priority task. ➡ P. 51

Tetsuro Yoshida
Product Development Section
Protein Business Department



As we go global with our pharmaceutical distribution, we will respond with quality management in conformance with each country's regulations and requirements. ➡ P. 44

Shohei Nakagawara
Quality Assurance Section
Quality Assurance Department
Regulatory Affairs, Pharmacovigilance and Quality Assurance Division



I began to think carefully about the meals I eat after the experience of cooking three meals a day and a serious injury. ➡ P. 49

Mika Shibata
Japan women's volleyball team

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.

At a Glance

Nippon Shinyaku's two businesses are Pharmaceuticals and Functional Food. In the Pharmaceuticals business, the Company aims to deliver high-quality, distinctive pharmaceuticals as quickly as possible to even one more patient.

In the Functional Food business, it aims to continually provide high-value-added products that meet market needs and help people lead happier lives.

Pharmaceuticals

Revenue
¥121.988 billion

84.6%

(FY2022)

Strategy

In the Pharmaceuticals business, since Nippon Shinyaku announced its intention in 2007 to “launch at least one product each year,” it has been consistently achieving this goal by not only undertaking in-house drug discovery based on the R&D capabilities built up since the founding of the company in 1919 but also introducing in-licensed products and undertaking PLCM*. The Sales and Marketing Division aims to deliver medicines required by patients as quickly as possible by sharing high-quality information and building a system to quickly respond to the needs of medical professionals.

The Company also proactively takes on challenges in fields that other companies avoid and moves forward with research and development of original treatments to create distinctive pharmaceuticals required by patients suffering from disease and their families and to be a company that is trusted by society.

* PLCM (product life-cycle management) is a way to increase the value of products through efforts such as pursuing new efficiency and adding new dosage forms for products on the market and drug candidates still in development.

Main Products

1. Urology

- For urinary disorder caused by benign prostatic hypertrophy
Zalutia
- For erectile dysfunction (ED)
Cialis
- For prostate cancer
Estracyt
- For pollakiuria
Bladderon
- For benign prostatic hypertrophy
Eviprost



Zalutia

2. Hematology

- For sinusoidal obstruction syndrome
Defitelio
- For CD20-positive follicular lymphoma or CD20-positive chronic lymphocytic leukemia
Gazyva
- For myelodysplastic syndromes or acute myeloid leukemia
Vidaza
- For relapsed or refractory acute promyelocytic leukemia
Amnolake
- For relapsed or refractory acute promyelocytic leukemia
Trisenox



Defitelio

- For acute leukemia and malignant lymphoma
Cylocide N
- For solid tumor and acute leukemia
Cylocide

3. Intractable and Rare Diseases

- For seizures associated with Dravet syndrome
Fintepla
- For Duchenne muscular dystrophy
Viltepso



Fintepla

- For pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension
Uptravi
- For pulmonary arterial hypertension
Opsumit
- For pulmonary arterial hypertension
Adcirca

4. Gynecology

- For iron deficiency anemia
MonoVer
- For dysmenorrhea
Lunabell ULD



MonoVer

- For dysmenorrhea
Lunabell LD

5. Others

- Dry powder inhaler for allergic rhinitis
Erizas
- Gargle liquid containing azulene
Azunol Gargle Liquid
- For allergic rhinitis and conjunctivitis
Livostin
- For vertigo
Cephadol



Erizas

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



Onetram

Functional Food

Revenue
¥22.187 billion

15.4%

(FY2022)

Strategy

In the Functional Food business, Nippon Shinyaku seeks to leverage its advanced technical expertise as a maker of pharmaceuticals to supply high-value-added products that meet market needs, focusing on supplements in addition to its bulk materials businesses in health food ingredients, preservatives, and protein preparations. The Company will “Help People Lead Healthier, Happier Lives,” through approaches other than pharmaceuticals, including by taking on the challenge of dealing with social issues, such as food loss, and contributing to better health through health food ingredients and supplements. It will show meaningful existence and contribute to the extension of healthy life expectancy for people by reinforcing its R&D capabilities and continually bringing to market highly original new products.

Main Products

Bulk Materials Business

1. Health Food Ingredients

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

2. Preservatives

- Mirai Ace Nu
- Vinessyu Deli
- Mikaku Fine S
- Mikaku Fine BK
- Mikaku Fine Z

3. Protein Preparations

- Wheyco W8002 Instant
- Lactocrystal plus
- PROGEL 800
- Enlacto HG
- Fitness S

Supplements Business

1. Sports Supplements

- WINZONE series

2. Aging Care Supplements

- Kiwami Select Collagen
- Kioku no Kobako
- Mangostia



Supplements

Revenue

¥144.175 billion

Increase of 4.9%
year on year ↑

Operating profit

¥30.049 billion

Decrease of 8.8%
year on year ↓

Profit attributable to owners of parent

¥22.812 billion

Decrease of 8.7%
year on year ↓

Research and development expenses

¥24.135 billion

Increase of 5.6%
year on year ↑

EPS

¥338

Decrease of 8.7%
year on year ↓

ROE

12.1%

Decrease of
2.4 percentage points
year on year ↓

Breakdown of revenue by region

Overseas ¥49.145 billion 34.1% Japan ¥95.029 billion 65.9%

(FY2022)

Message from the President

Nippon Shinyaku provides high-quality, unique products through its Pharmaceuticals business and Functional Food business. In the Pharmaceuticals business, we will create innovative new drugs for patients suffering from illnesses, focusing mainly on disease areas with unmet treatment needs, and ensure that these drugs are delivered to patients. In the Functional Food business, we will provide new value that will be recognized by society through high value-added products that meet market needs. To this end, we will promote global expansion while pursuing even more originality, with the aim of becoming a company with a meaningful existence in the global healthcare field.

FY2022 review

While various restrictions on activity due to the COVID-19 pandemic have eased and socioeconomic activities are showing signs returning to normal, the economic outlook remains uncertain due to soaring prices of energy resources and raw materials. Under these circumstances, consolidated revenue for FY2022 totaled ¥144.1 billion, a record high for the 13th consecutive year. On the other hand, both operating profit and profit attributable to owners of parent declined; however, this was due to a one-time factor, namely, loss of one-time revenue from the sale of the priority review voucher in the previous fiscal year, and we believe that we are essentially maintaining our growth trajectory. Total equity as of the end of FY2022 was ¥195.9 billion, and the ratio of equity attributable to owners of parent to total assets was 82.4%, maintaining a high degree of financial soundness.

In the Pharmaceuticals business, in Japan we launched Fintepla for the treatment of epileptic seizures in patients with Dravet syndrome in November 2022, and MonoVer for the treatment of iron deficiency anemia in March 2023; and obtained regulatory approval for a humanized anti-CD20 monoclonal antibody Gazyva for an additional indication of chronic lymphocytic leukemia in December 2022. As for Viltepso, a treatment for Duchenne muscular dystrophy (DMD) already marketed in Japan and the U.S., we presented long-term data (four years from the beginning of treatment) from a clinical trial conducted in North America at the World Muscle Society in October 2022, thus providing new information to medical professionals.

In the Functional Food business, we launched a new product in our WINZONE series of sports supplements, as well as the anti-aging care supplement Kiwami Select Collagen, which was designed to meet the diverse needs of customers in terms of flavor, quality, and functionality.

Where and how to develop business in order to fulfill our business philosophy

In fulfilling Nippon Shinyaku's business philosophy of Helping People Lead Healthier, Happier Lives, I focus on the "where" and "how" of our future business development and resolution of social issues.

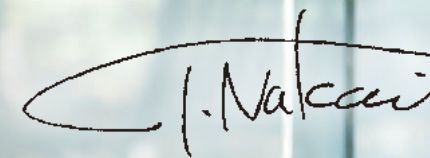
In the Pharmaceuticals business, "where" refers to disease areas where other companies are not focusing their efforts and where treatment needs have not yet been fully met. "How" refers to the provision of new drugs and value by leveraging new modalities such as gene therapy in addition to our unique fundamental technologies for drug discovery related to small molecule compounds and nucleic acid drugs.

As a manufacturer of new drugs, one of our challenges is to obtain returns on major investments that are essential in promoting our business activities, such as R&D expenses. We believe that we can solve this problem by expanding our business globally in order to deliver needed drugs to patients around the world who are suffering from diseases.

In the Functional Food business, we leverage our advanced technical expertise as a pharmaceutical company to supply highly original products in the bulk materials business for health food ingredients, preservatives, and protein preparations, as well as in the supplements business. Going forward, we will promote global expansion, with a focus on East Asia and Southeast Asia, where economic growth is remarkable.

➡ P. 22 Value Creation Process

We will continue to promote global expansion to deliver satisfaction to patients around the world and all those who support them.



Toru Nakai
Representative Director, President

Message from the President

Revision of issues of materiality

In 2021, Nippon Shinyaku identified its issues of materiality as matters deemed important for solving social issues and creating value. In recent years, as social conditions and the environment surrounding our Company have changed significantly and sustainability has become even more important, we revised the issues of materiality in March 2023. In proceeding with the revision, we considered the future of Nippon Shinyaku and thoroughly discussed what the issues are, what needs to be addressed, and what we should do to solve these issues. Going forward, we will continue to revise our issues of materiality on an ongoing basis in order to respond flexibly to changes in the social environment and to create sustainable value.

➡ P. 20 Materiality

Human resources to support sustainable growth

Employees are a company's most important asset. As a manufacturer of new drugs, we believe that developing diverse human resources and realizing employee well-being is essential for creating innovation and realizing sustainable growth, which was established in the revision of issues of materiality.

To cite an example of human resource development, we have launched the NS Academy, a new human resource development program that values self-directed learning, in order to provide an environment in which each individual can learn autonomously with their own future in mind, as opposed to the conventional method of putting all employees through the same training program. In addition, we are also recruiting highly specialized mid-career hires, with a particular focus on those who will promote global expansion.

Nippon Shinyaku also puts effort into promoting health and ensuring safety in the workplace so that our employees can lead happier and better lives, and in FY2022, we established the Well-being Promotion Section. The Well-Being Promotion Section is based on the three axes of "knowing your own well-being," "knowing the well-being of those around you," and



"deepening your understanding of well-being," and is working to promote well-being internally through messages from the president and various events such as online courses. In addition, we will continue to discuss with outside advisors about how we should promote well-being at Nippon Shinyaku.

➡ P. 52 Human Resources Development

Promoting patient-centered business activities

In order to share our mission and values throughout the organization, I make a point to use the term "patient centricity" in the hopes of promoting patient-centered activities. Therefore, when we revised our issues of materiality, we explicitly described the concept of patient centricity and the activities that lead to it.

Due to the highly specialized nature of the healthcare field, there are very large disparities in the amount of information and knowledge between patients and medical professionals, such as doctors. In the U.S., pharmaceutical companies can advertise prescription medicines to patients, and NS Pharma, our Group company in the U.S., provides information to patients through events organized by patient organizations. In Japan, pharmaceutical companies are currently restricted from providing information on prescription medicines directly to patients, but the industry as a whole is beginning to consider business activities that incorporate patients' perspectives. At Nippon Shinyaku, we have launched a

cross-divisional project to examine which specific activities promote patient centricity. In addition, we are fostering the awareness of each and every employee to incorporate patient feedback into our corporate activities. For example, the industry is considering initiatives such as conducting clinical trials without the use of placebos, especially in Phase III trials, for patients with serious diseases. Through communication with patients, their families, and patient organizations, we are also considering clinical trial protocols that take the patient's perspective into account.

Currently, DMD patients in countries and regions other than Japan and the U.S. who wish to receive Vilepso must participate in clinical trials, but their participation may be restricted due to age and other requirements. In 2021, in order to provide the drug continuously to patients who are unable to participate in clinical trials or who have completed clinical trials, we implemented the Vilepso Managed Access Program. In addition to aiming for early approval in countries and regions outside of Japan and the United States, we will make Vilepso available to as many patients as possible around the world as soon as possible through this managed access program.

Three commitments to achieve medium- and long-term growth

In order to keep pace with the diversification of drug discovery modalities, the globalization of the market, and the diversification of individual work styles and values, I set out our three commitments when I became president in 2021: Continue to launch at least one unique product each year; generate at least 50% of consolidated sales from overseas; and, target at least 100% gains in sales and operating profit.

Continuously launch new products to increase corporate value

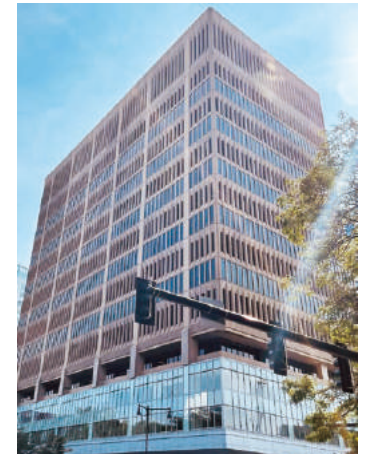
For R&D-led new drug manufacturers, corporate value is largely determined by the development pipeline, which is the driver for future growth. In a few years, the patent for Upravi, which has been driving Nippon Shinyaku's growth, will expire. Since it

is necessary to continuously launch new products to overcome this patent cliff, we are expanding our development pipeline through three R&D approaches: in-house drug discovery, in-licensing, and product life-cycle management (PLCM).

As for drugs discovered in-house, our new nucleic acid drugs for DMD following Vilepso, NS-089/NCNP-02 and NS-050/NCNP-03, have advanced to the clinical trial stage. In the area of small molecule compounds, NS-018 for myelofibrosis, NS-580 for endometriosis and chronic prostatitis/chronic pelvic pain syndrome are in Phase II trials; NS-229 for eosinophilic granulomatosis with polyangiitis is in preparation for Phase II trials; and NS-161 for inflammatory diseases and NS-025 for urological diseases are in Phase I trials. In addition, we have established a new overseas R&D center, Innovation Research Partnering (IRP), in Cambridge, Massachusetts. By increasing our access to the world's most advanced drug discovery and other technologies, we expect to accelerate our in-house drug discovery research and build a more diverse R&D portfolio.

We are also actively investing in licensing activities, including in-licensing and alliances for products on the market and drug candidates still under development. For the cell therapy CAP-1002, for which Capricor Therapeutics, Inc. is currently conducting Phase III trials in the U.S. for DMD, we entered into an exclusive partnership for distribution in the U.S. in January 2022, and for distribution in Japan in February 2023. As for progress in Japan, in June 2023, we filed an application for the approval of NS-87 for the expected indication of high-risk acute myeloid leukemia. In the same month, our partner company UCB S.A. filed an application for an additional indication of Fintepla for Lennox-Gastaut syndrome.

In the area of PLCM, we are expanding the indications of Upravi (NS-304) for pediatric pulmonary arterial hypertension



Building where IRP office is located

Message from the President

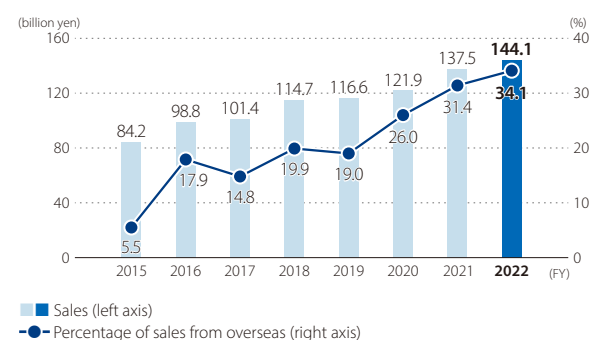
and arteriosclerosis obliterans, and Gazyva (GA101) for lupus nephritis and pediatric nephrotic syndrome. We will continue to actively develop additional indications and new dosage forms to meet the needs of patients and the medical practice field, and try to maximize the value of our products.

➡ P. 34 Pharmaceuticals Business

Promote global expansion through our own marketing and collaboration with partner companies

In Japan, the pharmaceutical market is experiencing sluggish growth due to a declining population and policies to curb medical expenses, such as the annual price revision by MHLW. However, Nippon Shinyaku aims to achieve sustainable growth by promoting global expansion and increasing the ratio of overseas sales. In overseas markets, for disease areas where the estimated number of patients is above a certain level, we will prioritize collaboration with partner companies that have a broad sales network. On the other hand, for disease areas where the number of patients is very small and the number of medical facilities to which we provide information is relatively limited, we are considering strategies that could include our own marketing. To give a specific example, Uptravi is currently sold in more than 70 countries overseas by our partner company to which it is out-licensed. As for Viltepso, I myself was stationed in the U.S. and spent about two and a half years establishing our own marketing system for the product. Although the launch of Viltepso in the U.S. market was slightly delayed due to the impact of the COVID-19 pandemic, our overseas sales ratio in FY2022 reached approximately 34%. We will strive to achieve our overseas sales ratio target of 50% as soon as possible by carefully analyzing regulatory approval

Sales and percentage of sales from overseas



systems and drug pricing systems and aggressively developing products in other countries and regions, including Europe and China.

➡ P. 12 Global Expansion

Toward strengthening our foundation for medium-to long-term growth

FY2023 is the final year of the 6th Medium-term Management Plan and also the formulation year of the 7th Medium-term Management Plan. During the 6th Medium-term Management Plan period, revenue was affected by the COVID-19 pandemic, but we made the decision to invest for future growth without reducing R&D expenditures in order to promote global development of nucleic acid drugs and other products. We believe that the increase in the percentage of in-house developed products in our development pipeline is the result of our aggressive R&D efforts. In addition, we were able to build a foundation for global expansion by establishing our own marketing system for Viltepso in the U.S. and establishing Group companies in China for the purpose of building our own marketing system there. We believe that we have been able to firmly address what needed to be addressed, and that we have been able to build a management foundation and identify issues for the next medium-term management plan.

Strengthening the foundation for making profits not only in the Japanese market but also in the global market will continue to be a major theme for us. We hope to clearly draw up in our 7th Medium-term Management Plan the roadmap that will serve as the foundation for becoming a company with sales of ¥300 billion and, in the future, a company with sales of ¥500 billion.

➡ P. 24 Medium-term Management Plan

Aiming to solve management issues by further promoting DX

Nippon Shinyaku obtained the DX certification from the Ministry of Economy, Trade and Industry of Japan in March 2022 and established the DX Division in the following April to



promote company-wide digital transformation (DX). The Digital Transformation Promotion Committee, which I chair, was established to visualize management and operational issues and solve them through the use of digital technology and data. The committee is working on a top-down basis to determine important DX themes that will serve management and to achieve them. Currently, there are 16 DX themes related to R&D, sales activities, production activities, etc. in progress. In the area of R&D, we are considering initiatives such as actively using AI to search for new compounds and using wearable devices to confirm drug efficacy. For production, we have begun using AI in demand forecasting and are also moving forward with a connected factory design that utilizes AI and IoT. These efforts have only just begun, but we intend to accelerate the transformation by focusing on training data scientists and other human resources who will be responsible for promoting DX.

In addition, we have formed a DX Team consisting of members with high IT literacy, aiming to visualize and solve business issues on-site in each department as a bottom-up activity. In FY2022, we planned the DIS* Challenge 2022 to foster a company-wide culture of taking on challenges. The ideas proposed in this project are reviewed by outside experts

and the DX Division, and those ideas that receive high evaluations are being implemented in our operations.

* DIS: Abbreviation for "digital ideas for smiles," a project to come up with DX ideas to bring smiles to people.

Message to stakeholders

I encourage all employees to step out of their comfort zone and into their learning zone, to keep challenging themselves to grow for the sake of bringing smiles to patients. In a rapidly changing society, we must envision what lies ahead, create new challenges, and move forward along the path less traveled. People grow by stepping out of their current comfort zone and placing themselves in a learning zone. We will build an organization that encourages taking on challenges more than ever before, including new personnel system reforms.

We will work to meet stakeholder expectations by engaging in active communication and dialogue about our efforts. I ask all stakeholders for their continued understanding and support for Nippon Shinyaku.

Global Expansion

Viltepso, a treatment for Duchenne muscular dystrophy (DMD) which received accelerated approval from the U.S. Food and Drug Administration (FDA) in August 2020, is the first product we marketed ourselves in the United States. In order to further expand the global business, Nippon Shinyaku has worked in collaboration with NS Pharma, Inc. (NSP), a Group company located in New Jersey in the United States, to strengthen research and development, supply chain, medical affairs, and marketing structures. In building the research and development structure at NSP, we actively employed human resources with experience in development related to rare diseases, as well as those with experience in handling regulatory affairs with the FDA. Moreover, in terms of the marketing structure, in addition to the sales and marketing department familiar in Japan, we established the departments needed for promoting sales in the United States, including the Market Access Department for direct negotiations with insurance companies and the Patient Support Department that helps patients and their families with drug delivery.

➡ P. 34 Pharmaceutical Business R&D

➡ P. 42 Pharmaceutical Business Resource Procurement, Production & Assurance

R&D and Business Development Activities in the United States

Nippon Shinyaku is developing multiple products in global trials, including Viltepso and subsequent exon skipping drugs. NSP serves the role of a global base for Nippon Shinyaku's clinical development and business development activities, and collaborates closely with Nippon Shinyaku on a daily basis in managing clinical trials as well as licensing and alliance activities. In addition to these roles, in January 2023, NSP opened the new Innovation Research Partnering (IRP) office in Cambridge Innovation Center (CIC) located in Cambridge in the United States, said to be one of the biggest innovation transmission centers. The Boston area of the United States lies at the heart of an ecosystem in which diverse players, including government, universities, research organizations, private-sector companies, and financial institutions, collaborate with each other to create constant innovation. By locating our own drug discovery seeds and technology search base here, we aim to accelerate our in-house drug discovery research and build a richly diverse research and development portfolio by increasing our access to world-leading drug discovery technologies and seeds and our opportunities for co-creation with world-class scientists leveraging open innovation.

Marketing Activities in the United States

Drug cost reimbursement in the United States

Since Japan has a national health insurance system, patients can receive medical services for a certain co-payment whichever medical institution they attend. However, in the

United States, individual patients are enrolled in private and public insurance, and co-payment amounts also vary. There are also a certain number of patients with no insurance.

Against this background, in the United States, pharmaceuticals are not always prescribed in accordance with a physician's treatment plan. If the insurer does not approve drug reimbursement, the patient covers the full cost of the drug out-of-pocket, which makes the process leading up to actual prescribing difficult. Therefore, pharmaceutical companies negotiate drug reimbursement with individual insurers, and the Market Access Department plays this role at NSP. The Market Access Department worked to establish favorable reimbursement policies (criteria for allowing insurance reimbursement) for the reimbursement of Viltepso drug costs by negotiating mainly with the major private- and public-sector insurers.

NS Support, a comprehensive patient support service

In order to receive insurance reimbursement for Viltepso, patients must attend a specialist medical institution for genetic testing and motor function evaluations. Due to the vast size of the United States, many patients find it difficult to attend such medical institutions regularly in addition to frequent visits for the administration of the drug. Consequently, many of these patients receive in-home administration of Viltepso. In these cases, making practical arrangements for drugs and coordination with hospitals is essential, but maintaining these arrangements for weekly administration is a major burden. As the actual insurance reimbursement procedures are all different depending on the insurer, it is necessary to look into the procedure first, and the work involved in making an application is a major burden for

both medical professionals and patients and their families. To alleviate these burdens, NSP offers a comprehensive patient support service called NS Support led by the Patient Support Department. Through this service NSP provides medical professionals, patients, and their families with guidance and support on insurance reimbursement procedures and help with practical arrangements related to drugs and nurses for in-home infusion treatments.



Overview of Marketing Activities

NSP engages in detailing activities for health professionals to provide information on Viltepso. Detailing activities using online interviews have become more widespread, partly due to the impact of COVID-19, and face-to-face interviews are also conducted alongside detailing activities at the moment. We published the four-year, long-term administration data on



Jonathan Cabral
NS Pharma, Inc.
Head of Patient Service

Helping patients and their families navigate many challenges

I have three main responsibilities. First, to manage NS Support; second, to manage the Patient Engagement Leads (PELs*); and third, to collaborate and support the patient advocacy group.

The most challenging part of the job is to help patients and their families navigate the many challenges of getting on and staying on Viltepso. These families have complex lives with many difficulties beyond Viltepso that take their time and attention. PELs speak directly with patients and their families, and they provide appropriate information. Many stakeholders including parents of patients and patient advocacy groups have a strong desire to cure their child's disease. NSP is committed to communicating the safety and efficacy of Viltepso based on solid evidence.

* PEL (Patient Engagement Lead): Responsible for providing total information and support to patients, including daily lives.

Global Expansion

Viltepso as an academic paper in May 2023, and, in addition to the academic activities conducted by the Medical Affairs Division so far, the Sales and Marketing Division has also started detailing activities utilizing this data. The Market Access Division and the Patient Support Division are also actively making use of the data to explain Viltepso's long-term effects and safety data to insurers, patients and their families.

The Supply Chain Department maintains close communication with 3PL providers*, medical facilities, specialty pharmacies, and companies that provide in-home drug administration services to ensure patients receive Viltepso at the required time and place, with a commitment to timely delivery and stable supply. The department is also seeking to establish a function as a supply center for other countries and regions besides the United States, in the future, such as Europe.

* 3PL provider (third party logistics provider): A company that is contracted to execute comprehensive logistics services, including the storage and delivery of products

Development of DMD Therapeutic Agents to Follow Viltepso

In DMD, dystrophin proteins are not produced due to dystrophin gene mutations. This causes progressive muscle strength deterioration leading to motor dysfunction and finally decline in respiratory and cardiac functions.

Nippon Shinyaku has been engaged in research and development of nucleic acid drugs for many years. An exon

skipping drug binds to a specific exon in a precursor of messenger RNA (pre-mRNA), removing the specific exon during the splicing process (exon skipping). This allows production of a shortened, but still functional, dystrophin protein. A variety of different genetic mutations are found in DMD. Viltepso is an exon 53 skipping drug, and approximately 8% of all DMD patients have a genetic mutation amenable to exon 53 skipping. Nippon Shinyaku is promoting research and development of other exon skipping drugs so that treatment opportunities can be offered to DMD patients with different genetic mutations.

At present, we are conducting clinical development in Japan and the United States for exon 44 and exon 50 skipping drugs as nucleic acid drugs to follow Viltepso. Besides these, we are also promoting research into exon 51, exon 45, and exon 55 skipping drugs with the aim of clinical development. If all these treatments are released in the future, it will be possible to offer therapeutic agents, including Viltepso, to around 40% of DMD patients.

Furthermore, to offer treatment opportunities to the remaining 60% of patients using modalities other than nucleic acid drugs, we are promoting research into gene therapy, and we have entered into a partnership with Capricor Therapeutics for the commercialization and distribution of CAP-1002, a cell therapy, in the United States and Japan.

Gene therapy for DMD is a method of treatment that involves administering a viral vector containing the microdystrophin (miniaturized dystrophin) gene into the

human body. At present, we believe that the main patients eligible for gene therapy will be DMD patients who are ambulatory and cannot be treated with exon skipping drugs.

CAP-1002 is a therapeutic drug that involves administering cells that secrete exosomes (extracellular vesicles), which act to reduce oxidative stress, inflammation, and fibrosis and promote increase in myocyte generation. Capricor Therapeutics is currently conducting a Phase III trial of CAP-1002 for non-ambulatory DMD patients in the United States. Unlike exon skipping agents such as Viltepso, CAP-1002 can be administered regardless of the type of genetic mutation, and is expected to be widely used among DMD patients, primarily non-ambulatory patients.

Going forward, we will continue working to expand our treatment lineup to ensure that more DMD patients can receive the best treatment in accordance with their different genetic backgrounds and degrees of disease progression. Making maximum use of our experience in global clinical development and our own marketing structure in the United States in addition to Japan cultivated through the launch of Viltepso, we will continue to deliver treatments to as many DMD patients as possible, as quickly as possible.

Further Accelerating Global Expansion

Efforts to obtain approval in more countries

Viltepso received conditional accelerated approval in the United States based on the results of Phase I/II trials in Japan and the Phase II trial in North America. Going forward, in order to expedite approval in countries around the world, we will submit applications for approval in countries where it is possible utilizing data from the Phase II trials conducted by Nippon Shinyaku and NSP to date and the Phase III global trial currently underway.

In terms of obtaining approvals in Europe and China, as a result of discussions with the relevant regulatory authorities, it was decided to submit applications for approval based on the results of ongoing global Phase III trial. In September and November of 2021, we established Beijing Nippon Shinyaku Co., Ltd. and Tianjin Nippon Shinyaku Co., Ltd., respectively, to promote the expansion of our China business, including the application for approval. Going forward, through these two group companies in China, we will put in place a system to provide Viltepso to patients and medical institutions that

need it in China. In Europe, we are considering a range of options, including building our own marketing structure or a strategic alliance with a partner company. With regard to submitting applications for approval in other regions, we are engaging in consultation and verification with the relevant authorities in individual countries on approval requirements and other matters.

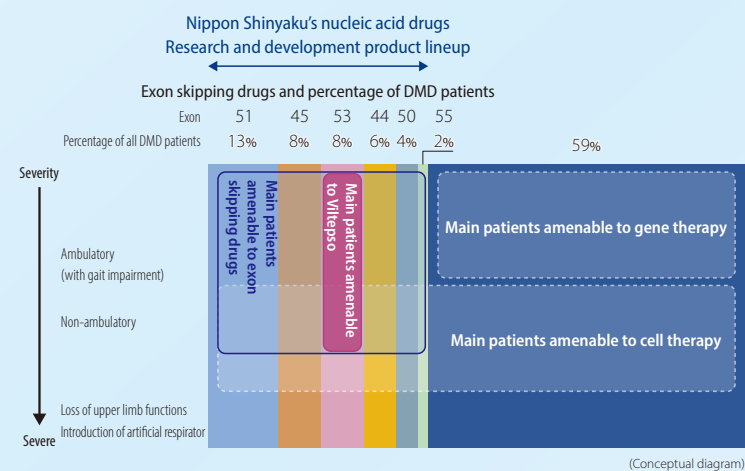
Supply program in countries where Viltepso is not yet approved

Currently, Viltepso is marketed in Japan and the United States only. When patients in other regions wish to receive Viltepso, one way to do so is by participating in clinical trials conducted by us and NSP. There are clinical trial sites around the world, but patients who can participate in clinical trials are limited by age restrictions and other enrollment requirements. In addition, even if patients are able to participate in clinical trials, there are concerns about no longer having the opportunity to receive Viltepso during the period from the completion of drug administration as part of the trial until approval is received in their respective countries. Therefore, we launched the "Viltepso Managed Access Program" in 2021 in order to provide the drug on an ongoing basis for patients who have participated in and completed clinical trials, as well as to those who are unable to participate.

By developing and delivering treatments in areas and fields with unmet treatment needs, Nippon Shinyaku aims to realize a society in which patients and their families around the world can live with smiles on their faces.

Upravi, a product discovered and developed in-house and launched in the United States in 2016, is now sold in over 70 countries through partner companies and has become a blockbuster product with sales in excess of \$1.0 billion a year. For Viltepso, which we launched in the United States in 2020, we developed our own marketing structure based on NSP, and sales surpassed ¥10.0 billion in FY2022. As this shows, we consider collaboration with partner companies or marketing products ourselves for each product and country to deliver the drugs required by patients around the world in the optimum way.

Patients amenable to skipping



Research and development products for DMD

Development products	Targets	Non-clinical	PI	PII	PIII	Launch
NS-065/NCNP-01 (viltolarsen)	Exon 53				PIII Underway	
NS-089/NCNP-02	Exon 44			PII In preparation		
NS-050/NCNP-03	Exon 50			PI/PII In preparation		
NS-051/NCNP-04	Exon 51					
Exon 45 skipping	Exon 45					
Exon 55 skipping	Exon 55					
CAP-1002	-					
Gene therapy	-					

History of Nippon Shinyaku

Nippon Shinyaku, as an R&D-led new drug manufacturer, has continued to create unique new drugs that are needed in every era to help people lead healthier and happier lives. The foundation of the Company's success is its venture spirit and pursuit of originality, which is reflected in the words of its founder, "Making Japanese medicines with Japanese hands."

FY1966

¥5.164 billion

Surpassed ¥5 billion in sales

Founding period–1969
Establishment of a business foundation focused on prescription medicines

- 1919** Founding
- 1940** Launch of Santonin, a vermicide for roundworms manufactured in Japan
- 1961** Start of Functional Foods business
- 1964** Completion of Odawara plant (now Odawara Central Factory)
- 1967** Completion of new premises at the Tokyo Business Office



Odawara plant (now Odawara Central Factory)

FY1992

¥50.534 billion

Surpassed ¥50 billion in sales

1970–1999
Venturing into global business development and drug discovery

- 1971** Launch of Cylocide for solid tumor and acute leukemia
- 1982** Completion of the Main Central Research Lab (now Building No. 1 of Discovery Research Laboratories)
- 1991** Opening of Düsseldorf Office
- 1994** Completion of Building No. 2 of the West Discovery Research Laboratories (now Building No. 2 of Discovery Research Laboratories) at the head office
- 1997** Opening of New York Office (transformed into the local subsidiary NS Pharma Inc. in 1999 and then moved to New Jersey in 2002)



Main Central Research Lab (now Discovery Research Laboratories Building No. 1)

FY2013

¥76.517 billion

Surpassed ¥75 billion in sales

2000–2013
Reinforcement of business foundation to respond to drastic changes in conditions

- 2000** Establishment of Business Philosophy and Management Policy
Start of the 1st Medium-term Management Plan
- 2007** Establishment of Guidelines for Action (Challenge, Speed, Investigation)
- 2011** Launch of Vidaza for myelodysplastic syndromes
- 2011** Opening of the Beijing Representative Office



Discovery Research Laboratories in Tsukuba

FY2017

¥101.448 billion

Surpassed ¥100 billion in sales

FY2022

¥144.175 billion

13th consecutive fiscal year of sales growth

2014–Present
Aiming for global recognition as a manufacturer in the healthcare field

- 2016** Launch of Upravi for pulmonary arterial hypertension (PAH) in the U.S.
- 2020** Launch of Viltepso for Duchenne muscular dystrophy in Japan and the U.S.
- 2021** Establishment of Chinese subsidiaries Beijing Nippon Shinyaku Co., Ltd. and Tianjin Nippon Shinyaku Co., Ltd.
- 2023** Establishment of Innovation Research Partnering, a drug discovery center in the U.S.



NS Pharma

Founding period–1969

In 1940, Nippon Shinyaku succeeded in manufacturing Santonin in Japan, a vermicide for roundworms, which contributed greatly to the reduction of Japan's roundworm infection rate and to the growth of Nippon Shinyaku's business performance. In the 1960s, Nippon Shinyaku diversified its prescription medicines-related activities by creating new drugs through the expansion of its R&D system, including the completion of a new research laboratory, and by introducing products through alliances with overseas companies. It also started its food business at this time. The Company built its business foundation by completing construction of the Odawara plant and building a network of sales bases.

1970–1999

Nippon Shinyaku strengthened its R&D structure by establishing the Main Central Research Lab (now Building No. 1 of Discovery Research Laboratories) and other facilities that comply with GLP standards that ensure the safety and appropriateness of non-clinical studies. In the 1990s, the Company opened offices in Germany and the U.S. and promoted internationalization through business expansion in Japan, the U.S., and Europe. It launched unique new products in the fields of gastroenterology, cardiology, urology, and otorhinolaryngology, and concentrated business resources into the cultivation of mainstay drugs. In the food business, the Company began providing health food ingredients.

2000–2013

In addition to clearly stating its Business Philosophy and Management Policy, Nippon Shinyaku formulated a medium-term management plan to clarify its corporate vision. It invested business resources in focal areas such as urology and hematology, and invested resources in research on nucleic acid drugs at the Discovery Research Laboratories in Tsukuba. By proactively searching for unmet medical needs, the Company has continuously launched products in areas not often handled by major companies, and some of these products have grown to become business drivers.

2014–Present

Under the theme of "pursuit of originality" set forth in the management strategy of the 5th and 6th Five-Year Medium-term Management Plans, Nippon Shinyaku has worked to build a unique foundation by continuously launching new products. These include a small molecule compound and a nucleic acid drug discovered in-house that have achieved global expansion, and have led to the establishment and development of a new business model for the Company, such as starting its own marketing by NS Pharma in the U.S. Nippon Shinyaku will continue to further promote its global business and aim to become a manufacturer that is globally recognized in the healthcare field.

Risks and Opportunities

To grow sustainably, the Nippon Shinyaku Group identifies risks and opportunities by analyzing social conditions, the market environment, and our internal condition. The identified issues are being addressed by the relevant departments, and each department will formulate quantitative and qualitative targets and promotion plans to achieve the targets in order to resolve material issues, enhancing effectiveness.

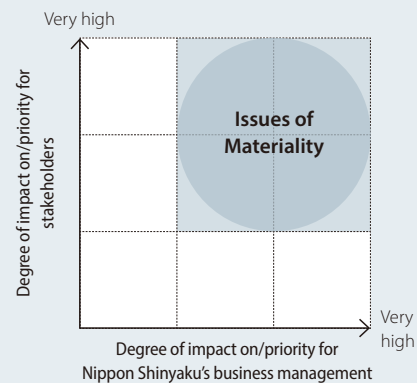
Process to determine issues of materiality

1 Listing issues

We list issues taken from the risks and opportunities identified through an analysis of international guidelines and standards, social conditions, the market environment, and our internal condition.


2 Assessing the importance of issues

The importance of listed issues is evaluated by mapping them on a two-axis graph—one axis is the degree of impact on/priority for stakeholders and the other axis is the degree of impact on/priority for Nippon Shinyaku's business management.



3 Formulating promotion plans and execution











For each of the issues, the relevant department formulates not only quantitative and qualitative targets, but also plans to achieve those targets. The Sustainability Committee regularly verifies progress in implementing the plans, and if necessary, improvements are made to activities.

Major risks	Major opportunities	Actions	Materialities
<ul style="list-style-type: none"> Lower value of existing therapies from emerging treatments/ approaches based on new technology Scaling down Japan-focused business due to Japan's declining population More intense natural disasters, more diverse business risks Impact of loss of end-user trust on business activities 	<ul style="list-style-type: none"> Creation of novel therapeutic agents using new technologies Higher demand for health-related products as focus shifts from treatment to prevention Discovery of unmet needs based on a patient-centric perspective 	<ul style="list-style-type: none"> Contributing to people's health through the creation of products and services with unique characteristics Maintaining a safe and high-quality supply of products Strengthening patient support and advocacy activities based on patient-centricity Promoting DX 	 <p>Realizing a healthy future by creating innovation</p>
<ul style="list-style-type: none"> Loss of personnel Reduced motivation due to lack of psychological safety 	<ul style="list-style-type: none"> Maintenance of employee health, diversification of human resources and work styles, and promotion of productivity and innovation by developing human resources A desirable place where people enjoy working 	<ul style="list-style-type: none"> Creating an environment where each person can grow and play an active role Promoting diversity, equity and inclusion Achieving well-being 	 <p>Developing diverse human resources and realizing employee well-being</p>
<ul style="list-style-type: none"> Loss of business opportunities due to delays in addressing healthcare disparities Loss of trust, and impact on business due to the occurrence of human rights issues 	<ul style="list-style-type: none"> Creation of new business opportunities by improving medical facilities through support of patients, and research in the medical and pharmaceutical fields Increased credibility both inside and outside the Company due to consideration of human rights and environmental improvements Stakeholder trust generated by child-related support initiatives 	<ul style="list-style-type: none"> Contributing to the healthcare field beyond the provision of medicines Improving medical access Respecting human rights Contributing to regions and cultures Contributing to the future of children 	 <p>Resolving social issues and coexisting with the community</p>
<ul style="list-style-type: none"> Climate change-related extreme weather and natural disasters Reputational risk due to increased waste (improper disposal), increased disposal costs Erosion of trust and brand value due to activities that lack consideration for animal welfare 	<ul style="list-style-type: none"> Reduced CO₂ emissions and facility operating costs due to climate change actions 	<ul style="list-style-type: none"> Climate change countermeasures Promoting resource circulation Conserving biodiversity Contributing to food waste reduction 	 <p>Strengthening efforts to protect the global environment</p>
<ul style="list-style-type: none"> Increased international legal compliance. Corruption due to reduced awareness of integrity and compliance Erosion of trust and brand value from cyberattacks, data leaks or other information security issues Decrease in credibility among stakeholders due to inappropriate responses 	<ul style="list-style-type: none"> Greater trust in the Company due to cultivation of compliance mindset and business ethics Trust generated by appropriate disclosures to stakeholders 	<ul style="list-style-type: none"> Promoting integrity Strengthening risk management Appropriate information disclosure 	 <p>Strengthening governance</p>

Materialities

In April 2021, we as the Nippon Shinyaku Group determined the mission we should fulfill in service of society and our stakeholders and identified 19 issues of materiality we consider important to resolve social issues and create value. In March 2023, as sustainability was taking on added significance globally, and because the environment

surrounding our businesses had significantly changed, we implemented a review of these issues of materiality. Going forward, in order to respond flexibly to environmental changes, we aim to create sustainable value by continuously reviewing issues of materiality and proceeding with relevant initiatives.

Materialities (Issues of materiality)		Description of Activities	Related SDGs
 Realizing a healthy future by creating innovation	Contributing to people's health through the creation of products and services with unique characteristics	<ul style="list-style-type: none"> Promoting drug discovery utilizing nucleic acid drugs, new modalities, and new targets and methods → P. 35 Promoting drug discovery research and clinical trials based on patient centricity → P. 35 Providing unique healthcare products and health food ingredients to promote health through food → P. 49 Establishing a global sales and supply system to provide pharmaceuticals and functional foods to the world → P. 42 Promoting treatment, diagnosis, medication guidance, and life improvement through the use of digital technologies → P. 45 	 
	Maintaining a safe and high-quality supply of products	<ul style="list-style-type: none"> Strengthening the stable supply system of products through risk management → P. 42 Establishing a mechanism for supplying safe and high-quality products, including new drugs such as nucleic acid drugs → P. 42 	 
	Strengthening patient support and advocacy activities based on patient centricity	<ul style="list-style-type: none"> Providing information to medical institutions and implementing disease awareness-raising activities for patients and their families → P. 41, 45 Promoting social understanding of diseases → P. 41 	
	Promoting DX	<ul style="list-style-type: none"> Promoting our Digital Strategy towards the realization of our Digital Vision 	
 Developing diverse human resources and realizing employee well-being	Creating an environment where each person can grow and play an active role	<ul style="list-style-type: none"> Fostering autonomous human resources and global leaders who are motivated to grow → P. 52 Building a flexible and resilient organization that can respond to change → P. 52 	 
	Promoting diversity, equity and inclusion	<ul style="list-style-type: none"> Fostering a culture that recognizes individuals regardless of factors such as age, gender, values, or disability → P. 56 	 
	Achieving well-being	<ul style="list-style-type: none"> Realizing a workplace that is comfortable and rewarding where psychological safety is ensured → P. 52 Promoting diverse work styles tailored to each individual → P. 52 Maintaining and improving employee health → P. 58 	
 Resolving social issues and coexisting with the community	Contributing to the healthcare field beyond the provision of medicines	<ul style="list-style-type: none"> Disseminating scientific findings through academic papers and conferences for the development of the scientific field → P. 35, 41 Enhancing the public research grant system to support medical and scientific research → P. 68 	
	Improving medical access	<ul style="list-style-type: none"> Implementing an unapproved drug delivery program and expanding the number of approved countries to support patients with intractable and rare diseases → P. 12 	 
	Respecting human rights	<ul style="list-style-type: none"> Implementing due diligence to prevent and mitigate adverse impacts associated with business activities → P. 57 Implementing in-house education and awareness-raising activities to promote understanding of human rights → P. 57 	 
	Contributing to regions and cultures	<ul style="list-style-type: none"> Implementing social contribution activities rooted in each region, including preserving Kyoto culture → P. 68 	
	Contributing to the future of children	<ul style="list-style-type: none"> Providing educational and mental well-being support for children through activities such as sports and reading opportunities → P. 68 Conducting dietary education activities for children in order to foster an interest in food → P. 49 	
 Strengthening efforts to protect the global environment	Climate change countermeasures	<ul style="list-style-type: none"> Promoting greenhouse gas reductions → P. 60 	 
	Promoting resource circulation	<ul style="list-style-type: none"> Promoting recycling of resources (water, waste, etc.) → P. 60 	
	Conserving biodiversity	<ul style="list-style-type: none"> Continuing activities to protect and cultivate endangered species at the Yamashina Botanical Research Institute → P. 60 Promoting animal welfare-friendly initiatives → P. 35 	 
	Contributing to food waste reduction	<ul style="list-style-type: none"> Developing high-quality stable preservatives that do not impair the taste of food, in order to extend shelf life and reduce waste → P. 49 	
 Strengthening governance	Promoting integrity	<ul style="list-style-type: none"> Strengthening governance, including Group companies → P. 70 Enhancing compliance → P. 76 Promoting fair and transparent business → P. 76 	 
	Strengthening risk management	<ul style="list-style-type: none"> Understanding critical risks and strengthening the management and response system for each risk → P. 77 	
	Appropriate information disclosure	<ul style="list-style-type: none"> Strengthening IR activities for investors → P. 66 Implementing information disclosure to stakeholders → P. 66 	

Value Creation Process

Business Philosophy Helping People Lead Healthier, Happier Lives

Capital Supporting Nippon Shinyaku

Financial capital

Total consolidated equity ¥195,933 million
(Equity attributable to owners of parent 82.4%)
Total consolidated assets ¥237,451 million

Human capital

- Number of employees
2,186 (consolidated) 1,857 (parent company)
- Total annual hours worked 1,841.69 hours
- Percent holding PhD or Master's degrees 36.2%
- Total investment in human resource development for regular employees ¥140,646 thousand (parent company)
- Investment in human resource development per regular employee ¥83 thousand (parent company)
- Training hours by level
Total 18,296 hours 10.01 hours per person
- Hours of self-development training
Total 18,835 hours 10.32 hours per person

Intellectual capital

- Pharmaceutical technologies (nucleic acid and small molecule)
- R&D investment ¥24,135 million
- Pipeline
- Patents held 974 patents
- Amount of digital content on owned website 153

Social and relationship capital

- Strong partnerships with medical professionals
- Open innovation with academia
- Provision of "Sherpa," a support program for patients with pulmonary hypertension
- Increase of access to medicine
- Implementation of Viltepso Managed Access Program

Manufacturing capital

- Odawara Central Factory
- Clinical trial API manufacturing facility

Environmental capital

- Energy consumption (electricity)
15,881 thousand kWh
- Water consumption (tap water + well water)
155 thousand m³

Nippon Shinyaku (Pharmaceuticals Business) Business Model

* See P.48 for business model of the Functional Food business

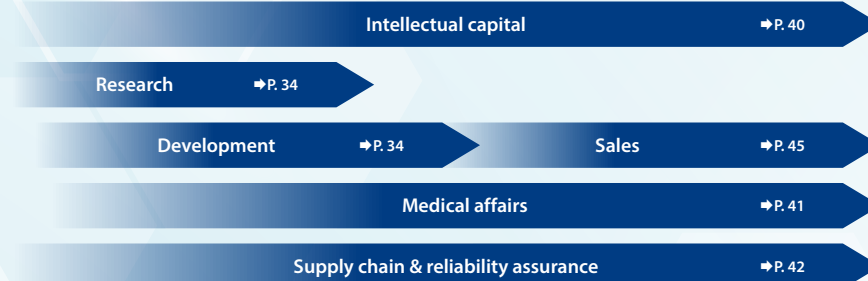
Pursuing originality on a global scale

Providing the world with quality pharmaceuticals to address diseases with unmet treatment needs



Fundamental technologies

Small molecule drugs, nucleic acid drugs, new drug discovery modalities



6th Five-Year Medium-term Management Plan

Aiming for Sustainable Growth ~Pursuit of Further Originality~

Materialities



Reallocation of value to capital

Outputs

Pharmaceuticals Business → P. 34

Segment revenue

¥121.988 billion

• Urology



Zalutia, for urinary disorder caused by benign prostatic hypertrophy

• Hematology



Defitelio, for sinusoidal obstruction syndrome (hepatic veno-occlusive disease)

• Intractable and rare diseases



Fintepla, for seizures associated with Dravet syndrome



Vidaza, for myelodysplastic syndromes or acute myeloid leukemia

• Gynecology



Viltepso, for Duchenne muscular dystrophy



MonoVer, for iron deficiency anemia

Functional Food Business → P. 48

Segment revenue

¥22.187 billion

Health food ingredients

Preservatives

Protein preparations

Supplements



Outcomes

Shareholders → P. 28

- TSR (for the past 5 years, cumulatively) -11.4%
- TSR (for the past 10 years, cumulatively) 385.4%
- ROE (FY2022) 12.1%

Employees → P. 52

- Human resources that create competitiveness
- Realizing work-life balance
Low turnover: 1.92%
- Improved employee engagement
Recognized as "White 500" firm
- Percentage of male employees taking childcare leave
69.3%
19.3 percentage point increase YoY
- Ratio of female executives 16.8%
0.7 percentage point increase YoY

Society → P. 42, 68

- (local communities, business partners, etc.)
- Increase of trust from local communities
- Strengthening of relationships with local communities and business partners, etc.

Customers → P. 34, 41, 42, 48

- (patients, consumers, medical professionals)
- Hosting online seminars about disease awareness 2
- Contributing to the future of medicine
Open recruitment research grants 10
- Upravi sold in about 70 countries
- Opening of Innovation Research Partnering, a drug discovery center in the U.S.
- New expertise in pharmaceutical research
- Expanding the development pipeline through strengthening of licensing activities 2
- Strengthening our global supply system

Environment → P. 60

- Plants preserved approximately 3,000 species
- Greenhouse gas emissions (Scope 1, 2)
5.2% reduction from FY2021
- Reduction of water consumption
6.1% reduction from FY2021

* See P.66 for stakeholder engagement

Medium-term Management Plan (MTMP)

Since the start of the 4th Five-year Medium-term Management Plan in FY2009, Nippon Shinyaku has provided new and unique products to the market at a pace of over one product on average per year in accordance with “Supply Unique and High-quality Products,” which is one of the elements of our management policy. This has resulted in net sales of approximately double and an operating profit of approximately five times that of FY2009 in FY2022. Going forward, it is conceivable that Nippon Shinyaku will face increasing operational uncertainty due to significant changes in the

business environment, including fundamental reforms to the health care system aimed at enhancing measures to curb medical expenses, technological innovation, and industry restructuring. The Company intends to adapt to the changing external environment and continue to provide unique pharmaceutical products around the world to more patients with unmet treatment needs than ever.

Nippon Shinyaku's Vision

A company with a meaningful existence in the healthcare field

4th Five-Year Medium-term Management Plan FY2009–2013		5th Five-Year Medium-term Management Plan FY2014–2018																																
Scenario	“Innovation and Growth”		“Aiming for New Growth –Pursuit of Originality–”																															
Business metrics	FY2013 results		FY2018 results																															
	Net sales	¥76.5 billion	Net sales	¥114.7 billion																														
	Operating income	¥8.0 billion	Operating income	¥20.6 billion																														
	Net income attributable to owners of the parent	¥5.7 billion	Net income attributable to owners of the parent	¥16.3 billion																														
Main results			EPS	¥242																														
			ROE	12.5%																														
Tasks for the next MTMP	<ul style="list-style-type: none">• Expansion of pipelines for in-house drugs• 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 for 5 years• Creation of CASA (CAreer Support Academy) for development support and training• Social contribution initiatives		<ul style="list-style-type: none">• Launch of seven products, including Uptravi for pulmonary arterial hypertension (PAH)• Pipeline enhancement through conclusion of in-licensing agreements for six products• Greater awareness of Nippon Shinyaku in PAH field• Major contribution to growth from the launch of Uptravi in multiple overseas markets• Significantly higher operating margin achieved in Functional Food business• Flextime system introduced for MRs (industry first in Japan)• Outside specialist personnel recruited																															
	<ul style="list-style-type: none">• 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		<ul style="list-style-type: none">• Pursue technological innovation to create new value by supplementing the existing drug discovery base for targeting small molecules and nucleic acid drugs with new modalities and technologies• Re-invest profits generated by Uptravi in NS-065/NCNP-01 and successor nucleic acid drugs, NS-018, and other drugs, to support accelerated global development																															
Net sales trend	<table border="1"><thead><tr><th>Fiscal Year</th><th>Net Sales (billion yen)</th></tr></thead><tbody><tr><td>2009</td><td>65</td></tr><tr><td>2010</td><td>65</td></tr><tr><td>2011</td><td>68</td></tr><tr><td>2012</td><td>70</td></tr><tr><td>2013</td><td>75</td></tr><tr><td>2014</td><td>80</td></tr><tr><td>2015</td><td>85</td></tr><tr><td>2016</td><td>95</td></tr><tr><td>2017</td><td>100</td></tr><tr><td>2018</td><td>110</td></tr><tr><td>2019</td><td>115</td></tr><tr><td>2020</td><td>120</td></tr><tr><td>2021</td><td>135</td></tr><tr><td>2022</td><td>135</td></tr></tbody></table>				Fiscal Year	Net Sales (billion yen)	2009	65	2010	65	2011	68	2012	70	2013	75	2014	80	2015	85	2016	95	2017	100	2018	110	2019	115	2020	120	2021	135	2022	135
Fiscal Year	Net Sales (billion yen)																																	
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2019	115																																	
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2021	135																																	
2022	135																																	

“Aiming for Sustainable Growth –Pursuit of Further Originality–”

	FY2022 results	FY2023 Quantitative Targets	
		Targets	CAGR
Revenue	¥144.1 billion	¥150.0 billion	5.5%
Pharmaceuticals	¥121.9 billion	¥133.0 billion	5.8%
Functional Food	¥22.1 billion	¥17.0 billion	3.4%
Operating income	¥30.0 billion	¥40.0 billion	14.2%
Net income attributable to owners of the parent	¥22.8 billion	¥30.0 billion	13.0%
EPS	¥338	¥445	13.0%
ROE	12.1%	10% over the period	

Summary

In the 6th Five-year Medium-term Management Plan for FY2019-2023, building on the management base laid in the 5th Medium-term Management Plan, Nippon Shinyaku has promoted **six actions** (see PP. 26-27) to solidify a foundation for sustainable growth.

- 1 Creation of new value through R&D
- 2 Development of global business
- 3 Increase in corporate value by strengthening ESG management
- 4 Creation of organizational climate in which every employee can flourish
- 5 Active use of AI and adoption of IT
- 6 Further strengthening of management base

Main results up to FY2022

- Launched Defitelio, a treatment for sinusoidal obstruction syndrome; nucleic acid drug Vilepso, a treatment for Duchenne muscular dystrophy (DMD); Fintepla, a treatment for epileptic seizures associated with Dravet syndrome; and MonoVer, a treatment for iron deficiency anemia
- Started marketing of Vilepso in the U.S., the first product marketed by Nippon Shinyaku itself in the U.S.
- Gained regulatory approval for the additional indication of acute myeloid leukemia for Vidaza, and chronic thromboembolic pulmonary hypertension (CTEPH) for Uptravi
- Established Beijing Nippon Shinyaku Co., Ltd. and Tianjin Nippon Shinyaku Co., Ltd., as bases for the Chinese business
- Opened Innovation Research Partnering (IRP), a drug discovery center in the U.S.
- Started co-promotional activities for the prostate cancer treatments Erleada and Zytiga with Janssen pharmaceuticals K.K.
- Entered into an exclusive partnership for distribution in the U.S. and Japan of a cell therapy developed by Capricor Therapeutics, Inc. for Duchenne muscular dystrophy (code no.: CAP-1002)
- Utilizing the metaverse, held online public seminars and get-together events on the theme of muscular dystrophy, as part of our activities to raise disease awareness
- Declared support for the Task Force on Climate-related Financial Disclosures (TCFD) recommendations and began information disclosure
- Revised and disclosed the Nippon Shinyaku Group Sustainability Policy, Nippon Shinyaku Group Human Rights Policy, Nippon Shinyaku Sustainable Procurement Policy, and Basic Environmental Policy
- Introduced flextime throughout the Company and continued to make use of telework
- Endorsed the “Challenge Initiatives for 30% of Executives to be Women by 2030” established by the Japan Business Federation in order to promote DE&I
- Established a new Digital Transformation Division to strengthen digitalization, and established and announced a digital vision and digital strategy
- Acquired “DX certification” from the Ministry of Economy, Trade and Industry
- Organized e-sports contests using an eye-controlled application for players with impaired bodily functions

Medium-term Management Plan (MTMP)

Six actions—FY2022 results and challenges

1 Creating new value through R&D

FY2022 Results

- UCB JAPAN gained marketing approval for ZX008 (a treatment for epileptic seizures associated with Dravet syndrome) in September 2022 and Nippon Shinyaku began distribution in November
- Launched MonoVer (iron deficiency anemia treatment)
- Co-developer Chugai Pharmaceutical Co., Ltd. gained regulatory approval in Japan for the additional indication of chronic lymphocytic leukemia for Gazyva in December 2022
- Entered into an exclusive partnership for distribution in Japan of a cell therapy developed by Capricor Therapeutics, Inc. for the expected indication of Duchenne muscular dystrophy (DMD) (code no.: CAP-1002)

Tasks for FY2023

- Promote drug discovery research and expand development pipeline
- Accelerate R&D

FY2023 initiatives

- Promote R&D of various pipeline items, in addition to nucleic acid drugs such as NS-089, NS-050, NS-051
- Promote research of new modalities centered on gene therapy
- Promote global in-licensing activity with a flexible and agile scouting system, to continuously create innovative products
- Revise R&D system and make effective use of outside consultants to improve and accelerate R&D activity and productivity

2 Development of global business

FY2022 Results

- Promoted preparations to develop Chinese business using local subsidiaries in China as bases
- Strengthened medical and business activities to maximize the value of Viltipso in the U.S. market
- Opened Innovation Research Partnering, a drug discovery center in the U.S.

Tasks for FY2023

- Formulate policy for business development outside of the U.S. and China, countries with Nippon Shinyaku bases

FY2023 initiatives

- Examine business model for Europe and investigate and promote business expansion in other regions
- Increase visibility of Nippon Shinyaku in the U.S.

3 Increase in corporate value by strengthening ESG management

FY2022 Results

- Revised and disclosed the Nippon Shinyaku Group Sustainability Policy
- Disclosed information based on the TCFD recommendations
- Took part in the Japan Climate Initiative
- Became selected as a constituent of the FTSE Blossom Japan Sector Relative Index
- Analyze changes in external and internal environments as well as the demands of society today to revise the Company's issues of materiality

Tasks for FY2023

- Promote activities in line with the Sustainability Policy

FY2023 initiatives

- Hold an ESG briefing to increase understanding among stakeholders of the Company's efforts related to sustainability
- Aim to acquire SBTi validation to promote the 7th Nippon Shinyaku Environmental Targets Plan (FY2023-2025)
- Promote business activities in line with the issues of materiality to realize sustainable growth

4 Creation of an organizational climate in which each employee can flourish

FY2022 Results

- Introduced a second job system with the aim of promoting the acquisition of diverse knowledge and skills by employees and to promote career autonomy and independence
- Introduced an hourly-based paid leave system to promote diverse work styles
- Revised the parental leave system and introduced a partial childcare leave system as part of realizing a supportive workplace environment
- Promoted the development of human resources to support global expansion
- Designated one of the FY2023 Certified Health & Productivity Management Outstanding Organizations "White 500" under the large enterprise category

Tasks for FY2023

- Become a company in which people can grow, be supported in their work, and feel rewarded

FY2023 initiatives

- Introduce job-based employment
- Launch NS Mind, which demonstrates the behavior, attitude and awareness that employees should aim for, NS Academy, which supports employees' self-directed career formation, and HONKI Juku, which nurtures managers for the next generation

5 Active use of AI and adoption of IT

FY2022 Results

- Planned and promoted DX initiative themes for key departments centered on the new Digital Transformation Division established in April
- Received certification from the Ministry of Health, Labour and Welfare for the Company's business adaptation plan for the DX Investment Promotion Tax Incentive
- Promoted efficient business activities through the use of digital technology, increasing target doctors, gaining awareness of candidate cases, and increasing new prescription cases
- Promoted production optimization through the utilization of digital technology at the Odawara Central Factory, including building an appearance defect sorting system for vials using automation and AI for some of the work involved in testing and inspection
- Promoted the digitalization of research departments and established an environment for data-driven drug discovery by introducing AI

Tasks for FY2023

- Promote work reform using digital technology

FY2023 initiatives

- Promote the use of digital technology to improve productivity, optimize costs, and create new businesses companywide

6 Further strengthening the business foundation

FY2022 Results

- Adopted International Financial Reporting Standards (IFRS) starting with the consolidated financial statement in the securities report for the fiscal year ended March 31, 2022 to increase international comparability of financial information
- Promoted managerial accounting with the aim of efficient management by introducing a new budget management system

Tasks for FY2023

- Promote management aimed at a highly profitable structure and efficient management

FY2023 initiatives

- Promote the formulation of the 7th Medium-term Management Plan

Financial/Capital Strategy



Nippon Shinyaku will strategically invest in the expansion of its development pipeline and global business development

Takanori Edamitsu

Director, Business Management & Sustainability

We will achieve long-term growth by making strategic investments to maximize the value of our development pipeline and product portfolio, thereby honoring the trust of our customers, society, and other stakeholders.

Progress and results of the 6th Medium-term Management Plan

In FY2022, although the impact of COVID-19 pandemic gradually subsided, higher energy resource and raw material prices due to the prolonged crisis in Ukraine, as well as the depreciated yen and price hikes, had a significant impact on our corporate activities. In this external environment, despite the revision of drug prices by the MHLW and the reactionary decline from the loss of sales revenue of the priority review voucher* designated by the U.S. Food and Drug Administration (FDA), revenue increased 4.9% year on year due to increased sales of Vilepso, a treatment for Duchenne muscular dystrophy (DMD) and Upravi, a treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, royalty income from overseas sales of Upravi, and sales growth in the Functional Food business. In the Pharmaceuticals business, revenue increased 1.1% year on year due to growth in sales of Vilepso and Upravi, as well as royalty income from overseas sales of Upravi. In the Functional Food

business, revenue increased 31.8% year on year due to growth in sales of protein preparations and other products. On the other hand, regarding profit, operating profit decreased 8.8% year on year and profit attributable to owners of parent decreased 8.7% year on year due to a reactionary decline following the lump-sum revenue from the priority review voucher in the previous fiscal year. However, we recognize that revenue and profit also increased, excluding the reactionary decline following the lump-sum revenue recorded in the previous period.

* Priority review voucher: A system under which a pharmaceutical company that has obtained approval for a new drug for an eligible rare disease is granted priority review rights (for three months) when applying for approval of its own new drug in another therapeutic area. The rights can also be transferred (sold) to a third party.

■ Forecast for the Final Year of the 6th Five-Year Medium-term Management Plan

Nippon Shinyaku has set quantitative targets for the final year of the 6th Medium-term Management Plan (FY2023) of ¥150 billion in sales, ¥40 billion in operating income, ¥445 in EPS, and 10% or more in ROE throughout the period of the plan. However, due to negative factors such as the impact of the off-year drug price revision by the MHLW and the delay in the

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

	FY2018 results	FY2022 results	FY2023 forecast	6th Five-Year Medium-term Management Plan targets
Net sales/Revenue	¥114.7 billion	¥144.1 billion	¥145.0 billion	¥150.0 billion
Pharmaceuticals	¥100.2 billion	¥121.9 billion	¥123.5 billion	¥133.0 billion
Functional Food	¥14.4 billion	¥22.1 billion	¥21.5 billion	¥17.0 billion
Operating income / Operating profit	¥20.6 billion	¥30.0 billion	¥32.0 billion	¥40.0 billion
Net income attributable to owners of parent / Profit attributable to owners of parent	¥16.3 billion	¥22.8 billion	¥25.0 billion	¥30.0 billion
EPS	¥242	¥338	¥371	¥445
ROE	12.5%	12.1%	—	10% or more during term of 6th Plan

launch of Vilepso in the U.S. due to the impact of the COVID-19 pandemic, the forecast for FY2023 falls short of these quantitative targets.

Although we must accept harsh evaluations for the fact that we fell short of our targets and that we are behind schedule in the development of some products, we believe that the establishment of our own marketing system in the U.S. and the increase in the pipeline of products developed in-house are commendable achievements.

Management policy and investment Strategy

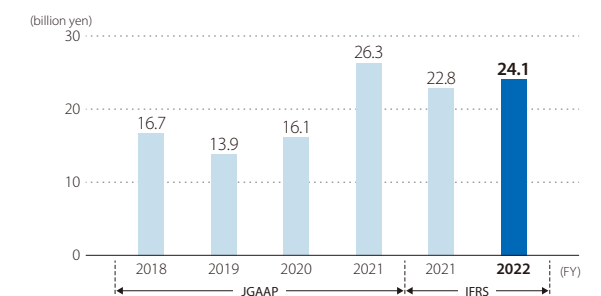
Our Company's management policy indicates that it will "Supply Unique and High-quality Products" and "Earn the Trust of Society." In businesses that deal with pharmaceuticals and functional food, stable supply is extremely important in gaining the trust of stakeholders including medical professionals, patients, and society. In order to ensure a stable supply amidst the current circumstances of a volatile external environment, our policy is to aggressively make necessary investments while maintaining a solid working capital position. Since we have no interest-bearing debt, i.e., enjoy a so-called a debt-free status, we use our weighted average cost of capital (WACC) based on our own analysis of the yield expected by shareholders from the Company as the hurdle rate, which is

one guiding factor in investment decisions. We have also set ROE as an indicator for capital efficiency, and a medium-term target of 10% or more ROE during the period of the 6th Five-Year Medium-term Management Plan.

■ R&D investments

In R&D, we are making strategic investments to maximize the value of our development pipeline and product portfolio in order to launch an average of at least one new product per year through R&D promotion of in-house products and in-licensing, as well as distribution partnerships. We are also conducting R&D to help DMD patients with other types of genetic mutations that are hard to treat with Vilepso, which was launched in 2020. The funds for R&D are being allocated from internal funds. During the period of the 6th Five-Year Medium-term Management Plan, we placed the highest priority on R&D investment, planning to invest ¥120 billion, which is now expected to total approximately ¥110 billion over the five years after adjusting for the FY2023 outlook.

R&D investments



Financial/Capital Strategy

■ Capital investment

Capital investments are made, with an awareness of cost of capital and other factors, to expand and streamline production facilities and to strengthen R&D capabilities, using our own funds. In December 2023, the ¥5.6-billion construction of a nucleic acid drugs API purification plant at the Odawara Central Factory is scheduled to be completed. Capital investment over the period covered by the 6th Five-Year Medium-term Business Plan is expected to total approximately ¥23 billion.

■ Human capital investment

Nippon Shinyaku believes that human resources are the driving force behind sustainable growth, and has adopted the management policy of “Develop Each Employee.” Based on the idea that unique products are the product of unique people, we are committed to investing in human resources with a respect for diversity. In FY2022, we invested ¥0.14 billion in human resource development, and we expect to invest ¥0.16 billion in FY2023. Although the results of our human resource development efforts will not be immediately reflected in our business performance, we believe that they will lead to sustainable growth in the future.

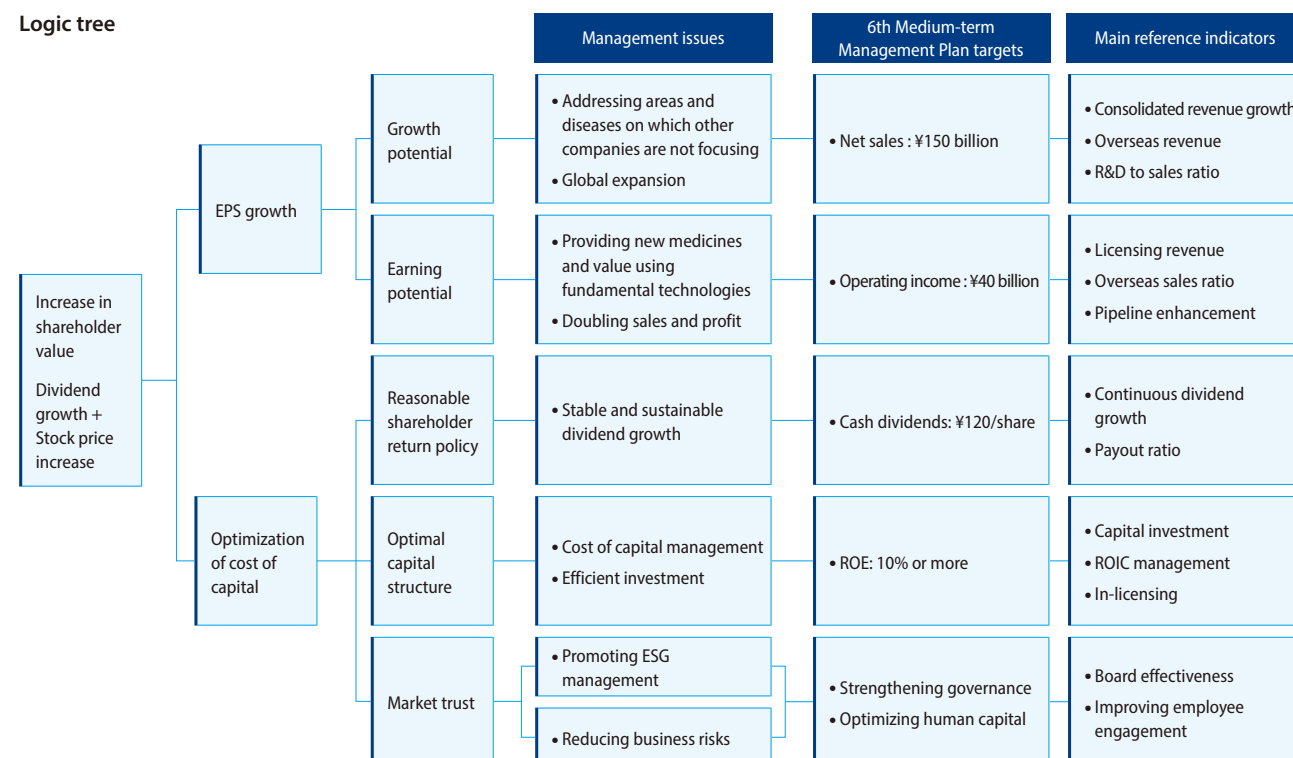
Shareholders’ return policy

■ Increasing shareholder value

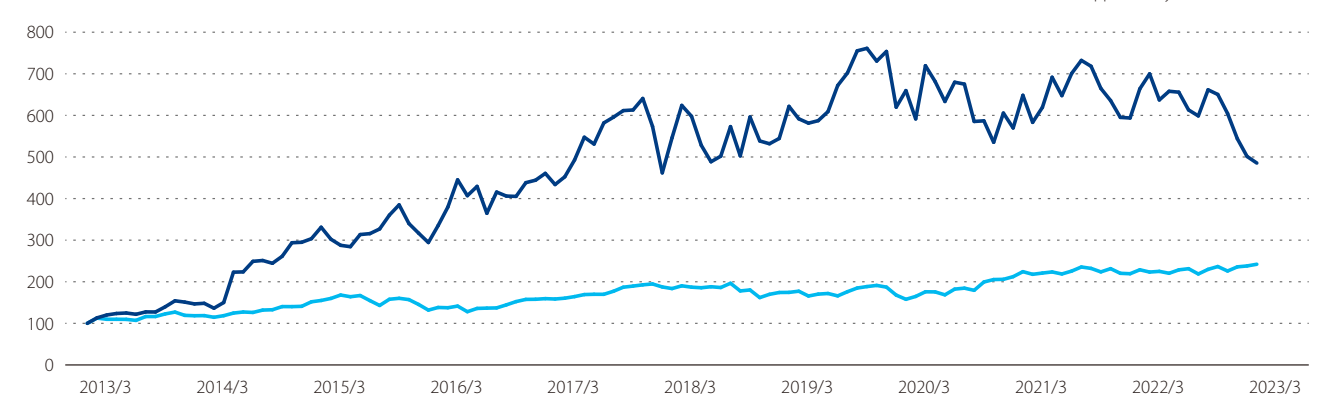
The Nippon Shinyaku logic tree is a graphical representation of the connection between related indicators to show how the Nippon Shinyaku Group’s management issues and strategies will lead to increased shareholder value, for the purpose of increasing said value. From a financial perspective, some of the factors that increase shareholder value are dividend growth and stock price rise, which are generally considered to be verifiable using long-term TSR. In addition, stock price is sometimes calculated as a multiple of EPS, and EPS growth is directly related to stock price growth.

Following its basic policy of maximizing corporate value, Nippon Shinyaku will strengthen its R&D structure and expand its development pipeline. Furthermore, we will make investments and return profits to shareholders in order to build an organizational structure that can withstand intensifying competition and adapt to global business development, while being conscious of our capital structure and cost of capital.

Logic tree



Total Shareholders’ Return (TSR)



Stock price performance

	One year	Three years		Five years		Ten years	
		Cumulative	Annualized rate	Cumulative	Annualized rate	Cumulative	Annualized rate
Nippon Shinyaku	-28.6%	-27.4%	-10.1%	-11.4%	-2.4%	385.4%	17.1%
TOPIX	5.8%	53.4%	15.3%	31.8%	5.7%	142.1%	9.2%

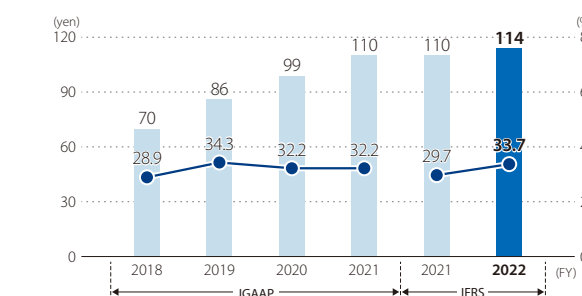
• Total shareholder's return (TSR) is the total return on investment that takes into consideration capital gains and dividends.
 • Nippon Shinyaku calculates TSR using cumulative dividends and change in stock price, and for the TOPIX, the dividend-included stock price index is used (calculated by Nippon Shinyaku using Bloomberg data, etc.)
 • Figures in the graph assume the closing price on March 31, 2013, is 100, and the TSR-based market value is indexed to that (held through March 31, 2023).
 • The return is the percent change of the initial investment generally used when calculating return on investment.

■ Sustainable dividend growth

Over the past 10 years, Nippon Shinyaku's TSR has outperformed the Tokyo Stock Price Index. We review our shareholder return policy each time we formulate our Medium-term Management Plan, and we will work to grow EPS to increase shareholder value over the medium to long term with TSR in mind to grow dividends and to increase the stock price.

We have set a dividend payout ratio of around 35% on a consolidated basis as a performance-linked dividend for the period of the 6th Five-Year Medium-term Management Plan, and in FY2022 we paid a dividend of ¥114 per share. In

Dividend per share / Payout ratio



FY2023, we plan to increase this by ¥6 to ¥120 per share. We have increased dividends for 11 consecutive years since FY2012, and we intend to achieve sustainable dividend growth in the future.

In addition, by promoting ESG management not only from a financial perspective but also from a non-financial perspective, we strive to gain the trust of the market and optimize our cost of capital.

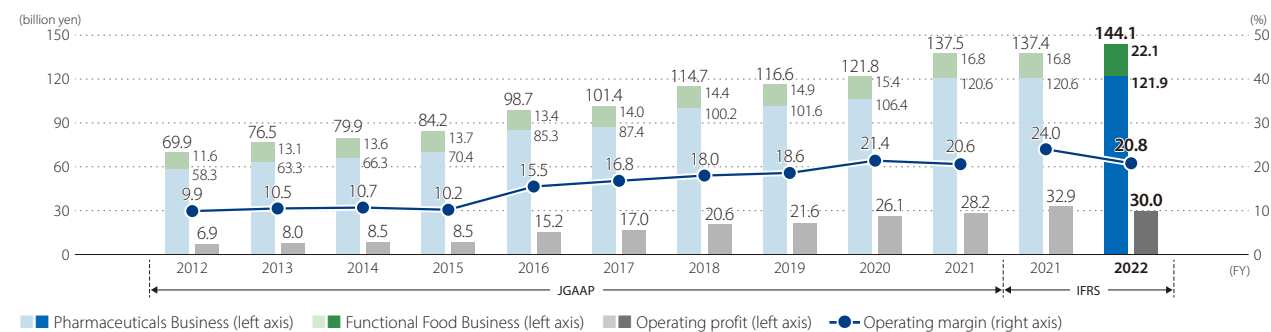
During the period of the next 7th Medium-term Management Plan, the patent for Upravi, which has large sales volume, will expire. In the area of intractable and rare diseases, the shift to generic drugs tends to be gradual, but is also affected by price revisions by the MHLW. Therefore, we hope to overcome this patent cliff and achieve an increase in revenue and profit by expanding the market for Vilepso and sequentially launching other products. We will consider asset allocation in the discussions about the formulation of the 7th Medium-term Management Plan and will indicate it at the time of the announcement.

Financial and Non-Financial Highlights

Financial highlights

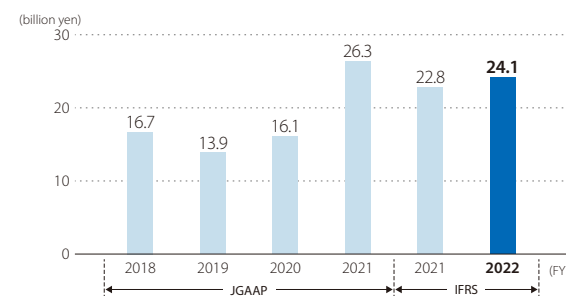
Nippon Shinyaku adopted the International Financial Reporting Standards (IFRS) in the fiscal year ended March 31, 2022 (FY 2021). Financial figures up to the fiscal year ended March 31, 2022 (FY2021) are also presented in accordance with the previously applied Japanese GAAP (JGAAP).

Net sales & Revenue / Operating income & Operating profit / Operating margin



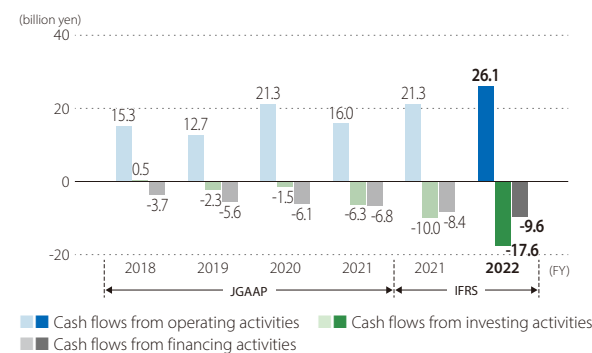
In FY2022, revenue stood at ¥144,175 million, up 4.9% year on year. Operating profit was ¥30,049 million, down 8.8% year on year, due to reactionary decline from the loss of sales revenue from the priority review voucher, and the operating margin was 20.8%. In the Pharmaceuticals business, sales of leading products such as Uptravi and Viltepso, as well as royalty revenue from overseas sales of Uptravi, contributed to results. In the Functional Food business, sales of protein preparations and preservatives increased.

R&D expenses



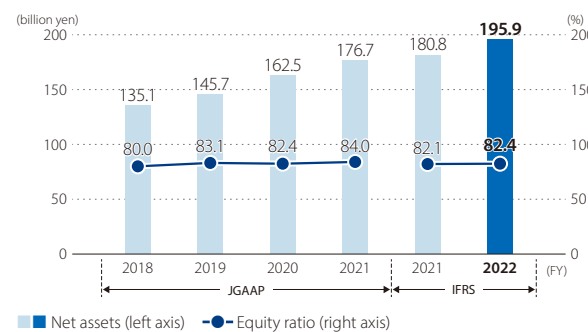
In FY2022, the amount of investment increased due to increases in expenses for the manufacturing of nucleic acid drugs and contract research expenses, in line with the progress of clinical trials. Nippon Shinyaku endeavored to expand the development pipeline in its focus disease areas based on the R&D approaches of in-house drug discovery, in-licensing, and product life cycle management (PLCM) with the aim of launching new drugs steadily and continuously.

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



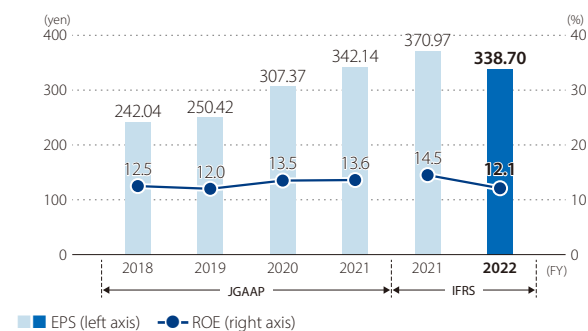
Net cash provided by operating activities stood at ¥26,170 million. The main components included profit before tax of ¥30,489 million in cash inflows and income taxes paid of ¥7,169 million in cash outflows. Net cash used by investing activities stood at ¥17,631 million, mainly due to purchase of property, plant, and equipment, and intangible assets. Net cash used in financing activities stood at ¥9,605 million, mainly due to dividends paid. As a result, cash and cash equivalents at the end of the period totaled ¥60,047 million.

Net assets & Total equity / Equity ratio & Ratio of equity attributable to owners of parent to total assets



Total equity amounted to ¥195,933 million, an increase of ¥15,047 million year on year. Total assets stood at ¥237,451 million, and equity attributable to owners of parent amounted to 82.4%.

EPS & Basic earnings per share / ROE & Return on equity attributable to owners of parent

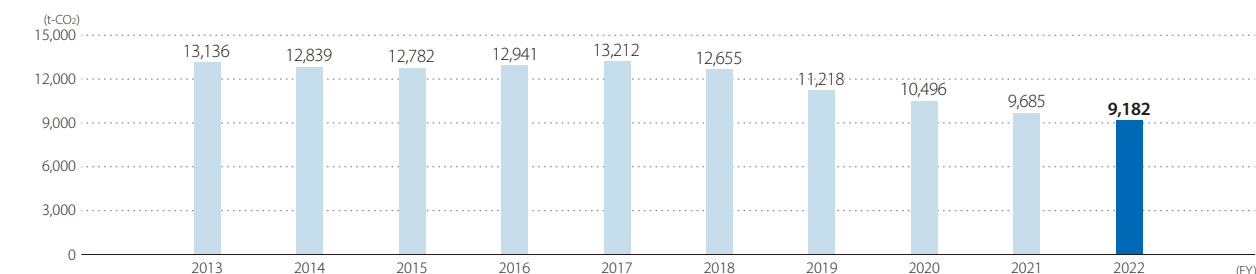


Profit attributable to owners of parent amounted to ¥22,812 million, down 8.7% year on year, with EPS of ¥338.7. ROE stood at 12.1%. The Company is aiming for ROE of 10% or more throughout the term of the 6th Five-Year Medium-term Management Plan, and exceeded the target again in FY2022.

Non-financial highlights

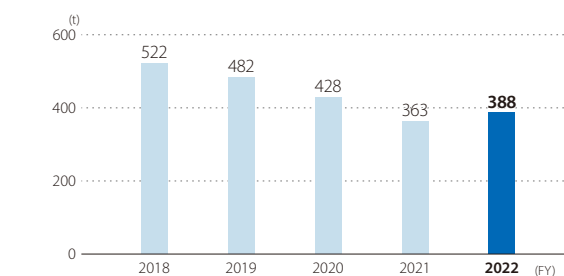
Entities covered: Non-consolidated Nippon Shinyaku

CO₂ emissions



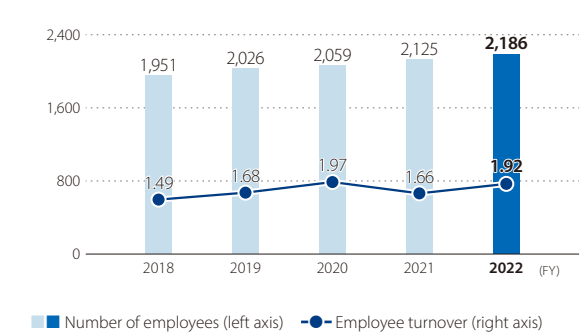
In order to achieve the target of a 42% reduction in CO₂ emissions compared to FY2020 by 2030 set in the 7th Nippon Shinyaku Environmental Targets Plan, since 2021 Nippon Shinyaku has been reducing CO₂ emissions by switching to electricity derived from renewable energy sources. In order to obtain SBTi validation, it also started calculating emissions of Group companies in Japan in FY2022.

Waste substances generated



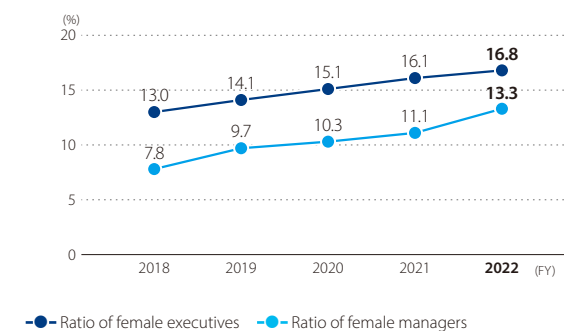
The waste substances generated in 2022 increased by 25 tons year on year, mainly due to the full-scale operation of the building for highly active solid formulations within the Odawara Central Factory. Nippon Shinyaku will continue to promote waste reduction efforts by reviewing its waste generation processes while promoting proper disposal of waste.

Number of employees (consolidated) / Employee turnover



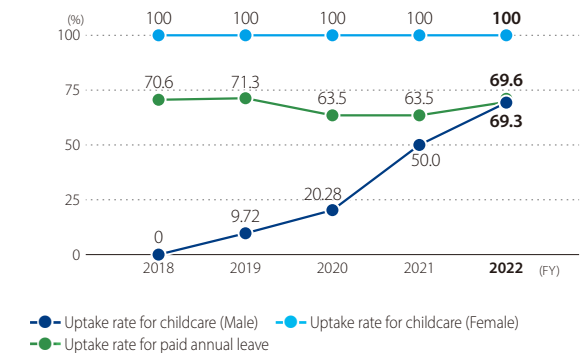
Nippon Shinyaku actively recruits new graduates and experienced mid-career professionals to respond to business expansion, and the number of its employees is increasing year by year. The Company has kept employee turnover due to personal reasons and early retirement low in the 1% range by ensuring that employees have a deep understanding of its Business Philosophy and promoting the establishment of a supportive working environment.

Ratio of female executives / Female managers



Nippon Shinyaku has established "promoting diversity, equity & inclusion" as one of its issues of materiality, and is working to develop a workplace environment in which each and every employee can utilize their diverse individuality to thrive and succeed. It is reviewing its personnel system and making efforts to promote diverse work styles. The Company will continue to further strengthen its efforts to draw on the perspectives of diverse human resources, including women, for Nippon Shinyaku's sustainable growth.

Uptake rate for childcare leave / Paid annual leave



Since April 2022, when the Act on Childcare Leave, Caregiver Leave, and Other Measures for the Welfare of Workers Caring for Children or Other Family Members was revised, childcare leave has been partially paid (up to a total of 14 days paid when taken for at least 5 consecutive working days). Nippon Shinyaku has been promoting the uptake of childcare leave by male employees, and the male uptake rate reached 69.3% in FY2022. To continue increasing the uptake rate, it will take such measures as enhancing the childcare leave system and sharing the experiences of employees who have taken childcare leave. The Company has also established a number of periods during the year when it recommends employees take consecutive days of paid annual leave to encourage uptake of leave.

Pharmaceuticals Business

Nippon Shinyaku brings to market on average at least one new product a year by not only undertaking in-house drug discovery based on our R&D capabilities built up since the founding of the Company in 1919 but also introducing in-license products and undertaking PLCM. We also proactively take on challenges in fields that other companies avoid and move forward with research and development of original treatments to create unique pharmaceuticals required by patients suffering from disease and their families and to be a company that is trusted by society.

R&D

Select the best modalities to treat diseases and explore their potential



Kazuchika Takagaki
Director, Research & Development

The R&D Division is responsible for the creation of new value for pharmaceuticals, which is the most important part of an R&D-oriented pharmaceutical company. With originality as our keyword, we are committed to working on themes and approaches that other companies avoid, and this has led to the development of small molecule drugs for pulmonary hypertension and the creation of nucleic acid drugs, an original modality. In order to fulfill our issue of materiality of realizing a healthy future by creating innovation, we will work to expand the application of nucleic acid drugs, research new modalities, and search for new drug discovery targets and compounds by utilizing AI.

In selecting themes, we place importance on scientific validity and business potential in addition to originality. In the area of intractable and rare diseases, one of our focal areas, patients are few and clinical trials must be conducted on a global scale. Obtaining approval in the U.S. is not an easy task, as the approval review process changes depending on the R&D status of other companies and the circumstances surrounding the disease, and more stringent scientific backing is often required. However, as we believe the high safety and efficacy of the compounds we discover are important and will lead to early approval, we will continue our uncompromising dedication to drug discovery.

The center of our concerns is always what we can do for patients. We will also achieve patient centricity in clinical trials by trying to make patient participation easier and pursuing what they most want to be addressed. I want to make Nippon Shinyaku a pharmaceutical company that attracts attention for its science-based drug development. To achieve this goal, we will select the best modalities to treat diseases and explore their potential so that we can contribute to people's health through original, world-class products.

Feedback from a Patient

A future in which all patients have the freedom to choose their own treatment

Tamotsu Takeda Representative Director Japan Muscular Dystrophy Association

I have no memory of ever being able to stand and walk on my own since I was an infant. Back then, there was no awareness of my intractable disease, and we did not know its cause or how to treat it. Later, I was diagnosed with spinal muscular atrophy (SMA) by a muscular dystrophy specialist, but I had become alienated from medical care and rehabilitation after learning that there was no known cause or treatment for my disease.



SMA is a progressive, intractable disease that reduces the number of things one can do alone with each passing day, but I have recently learned that there is a treatment. With the advancement of medicine, I feel that the day is close when intractable diseases, previously said to have no treatment, become treatable. I believe that someday soon I will be able to keep doing tomorrow the things I can still do today, and even more activities like eating ramen by myself, playing sports, and enjoying life.

In order to make this future possible, it is important for all patients to have the freedom to choose their own treatments. I and everyone from the Japan Muscular Dystrophy Association hope that pharmaceutical companies, physicians, and patients will be able to share treatment information with each other so that patients can choose the treatment that is right for them.

I hope that everyone at Nippon Shinyaku will continue to make further efforts in development and mutual collaboration to meet the needs of patients and deliver treatments, so that together we can envision a brighter future.

Materiality		Realizing a healthy future by creating innovation						
Main Activities		FY2022 Activities		Issues and FY2023 Strategies				
<ul style="list-style-type: none">Promoting drug discovery utilizing nucleic acid medicines, new modalities, and new targets and methodsPromoting drug discovery research and clinical trials based on Patient Centricity		<ul style="list-style-type: none">Enhanced technologies related to small molecules and nucleic acids and introduced data-driven drug discoveryVentured into new drug discovery modalities, including gene therapyEstablished a drug discovery center in Boston, the heart of the drug discovery ecosystemStrengthened human resource development initiatives in each department		<ul style="list-style-type: none">Diversifying in-house drug discovery by increasing access to the world's most advanced drug discovery innovations and increasing opportunities for partneringPlanning and implementing IP strategies that support drug discovery utilizing a wider range of new modalities				

Materiality		Strengthening efforts to protect the global environment					
Main Activities		FY2022 Activities		Issues and FY2023 Strategies			
<ul style="list-style-type: none">Promoting animal welfare-friendly initiatives		<ul style="list-style-type: none">Implemented humane animal research and environmental maintenance with consideration of animal welfareConducted introductory and continuing education to raise animal welfare awareness		<ul style="list-style-type: none">Maintaining an animal research environment that is up-to-date and promoting humane animal research based on the 3Rs.			

Materiality		Resolving social issues and coexisting with the community					
Main Activities		FY2022 Activities		Issues and FY2023 Strategies			
<ul style="list-style-type: none">Disseminating scientific findings through academic papers and conferences for the development of the scientific field		<ul style="list-style-type: none">Contributed to the development of related science fields by presenting scientific findings through academic papers or conferencesProtected and utilized scientific findings (inventions) through intellectual property		<ul style="list-style-type: none">Publishing scientific findings through academic papers and conferencesContinuing to protect and utilize scientific findings (inventions) through intellectual property			

Pharmaceuticals Business

Delivering Our Unique Products Globally

Nippon Shinyaku has excellent R&D capabilities which have produced products such as the small molecule drug Upravi and the nucleic acid drug Viltepso. We are also working on new modalities, including gene therapy, to increase the number of diseases that can be treated. We will continuously improve our drug discovery capabilities by combining them with data-driven drug discovery, our current focus. This will promote the creation of new research themes and promote in-house drug discovery, centered around our focal areas and fields. Furthermore, in addition to PLCM to increase product value by expanding the range of indications and developing new dosage forms for existing products and products under development, we are enriching our pipeline through in-licensing of products from other companies and open innovation activities.

Through these R&D activities, based on the concept of patient centricity, we will continually deliver unique new drugs to patients in disease areas with unmet treatment needs. To this end, we have developed an organizational structure that is capable of conducting R&D on a global basis.

Progress of the Medium-term Management Plan and FY2022 Overview

Expanding the pipeline in our focal areas

In March 2022, we obtained manufacturing and marketing approval for MonoVer (code no.: NS-32, generic name: ferric derisomaltose), an iron deficiency anemia treatment in-licensed from Pharmacosmos A/S in 2016, and it launched in March 2023.

Upravi (code no.: NS-304, generic name: selezipag), a

pulmonary arterial hypertension (PAH) treatment launched in 2016, is in a Phase II trial for pediatric indications. In addition, a late-stage Phase II clinical trial is underway to add arteriosclerosis obliterans to the indications for Upravi.

A global Phase III clinical trial is underway for Viltepso (code no.: NS-065/NCNP-01, generic name: viltolarsen), a Duchenne muscular dystrophy (DMD) treatment launched in Japan and the U.S. in 2020.

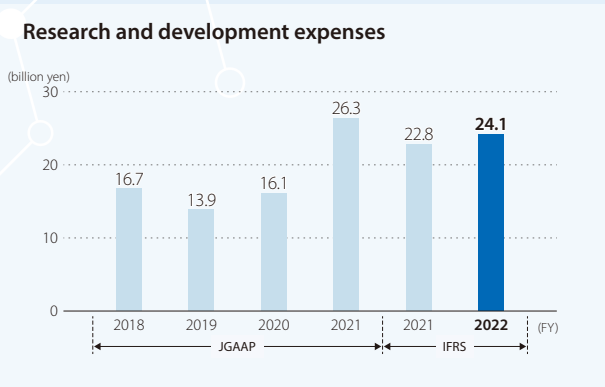
In December 2022, Chugai Pharmaceutical Co., Ltd. obtained approval for an additional indication of chronic lymphocytic leukemia for humanized anti-CD20 monoclonal antibody Gazyva (code no.: GA101, generic name: obinutuzumab), and in June 2022, we initiated a Phase III clinical trial for lupus nephritis in collaboration with them. In addition, in March 2023 we initiated a Phase III clinical trial for pediatric nephrotic syndrome in collaboration with Chugai.

In 2019, we entered into an exclusive distribution agreement in Japan with UCB S.A. (formerly Zogenix, Inc.) for Fintepla Oral Solution 2.2 mg/mL (code no.: ZX008, generic name: fenfluramine hydrochloride), a treatment for epileptic seizures associated with Dravet syndrome. In September 2022, UCB S.A. obtained approval for manufacturing and marketing, and Nippon Shinyaku began distribution of the product in November 2022.

NS-161 and NS-025 are now in Phase I clinical trials in Japan for inflammatory and urological diseases, respectively.

Promoting licensing activities

In February 2023, we entered into an exclusive partnership for the Japan distribution of CAP-1002 for the expected indication of DMD with U.S. company Capricor Therapeutics Inc. This agreement follows the exclusive partnership for U.S. distribution we entered with them in January 2022. CAP-1002 is comprised of human allogeneic cardiosphere-derived cells and is expected to be effective in a wide range of DMD patients, regardless of the type of genetic mutation. Capricor Therapeutics Inc. is currently conducting a Phase III clinical trial in the U.S.



Pipeline (As of August 10, 2023)

Nippon Shinyaku's latest pipeline

WEB <https://www.nippon-shinyaku.co.jp/english/ir/financial/develop.php>

Japan

Code no. (generic name)	Origin	Development	Indications	Phase						NDA filing	Launch
				I	I/II In preparation	I/II	II In preparation	II	III		
NS-065/NCNP-01 (Viltolarsen)	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	Duchenne muscular dystrophy						Underway		
NS-87 (daunorubicin/cytarabine)	Licensed-in from: Jazz Pharmaceuticals plc	Nippon Shinyaku	High-risk acute myeloid leukemia								
ZX008 (Fenfluramine hydrochloride)	Distribution partnership UCB S.A. (formerly Zogenix, Inc.)	UCB S.A. (formerly Zogenix, Inc.)	Lennox-Gastaut syndrome								
ZX008 (Fenfluramine hydrochloride)	Distribution partnership: UCB S.A. (formerly Zogenix, Inc.)	UCB S.A. (formerly Zogenix, Inc.)	CDKL5 deficiency disorder								
GA101 (Obinutuzumab)	Licensed-in from: Chugai Pharmaceutical Co., Ltd.	Co-development: Chugai Pharmaceutical Co., Ltd.	Lupus nephritis								
GA101 (Obinutuzumab)	Licensed-in from: Chugai Pharmaceutical Co., Ltd.	Co-development: Chugai Pharmaceutical Co., Ltd.	Pediatric nephrotic syndrome								
NS-304 (Selezipag)	Nippon Shinyaku	Nippon Shinyaku	Arteriosclerosis obliterans								
NS-304 (Selezipag)	Nippon Shinyaku	Co-development: Janssen Pharmaceutical K.K.	Pediatric pulmonary arterial hypertension								
NS-580	Nippon Shinyaku	Nippon Shinyaku	Endometriosis								
NS-580	Nippon Shinyaku	Nippon Shinyaku	Chronic prostatitis / Chronic pelvic pain syndrome								
NS-089/NCNP-02 (brogidirsen)	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	Duchenne muscular dystrophy								
NS-229	Nippon Shinyaku	Nippon Shinyaku	Eosinophilic granulomatosis with polyangiitis								
NS-401 (tagraxofusp)	Licensed-in from: The Menarini Group	Nippon Shinyaku	Blastic plasmacytoid dendritic cell neoplasm								
NS-050/NCNP-03	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	Duchenne muscular dystrophy								
NS-917 (radgocitabine)	Licensed-in from: Delta-Fly Pharma, Inc.	Nippon Shinyaku	Relapsed/refractory acute myeloid leukemia								
NS-161	Nippon Shinyaku	Nippon Shinyaku	Inflammatory diseases								
NS-025	Nippon Shinyaku	Nippon Shinyaku	Urological diseases								

Overseas

Code no. (generic name)	Origin	Development	Indications	Phase						NDA filing	Launch
				I	I/II In preparation	I/II	II In preparation	II	III		
NS-065/NCNP-01 (Viltolarsen)	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	Duchenne muscular dystrophy						Underway		
CAP-1002	Partnership: Capricor Therapeutics Inc.	Capricor Therapeutics Inc.	Duchenne muscular dystrophy								
NS-018 (Ilginatnib)	Nippon Shinyaku	Nippon Shinyaku	Myelofibrosis								
NS-089/NCNP-02 (brogidirsen)	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	Duchenne muscular dystrophy								
NS-229	Nippon Shinyaku	Nippon Shinyaku	Eosinophilic granulomatosis with polyangiitis								
NS-050/NCNP-03	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	Duchenne muscular dystrophy								

Pharmaceuticals Business

FY2023 Initiatives and Strategy

In the area of intractable and rare diseases, in addition to the DMD treatments to follow Viltepso (NS-089/NCNP-02, NS-050/NCNP-03, and NS-051/NCNP-04), we will develop NS-229 and NS-161 for inflammatory diseases.

As for Nippon Shinyaku's focal areas and fields, in hematologic malignancies, we will promote the development of a treatment for high-risk acute myeloid leukemia (NS-87) and for myelofibrosis (NS-018). In gynecology, we will promote the development of a treatment for endometriosis (NS-580), and in urology, we are developing NS-025.

As for licensing activities, we will promote the introduction of unique products and developments that complement our R&D activities and expand our R&D pipeline.



Enriching the pipeline with in-house drug discovery, in-licensing, and PLCM

mechanisms. In addition, we are accelerating R&D through data-driven drug discovery and promoting the strategic creation of new drug discovery themes.

Promoting PLCM strategies

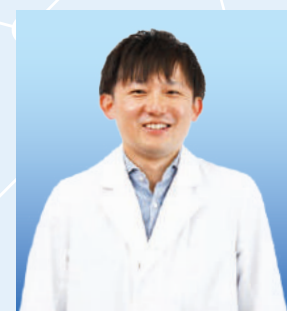
Due in part to depletion of drug discovery targets, the cost and duration of new drug development continues to increase, adding to the difficulty of drug discovery each year. In addition, the external environment is changing dramatically as NHI drug prices are revised annually. Against this backdrop, pharmaceutical companies are finding it ever more important to secure profitability via initiatives to maximize product value. Nippon Shinyaku works to maximize the value of existing products such as Uptravi by utilizing comprehensive analysis technologies and large-scale data to proactively expand the range of indications and develop new dosage forms. We also engage in strategic PLCM planning for drug candidates still in development, based on these compounds' distinguishing features.

Value Creation Initiatives

In-house drug discovery initiatives

In recent years, the use of new drug discovery modalities has increased in the field of drug discovery research. In addition to small molecule drugs and nucleic acid drugs, Nippon Shinyaku is also working on new modalities including gene therapies. To assist in our endeavors, we have strengthened collaboration with academic institutions and other external parties. We will increase our access to the world's most advanced drug discovery technologies not only in Japan but also through our overseas drug discovery centers, analyze the attributes and potential of various drug discovery modalities and select the modalities we consider optimal for specific diseases and

Voice



Tatsuhiko Arakawa
Proposal Strategy Section
Strategic Planning and
Research Department

Unraveling new pathological mechanisms of rare hereditary diseases during overseas study

Using Nippon Shinyaku's support for overseas study, I studied at a lab in the U.S. for two and a half years, from April 2019 to October 2021. The lab where I studied is working to unravel new pathological mechanisms of rare hereditary diseases using cutting-edge genome editing technology, and the purpose of my overseas study was to gain this expertise. Since returning to Japan, I am applying the techniques I learned to drafting new drug discovery themes. In addition, as I was studying in the Texas Medical Center, one of the largest medical research complexes in the U.S., I was able to build a network of contacts with many researchers there through joint research and seminars, and learn about diverse values. I would like to make use of these connections and perspectives in my work in the future.

Enriching the pipeline through in-licensing

In addition to in-house drug discovery, Nippon Shinyaku actively utilizes in-licensed products and development articles to enrich its pipeline. In the past, we have collaborated with many partner companies in a wide range of fields, and we have been first to meet the challenge of conducting research in areas where other companies are not involved. Through in-licensing, we will develop and market products of new value in cooperation with our partners and, as with our pharmaceuticals discovered in-house, we will continue to provide unique new drugs in Japan and internationally in disease areas with unmet treatment needs.



Promoting Research on Nucleic Acid Drugs

Human resource development in R&D

The R&D Division has defined the type of human resources it seeks in employees who are committed to successful drug discovery research, and is working on a training program to cultivate them. Drug discovery is challenging and requires numerous processes and a lot of time. Cross-divisional teamwork is essential to steadily reach market launch and further speed up the process. Through the training program, we aim to create an organization that values cooperation and altruism, while developing individuals and the R&D Division as a whole so that they lead us to a high rate of drug discovery success.

We believe that it is important to always maintain a passion for drug discovery and a sense of care for patients and their families who are waiting for medicines in order to unrelentingly follow through with the R&D of pharmaceuticals. Which is why the R&D Division has also initiated activities related to patient centricity, through which we will conduct R&D that incorporates the perspectives of patients and their families, leading to the type of drug discovery that patients truly want.

Basic approach to animal welfare

We have established internal regulations in accordance with relevant laws and regulations, and established an Animal Research Committee to examine if all animal research is carried out with appropriate consideration based on the principles of the 3Rs (Replacement [with alternative methods], Reduction [of the number of animals used], and Refinement [to reduce pain and discomfort suffered by animals]). As for our animal research implementation system, we periodically conduct self-inspections, and we have also been accredited by a third-party organization. We maintain an appropriate breeding environment for animals used in our experiments in consideration of animal welfare. In addition, as part of our efforts to protect the global environment, for the preservation of biodiversity, experiments using genetically modified animals are conducted in compliance with the Cartagena Act. Furthermore, waste generated by our animal research is disposed of by contractors licensed by the government.

Topics Holding of the R&D Conference

The R&D Conference is held every year to share the progress and results of R&D with all members of the R&D Division and link them to daily R&D activities and activities for maximizing product value. In FY2023, we held the 11th R&D Conference in July. Due to the impact of the COVID-19 pandemic, the last few conferences were held online, but this time, for the first time in four years, the meeting was held in a hybrid format, with a face-to-face meeting in the auditorium of the head office in addition to the online meeting. Lively discussions took place with many internal and external directors participating.

At the conference, business development activities in the U.S. at NS Pharma were presented in real time from the U.S. News, products under development and exploratory themes were reported, and the progress and results of items in each phase were shared. New and unprecedented initiatives in R&D were also presented, and all topics attracted a great deal of interest from the participants, and some discussions had to be cut off prematurely in the hall due to the time constraints. Through discussions at the R&D Conference, we will pursue the creation of new value and continuously bring new drugs to the market.

Pharmaceuticals Business

Initiatives Related to Intellectual Property

Nippon Shinyaku is committed to tackling the challenge of new modalities in drug discovery and globalization in order to realize our business philosophy of “Helping People Lead Healthier, Happier Lives.” We recognize that intellectual property (IP) plays an important role in promoting these purposes, and through the protection and utilization of IP, we will strengthen the superiority of our business and continuously improve our corporate value. We also respect third-party IP rights, practicing thorough IP-related risk management including ownership investigations.

R&D activities and intellectual property

At Nippon Shinyaku, the Intellectual Property Department collaborates with the R&D Division from the early stages of research. By doing this, we can protect pharmaceuticals and functional foods produced in-house in a multifaceted and strategic way, using not only substance patents, but also use patents, process patents, formulation patents, dosage and administration patents and so on. In addition, we are considering building and utilizing a patent portfolio to strengthen our global R&D strategy in an internal committee consisting of multiple department managers.

Understanding and analyzing intellectual property

With the basic attitude of respecting third-party IP rights, the Nippon Shinyaku Group regularly conducts ownership investigations regarding its products. We also conduct patent trend analysis in specific technical fields and IP analysis of competitors. As a result, we manage IP risk at an early stage and utilize the obtained analysis results in our R&D strategy and business strategy.

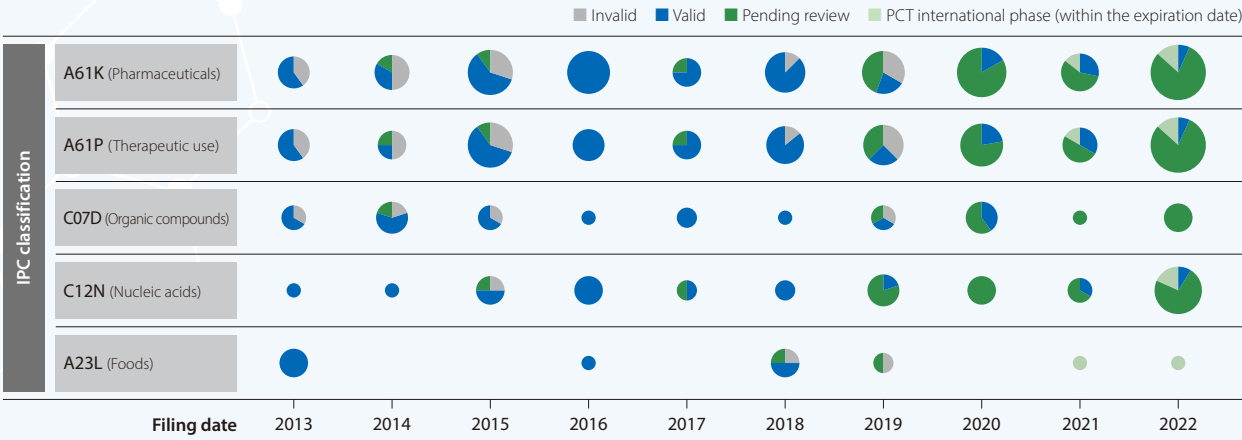
Building our reputation and brand based on trademarks

The Nippon Shinyaku Group determines the appropriate product names according to the medicines and functional foods produced in-house. By protecting them with trademark rights, we build the reputation and brand of our products.

Patent application trends

Our number of patent applications for pharmaceuticals and their uses has been increasing since 2019. This is especially clear in the field of nucleic acids, and we will protect the future business of Nippon Shinyaku in terms of intellectual property by ensuring that we protect the rights to the results of our efforts in our focal fields through patents. In addition, as research findings that can be patented stably emerge, mainly in our focal areas, we will continue to file patent applications for them in a timely manner, and acquire and utilize patent rights to protect our future business.

Application trends by International Patent Classification (IPC) (Top 5 classifications)



Invalid: A patent that has already expired or has been abandoned, or an application that has not been granted (e.g., rejected during review, abandoned by the applicant, etc.)
Valid: A patent that has been registered and the rights have been validly accrued
Pending review: A patent application that is under review in the patent office of the respective country
In the PCT international phase: A patent application that has been filed under the Patent Cooperation Treaty (PCT) but has not yet been reviewed by the national patent offices.

* Data analysis and compilation was conducted independently by Nippon Shinyaku using PatSnap Analytics.

Medical Affairs

Materiality			Realizing a healthy future by creating innovation		
Main Activities		FY2022 Activities		Issues and FY2023 Strategies	
<ul style="list-style-type: none">Providing information to medical institutions and implementing disease awareness-raising activities for patients and their familiesPromoting social understanding of diseases		<ul style="list-style-type: none">Pulmonary hypertension: Held co-sponsored seminars for medical professionals and public lectures for patients and their familiesMuscular dystrophy: Held public lectures online and patient networking events utilizing the metaverse		<ul style="list-style-type: none">Promoting patients' understanding of their diseasesPlanning events with a focus on patientsContinuing to hold public lectures and events for diseases such as pulmonary hypertension and muscular dystrophy	

Materiality			Resolving social issues and coexisting with the community		
Main Activities		FY2022 Activities		Issues and FY2023 Strategies	
<ul style="list-style-type: none">Disseminating scientific findings through academic papers and conferences for the development of the scientific field		<ul style="list-style-type: none">Took initiatives that included non-clinical research, clinical research, database research, and registry research as evidence generating activities in disease areas related to the pharmaceuticals handled by the GroupPublished paper on research findings related to anemia		<ul style="list-style-type: none">Responding to changes in the environment surrounding researchPresenting research findings at academic conferences and disseminating information through papersFulfilling unmet medical needs through new research	

Increasing Benefits for Patients by Disseminating Information

The mission of Medical Affairs is to engage in medical and scientific exchanges with key external experts using advanced, cutting-edge scientific knowledge to identify unmet medical needs*, generate scientific evidence to fulfill them, and disseminate information to medical professionals and patients in order to deliver the optimal medical care for all patients. At Medical Affairs, the goal is to optimize the value of the pharmaceuticals handled by the Group and contribute to increasing benefits for patients.

* Unmet medical needs (UMNs): Refers to medical needs that are not adequately satisfied for medical professionals and patients. Examples include needs for diseases for which no effective treatments have yet been found and needs for new therapeutic drugs or treatment methods.

with respect to its evidence generating activities, the Company is pushing ahead with preparations for new research on hematological malignancies, pulmonary hypertension, Duchenne muscular dystrophy, and anemia. In regard to its patient support activities, it plans to continue with its public lectures and networking events on pulmonary hypertension and muscular dystrophy. Nippon Shinyaku will act to make contributions to the healthcare field beyond the provision of pharmaceuticals in cooperation with medical science liaisons (MSLs)* who are responsible for medical affairs activities in medical institutions.

* Medical Science Liaison (MSL): Refers to employees belonging to an organization which is independent of the Sales and Marketing Division whose main role is to engage in exchanges with key external experts in the fields of medicine and science.

Progress of the Medium-term Management Plan and FY2022 Overview

In FY2022, in its evidence generating activities, Nippon Shinyaku worked on initiatives in non-clinical research, clinical research, database research, and registry research, and published a paper on its findings in database research. In term of patient support activities, it held online public lectures on pulmonary hypertension, and online public lectures and patient networking events on muscular dystrophy. In FY2023,

Value Creation Initiatives and Strategy

In recent years, the environment around healthcare has been changing significantly due to rapid advances in digital technologies. Nippon Shinyaku will also consider making use of these technologies to solve medical issues and generate evidence that bring benefits for patients. For example, the Company would like to take on the challenge of contributing to better healthcare with a focus on digital healthcare using the latest technologies, including wearable devices and applications, artificial intelligence (AI), and big data analysis to improve the effectiveness of medical and healthcare.

Pharmaceuticals Business

Resource Procurement, Production & Assurance

Stably delivering Nippon Shinyaku's highly original pharmaceuticals to those who need them

Hitomi Kimura

Director, Resource Procurement, Production & Assurance

The tasks of the Resource Procurement, Production & Assurance Division are wide-ranging. We single-handedly manage defensive operations spanning everything from raw material procurement to production planning, manufacturing, delivery, product and data quality assurance, safety information collection and assessment, and approval application and maintenance. A single misstep on our part at any point would prohibit us from fulfilling our most important duty—stable product supply. Accordingly, each day I am keenly aware of the importance of complying with laws and regulations, assessing risk, controlling inventory, and managing our suppliers. In addition to implementing the expected credit checks and due diligence, we also place importance on interpersonal communication in management. We hold weekly online meetings with the Odawara Central Factory and other relevant divisions. We also share information and engage in technical cooperation with affiliated companies. Through these means, we build better relationships. We in the Resource Procurement, Production & Assurance Division are frequently aided by such excellent relationships. For example, at the start of the COVID-19 pandemic when there was a shortage of sterile filters for injection production, the Raw Materials Procurement Department was able to successfully procure such filters from the United States through affiliated companies.

As Nippon Shinyaku seeks greater expansion globally, building a global supply system is a massive challenge. Issues such as environmental considerations as well as differences in regulations and business practices in supply destination countries require the prior gathering of sufficient information. In addition, even with raw materials that are within legal limits, there can be slight differences in quality between lots. We are thus also launching initiatives to promote the digitalization of information, avoid human error, and enhance stable product supply, such as integrating and analyzing data on quality and manufacturability.

Materiality

Realizing a healthy future by creating innovation



Main Activities

FY2022 Activities

Issues and FY2023 Strategies

Supply chain

- Establishing a global sales and supply system to provide pharmaceuticals and functional foods to the world
- Strengthening the stable supply system of products through risk management

- Surveyed suppliers on supply chain and CSR matters with the aim of sustainable and stable procurement
- Achieved a 100% risk assessment implementation rate regarding Nippon Shinyaku products, APIs, formulations, and important raw materials (149/149 items)
- Began construction of a nucleic acid API purification plant at the Odawara Central Factory

- Sharing the Nippon Shinyaku Sustainable Procurement Policy throughout the Group and with business partners
- Enhancing stable product supply by increasing demand forecasting precision using AI and other digital technologies
- Completing construction of the nucleic acid API purification plant at the Odawara Central Factory and making preparations for its operation

Reliability assurance

- Establishing a mechanism for supplying safe and high-quality products, including new drugs such as nucleic acid medicine

- Implemented thorough plant management regarding products and built a reliability assurance system for marketing in China

- Implementing integrated safety information management from the development stage and thorough plant management regarding products

Aiming for Stable Product Supply and the Construction of a Global Supply System

We are working to manufacture pharmaceuticals under new modalities to provide medicines and new treatments for diseases for which there are no therapeutic agents yet, such as nucleic acid drugs in addition to conventional pharmaceuticals. In order to deliver these to patients not only in Japan but around the world, it will be necessary to build a global supply system able to comply with each location's regulations, environment, and customs. Amid an uncertain social landscape, the environment around pharmaceuticals is turning more challenging. However, by implementing solid quality assurance and stable product supply under all conditions, and by providing appropriate safety and other product information, we will deliver peace of mind and confidence to patients and all of our stakeholders.

Progress of the Medium-term Management Plan and FY2022 Overview

In FY2022, we leveraged our experience building a pharmaceutical supply system for the United States to further the creation of a supply chain and reliability assurance system for the Chinese market. In addition, in order to respond to the increase in demand for nucleic acid drugs that will accompany further global expansion, we worked to enhance our supply system. For example, we began construction of a plant to handle a portion (the purification) of the nucleic acid manufacturing process at our Odawara Central Factory. We also added second suppliers for nucleic acid APIs, formulations, and raw materials.

Value Creation Initiatives and Strategy

In FY2023, we will continue to enhance our supply systems for the United States and Chinese markets and, with an eye toward expansion into new territories, work to gather necessary information and build required systems. In addition, in accordance with completion of construction on the nucleic acid API purification plant at the Odawara Central Factory, we will begin manufacturing pharmaceuticals that belong to new modalities.

We will further enhance the reliability assurance systems we have built, continue to provide appropriate information to society and patients, and work to secure even further reliability.

Building a Supply Chain that Can Support Stable Product Supply

A pharmaceutical supply chain which involves suppliers from multiple countries and regions faces the risks of natural disasters, infectious diseases, and geopolitical strife, the challenges involved in providing a stable supply of generics increased further in FY2022. Believing that avoiding the various supply chain risks and maintaining a stable product supply is our greatest challenge, the Nippon Shinyaku Group is promoting the following three strategies in order to increase its pharmaceutical supply chain capabilities.

1. Constructing a nucleic acid API purification plant at the Odawara Central Factory

We aim to complete this new nucleic acid purification plant in December 2023. We are positioning this facility as an investment to further build up our manufacturing technologies and to establish a strong global supply system.



Satoshi Asano

SC Management Section
Supply Chain Management
Department

Realizing Stable Product Supply for Patients Around the World

Viltepsa, released as Japan's first antisense oligonucleotide, is also the first product that Nippon Shinyaku has marketed itself in the United States. Unlike with the domestic products with which Nippon Shinyaku has accumulated an abundance of data and knowhow, we have had almost no experience marketing products ourselves overseas. The demand for such products cannot be accurately perceived or predicted based on what we have learned through our products in Japan alone. We engage in periodic meetings with the supply chain division of NS Pharma, a local Group company, to share detailed information on topics such as the state of sales domestically and overseas, future prospects, and production and shipping schedules, and in turn develop plans that enable the stable provision of Viltepsa both in Japan and internationally. Going forward, Nippon Shinyaku will strive to build a global supply chain that is even stronger and more optimized so that we may deliver our unique, high-quality pharmaceuticals quickly and stably to patients not just in Japan or the United States but around the world.

Pharmaceuticals Business

2. Building a risk management system to dynamically manage potential supply chain risks

Having a detailed grasp of our supply chain will help Nippon Shinyaku to manage risks. We are striving to maintain an accurate awareness of the stable supply and BCP* initiatives our suppliers engage in by conducting written surveys of suppliers involved in all APIs and formulations. Through a risk-based approach rooted in the results of these surveys as well as quality information and business records, we are taking thorough steps to reduce risks.

* BCP: An abbreviation of "business continuity plan."

3. Promoting the DX of our supply chain

At the Odawara Central Factory, we are moving forward with preparations to create a connected factory by creating a vial inspection system utilizing AI image recognition and connecting manufacturing facilities via IoT for improved quality and preventative maintenance. We are also investigating predictive modeling utilizing AI to detect environmental changes and other threats which could impact stable product supply and aid in highly accurate demand prediction.

Through these three strategies, we will reduce pharmaceutical supply risks and at the same time increase our competitiveness, propelling us further in our transition to a resilient supply chain.

Reliability Assurance Initiatives

The Production & Assurance Division handles compliance with relevant laws and ordinances as well as tasks spanning the

entire pharmaceutical life cycle, from the R&D stage through to product launch and beyond. Taking charge of product quality assurance, data reliability maintenance, safety information management, pharmaceutical applications, and post-manufacture and marketing surveys and medicine consultations, we strive to ensure the effectiveness and safety of pharmaceuticals.

In addition, through solid coordination between the various reliability assurance divisions under the general marketing supervisor, QA manager, and safety manager, we ensure compliance with the terms of approvals; maintain and manage pharmaceutical manufacturing and marketing licenses; and implement compliance with the GQP*¹, GVP*², and GPSP*³ ministerial ordinances. Through these means, we aim to further enhance our manufacturing and marketing systems to ensure product quality, effectiveness, and safety.

Additionally, in accordance with the global supply of products, we continuously revise our structure and procedures to ensure compliance with the regulations of new countries whose markets we are entering. In FY2022, we worked with a local subsidiary to build a reliability assurance system in China. In FY2023, we will be working steadily on operations to ensure product reliability in the United States and China. We will also be further developing our systems with an eye on future moves.

*1 GQP: An abbreviation of Good Quality Practice. A standard for the quality management of, among others, pharmaceuticals, quasi-drugs, cosmetics, and regenerative medicine products. Conformity to this standard is one of the requirements of pharmaceutical manufacturing and marketing licenses.

*2 GVP: An abbreviation of Good Vigilance Practice. A standard for post-manufacture and marketing safety management of pharmaceuticals, quasi-drugs, cosmetics, medical devices, in vitro diagnostic products, and regenerative medicine products. Conformity to this standard is one of the requirements of pharmaceutical manufacturing and marketing licenses.

*3 GPSP: An abbreviation of Good Post-marketing Study Practice. A standard for post-manufacture and marketing surveys and testing.



Shohei Nakagawara
Quality Assurance Section
Quality Assurance Department
Regulatory Affairs, Pharmacovigilance
and Quality Assurance Division

Globalizing the Work of Quality Assurance in Line with Each Country's Regulations and Requirements

When we engage in quality assurance, we strive to ensure that customers can take our products with peace of mind, focusing on appropriately maintaining and managing quality so that pharmaceuticals have the expected safety and work effectively. We have built a pharmaceutical quality system based on our quality policy. Under this system, we appropriately manage and supervise manufacturing facilities, assess product quality, and also engage in communication with regulatory authorities. As we globalize our pharmaceutical distribution, we need quality management which is in conformance with each country's regulations and requirements. Accordingly, we are gathering information about these so that we may respond swiftly even in the event of a quality issue at a factory, and so that we can ensure a stable product supply. Among our efforts in this area, our experience building our own marketing system in the United States for Vilepso was of great use when we created a reliability assurance system in China. Going forward, we will continue to strive to deliver our high-quality, unique pharmaceuticals to patients around the world.

Sales



Aiming to be a trusted treatment partner with high-quality information and integrity

Shouzou Sano

Managing Director, Sales and Marketing

The primary mission of our Sales and Marketing Division is to "deliver our unique products to as many patients suffering from illness as possible, as quickly as possible." To this end, we aim to become a treatment partner trusted by doctors and patients through providing high-quality information based on the spirit of patient centricity.

The Sales and Marketing Division also bears a great deal of responsibility in fulfilling President Nakai's three commitments. To achieve the continued launch of at least one unique product each year on average, it is essential to introduce in-licensed products and undertake PLCM. Demonstrating Nippon Shinyaku's relevance in our focal areas and fields and proving the strength of our marketing will lead to successful in-licensing.

Another role of medical representatives (MRs) is to grasp the needs of medical professionals and patients from their daily activities to obtain leads for PLCM. Concentrating on intractable and rare diseases, one of our focal areas, we help patients access early diagnosis and appropriate treatment by providing up-to-date information through ongoing communication, and collaborating with medical professionals in hospitals and clinics.

We are sometimes recognized by people outside the Company for the high integrity of our employees. Our work in Sales and Marketing is based on integrity, and without that integrity, and without knowledge, we cannot achieve results. Through the introduction of an in-house certification exam program and a team system for MR activities, we are striving to build a highly cohesive organization where we can grow through friendly internal rivalry. We must further hone our expertise and improve our marketing capabilities toward the critical goal of global expansion. Each Sales and Marketing team member will keep the spirit of patient centricity in mind and continue to fulfill our roles and responsibilities.

Materiality

Realizing a healthy future by creating innovation



Main Activities

- Promoting treatment, diagnosis, medication guidance, and life improvement through the use of digital technologies
- Providing information to medical institutions and implementing disease awareness-raising activities for patients and their families

FY2022 Activities

- Promoted medication guidance through "Sherpa," a support program for patients with pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension
- Provided information by combining MR activities with digital services (our owned site and third-party services) according to the following sequence of phases: disease recognition → diagnosis → treatment → continued medication
- Provided information on our disease awareness and product information websites created for patients

Issues and FY2023 Strategies

- Familiarizing physicians with the value of "Sherpa" (high patient satisfaction)
- Providing information using digital technology
- Combining MR and digital activities
- Providing information digitally using customer journey maps
- Considering and implementing marketing automation

Pharmaceuticals Business

Earn the Trust of Physicians by Providing High-Quality Information

The Sales and Marketing Division is committed to its mission to deliver our unique products to as many patients as possible, as quickly as possible based on the concept of patient centricity, where the patient is at the center of thoughts and actions in medical care. To achieve this mission, we will establish a system that enables us to accurately provide medical professionals involved in patient care with the information they need when they need it. We aim to become a treatment partner trusted by medical professionals by training MR as well as digital human resources and providing high-quality information through a combination of MR and digital activities.

Progress of the Medium-term Management Plan and FY2022 Overview

In FY2022, we focused our activities on our most important strategic products, Uptravi in the area of pulmonary hypertension and Viltepso in the area of pediatric neurology, both of which were discovered and developed in-house. Since providing information to specialists alone is not enough to deliver drugs to potential patients, we also conducted disease awareness and medical coordination activities geared toward non-specialists to ensure that patients receive optimal treatment as soon as possible.

As for new products, in 2022, in the area of pediatric neurology, we launched Fintepla for the treatment of epileptic seizures in patients with Dravet syndrome, a disease designated as intractable by the Japanese government. This is the first new drug for the treatment of Dravet syndrome in ten

years and has been eagerly awaited by many patients. In March 2023, in the area of gynecology, we launched MonoVer for the treatment of iron deficiency anemia. Many patients with anemia suffer in silence as they believe that their illness is common. Left with no treatment option, they choose to simply accept the disease. Since both drugs meet the needs of patients and have a significant role to play in fulfilling our social mission, we will achieve early market penetration in FY2023.

In the area of pulmonary hypertension, we launched the patient support program “Sherpa” in April 2022. “Sherpa” provides regular support by telephone to patients by nurses who have received specialized training in the program. We have received comments such as, “It is such a relief to have someone who understands my situation listen to me talk about my problems and anxieties,” and “I’m very grateful to be able to get accurate answers for the questions I have between appointments about the disease and the medications.” We will continue to provide the program for patients in FY2023.

Developing human resources to strengthen information provision activities

MR human resources

In order to implement high-quality information provision activities by MRs, we have continued training in problem-solution based detailing since FY2021, in which MRs communicate the benefits that our products bring to physicians and patients based on an understanding of each patient’s background, values, and treatment issues. In FY2023, we will promote further improvement of problem-solution based detailing by focusing on training for sales office managers, who are the main actors in OJT, and role-playing drills.

In addition, each branch office has an area product marketing (aPM) personnel who serves as the main area marketing contact. aPM personnel are focused on specialty products, while MRs oversee all products, so that a synergistic effect can be achieved by accompanying MRs and aPMs.

Digital human resources

In FY2023, we established the Digital Solutions Department to expand and further strengthen our digital operations. This department will, in collaboration with the Product Marketing Department at the head office, produce and distribute digital content to strengthen information provision activities utilizing digital technology. Digital content will be expanded and

enhanced to meet challenges and objectives, ranging from disease awareness for the purpose of market expansion, to evidence supporting the selection of Nippon Shinyaku’s pharmaceutical products, and measures to prevent side effects ensuring proper use of drugs. By analyzing the delivery data and implementing the PDCA cycle, we will promote the use of digital content so that medical professionals can obtain the information they need, when they need it.

We have also established a system that allows MRs to use iPads equipped with all our digital content to deliver information, and we are working on a system that enables high-quality information provision by combining MR activities with digital content.

Disease Awareness Initiatives

Among Nippon Shinyaku’s focal areas, intractable and rare diseases present a particular need for providing information to medical professionals and patients, as there is often insufficient information about patients, symptoms to watch out for, and treatment methods. In addition to enhancing digital content for

Amount of digital content on Nippon Shinyaku’s owned websites

	FY2022 results	FY2023 target
Page content	63	73
Brochure content	10	57
Video content	80	82
Total	153	212



Erina Kouno

FerrCare Product Marketing Group,
Primary Care Product Marketing
Department
Sales and Marketing Planning Division
Sales and Marketing Division

Uplifting as many patients needing treatment as possible

In my work in the Product Marketing Department, I try to deliver the right information to patients. I have been involved in planning and managing a support program for patients taking medications. The anxiety patients feel during treatment can cause them to give up taking their medications, so we set up a program that can support them in continuing their treatment.

Sometimes patients tell me that they are grateful for this program for helping them through their loneliness and anxiety regarding their treatment. Moments like these make me newly aware of my mission, and I will continue to uplift as many patients as possible by conveying the importance of going through treatment and the value of Nippon Shinyaku’s products.



Implementing high-quality information sharing activities

MRs to exchange information face-to-face with medical professionals and strengthening information provision activities, we are focusing on providing information through digital media such as websites. We will approach patients in need of treatment through disease awareness efforts to ensure that necessary medications reach those who need them as soon as possible.

In addition, the area-specific aPM personnel assigned to each branch office work with MRs to promote disease awareness initiatives suited to regional characteristics and conditions. We believe that providing medical professionals with specialized information in their areas of expertise, accurately identifying problems that patients face based on information collected on a case-by-case basis, and promoting initiatives to solve these problems will lead to patient centricity. We aim to become a trusted presence by working together as a united Sales and Marketing Division team and taking the correct approach to the problems faced by medical professionals and patients.



MRs and aPMs Focused on Specialty Products Collaborate

Functional Food Business

The Functional Food Division engages in business activities based on its vision which is “Operating within a pharmaceutical company, the Functional Food Division proposes solutions to social challenges, including promoting health and ensuring food safety and security, thereby contributing to building a sustainable society.” To realize this vision, Nippon Shinyaku pursues product development and awareness raising activities to provide value that helps people continue to lead healthier and happier lives, and contributes to solving issues faced by society, such as improving health through food and nutritional problems.

Developing products that contribute to solving social issues from the unique perspective of a pharmaceutical company

Hitoshi Ishizawa

Director, Functional Food

The Functional Food Division operates the B2B bulk materials business in health food ingredients, preservatives, and protein preparations, and the Supplements business, which is mainly B2C. Food is a daily necessity, but at the same time, food loss has become a social problem. Therefore, there is high demand for preservatives, which have been achieving annual growth of around ¥100 million as a product that helps to extend the shelf life of food. Nippon Shinyaku has started using AI at the research and development stage and has developed a system that can identify putrid bacteria formed in food to verify the effectiveness of preservatives in a day, a process which used to take over a fortnight. In the future, the Company will aim to further contribute to food waste reduction by responding rapidly to the requests of food manufacturers.

WINZONE Whey Protein, a B2C product, has strong support among casual users as well as athletes due to its great taste, in addition to the fact it is easy to drink and nutritionally balanced, which differentiates it from rival products. In Japan, there is data indicating that protein intake among the elderly and children is inadequate. Nippon Shinyaku approaches these groups through food education activities and promotes initiatives to solve the social issue of extending healthy life expectancy. It is also looking to expanding into East and Southeast Asia, where economic growth is striking.

Researchers in the Functional Food business incorporate different perspectives into their research by gaining new inspiration through exchanges with researchers from the Pharmaceuticals business. The Company will continue aiming to develop products that live up to the high level of trust users them have in pharmaceutical companies.

Feedback from an Athlete

A feeling of confidence supported my physical health during a grueling schedule

Mika Shibata Japan women's volleyball team

The most difficult thing for me about playing in the French professional league was the three daily meals. I had to think seriously about the meals I ate as I was cooking the three meals myself and had experienced a serious Achilles tendon rupture in the past.

In France, there is a game nearly every week during the season, and we travel around a big country in an eight-seater minibus. One of the factors that got me through the season without getting sick in this grueling environment is WINZONE Whey Protein and the sports supplement WINZONE Energy Series.

I found I was less likely to still be tired the next day if I took WINZONE Whey Protein during training and before going to bed. Also, some games last more than two hours, but using WINZONE Energy Series stopped me running out of stamina. Nippon Shinyaku's products are made in Japan and have received anti-doping certification*, so they can be used with safely.

In the future, I think that if the required intake and timing for each sport was indicated, the products would be easier to use for people who don't know how much to use for their sport or when.

I hope you will continue to provide support for athletes.

* Anti-doping certification: A global standard anti-doping certification program for sports supplements with a system for checking whether supplements are contaminated by substances whose use is prohibited by the World Anti-Doping Agency (WADA) using advanced analysis technologies and manufacturing plant audits

Mika Shibata

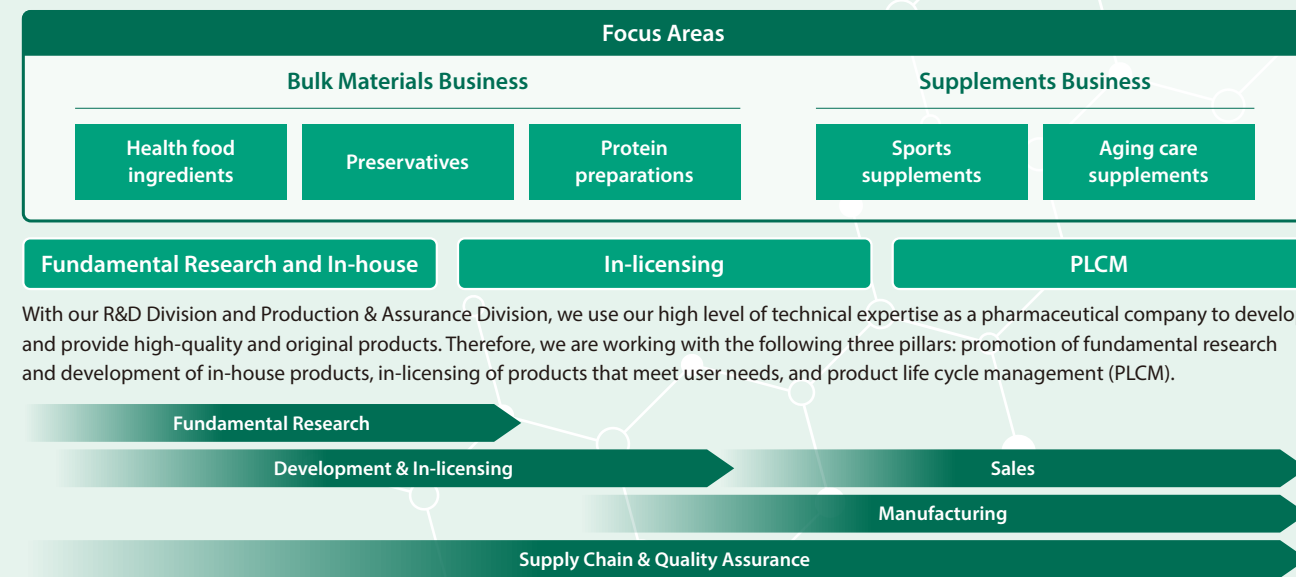
Born in 1994 in Kyoto City, Kyoto Prefecture. She played for JT Marvelous in Japan's V. League before joining Vandoeuvre Nancy Volley Ball (VNVB) in the French women's A league for the 2022-2023 season. In 2022, she represented Japan in the AVC Cup, contributing to the team winning the competition, and also receiving the MVP prize. She plays as setter.



Materiality			Realizing a healthy future by creating innovation			3	8	9	12	17
Main Activities			FY2022 Activities			Issues and FY2023 Strategies				
• Providing unique healthcare products and health food ingredients to promote health through food			• Launched WINZONE Soy Protein and Kiwami Select Collagen as new healthcare products • Foods with Function Claims accepted for products containing the Company's health food ingredients, such as garcinia extract: 16			• Enhancing healthcare product lineup • Further increasing number of Food with Function Claims accepted • Providing new value through PLCM activities for existing products				
Materiality			Strengthening efforts to protect the global environment			7	12	13	15	
Main Activities			FY2022 Activities			Issues and FY2023 Strategies				
• Developing high-quality stable preservatives that do not impair the taste of food, in order to extend shelf life and reduce waste			• Isolated and genetically analyzed bacteria that cause food spoilage from commercially-available lunch boxes, processed foods and other food products			• Investigating additives that are effective against low temperature growth and acid resistance of isolated bacteria that cause food spoilage				
Materiality			Resolving social issues and coexisting with the community			3	4	10	11	
Main Activities			FY2022 Activities			Issues and FY2023 Strategies				
• Conducting dietary education activities for children in order to foster an interest in food			• Created booklets for the lower grades of elementary school to raise awareness about the importance of protein intake and reducing food loss and distributed them in public facilities in Kyoto • Provided on-site classes at several elementary schools and other facilities in Kyoto			• Launching WINZONE Junior Protein, the first product related to food education activities • Promoting activities centered on WINZONE Junior Protein for junior high school students to raise awareness about eating breakfast, such as on-site classes and sponsoring events organized by local governments				

Functional Food Business

Functional Food Division Business Model



With our R&D Division and Production & Assurance Division, we use our high level of technical expertise as a pharmaceutical company to develop and provide high-quality and original products. Therefore, we are working with the following three pillars: promotion of fundamental research and development of in-house products, in-licensing of products that meet user needs, and product life cycle management (PLCM).

Helping to Solve Social Issues Related to Food

The Functional Food Division engages in fundamental research and obtains evidence for ingredients traditionally assumed to be good for the body, with the priority on the safety and quality that Nippon Shinyaku has built up as a pharmaceutical company. The Company works to improve the quality of life of all people and solve social issues by developing and providing products that are highly nutritious and cost-conscious to ensure affordability for all. These products include protein-fortified foods to improve health and extend healthy expectancy and products suited for the complete and balanced nutrition field such as concentrated liquid foods used in medical institutions and care facilities for the elderly.

Applying the high-level technology built up in the pharmaceutical field to microbial control, Nippon Shinyaku also pursues initiatives for food safety and security to help solve long-standing social issues with the aim of realizing a sustainable society, such as reducing food waste by extending the best before dates for food. In addition, by developing awareness-raising activities for food education and developing products, it will continue helping to solve social issues related to food for all generations. These food-related issues include the problem of younger people not eating breakfast and frailty, sarcopenia among the elderly and extreme weight loss among women caused by low nutrition. The Company is implementing initiatives with local governments, educational institutions, and other organizations to foster interest in food and promote healthy eating habits.

Progress of the Medium-term Management Plan and FY2022 Overview

Bulk Materials business

In the health food ingredients field, Nippon Shinyaku is promoting the development of ingredients with health-promoting benefits likely to be accepted as Foods with Function Claims by the Consumer Affairs Agency. Going forward, the Company will continue providing products that contribute to improving health by searching for original ingredients that can precede the needs of the health food industry and engaging in joint development with major health food manufacturers based on those ingredients. In the preservative field, Nippon Shinyaku is aggressively promoting consulting services for processed food manufacturers on extending best before dates as an approach aimed at solving the social issues of food waste. In the protein preparation field, it is introducing high-function proteins and other preparations to meet social needs and working to break away from price competition resulting from commoditization, in addition to promoting joint development with major food manufacturers, both for healthcare and everyday foods.

Supplements business

In November 2022, Nippon Shinyaku launched Kiwami Select Collagen, an aging care supplement. This is a high-quality product manufactured in Japan which has minimized the distinctive odor and taste of ordinary collagen. In FY2023, the Company will conduct campaigns to increase product recognition, and launch additional products in the series

containing carefully selected beauty and health ingredients to fulfill a wide variety of customer needs. In February 2023, with the launch of SOY PROTEIN PERFECT CHOICE Kinako Chocolate Flavor, a sports supplement, Nippon Shinyaku added a product made from soybeans to the series, which had up to then used milk-derived whey. In FY2023, the Company will actively expand its presence at sports events and engage in direct communication to increase product recognition and strengthen relationships, thereby providing new value.

New initiatives to resolve social issues and expand businesses

As part of the food education-related activities launched in FY2021, Nippon Shinyaku prepared on-site classes and booklets on food education, developed protein and other products for children and the elderly, and investigated the development of an application for collecting and utilizing health information. In its first initiative in overseas expansion, the Company will promote the development of sports supplements in Taiwan.

FY2023 Initiatives and Strategy

Cooperation with Local Governments to Spread Food Education

WINZONE Junior Protein, developed through our educational activities, enables the easy absorption of protein at breakfast by children who tend to lack this nutrient while they grow up.

In popularizing this product, Nippon Shinyaku has collaborated with local governments in the organization of various events aiming to spread food education and promote a balanced nutritional intake and regular eating habits.



Developing products with higher nutritional value with safety and quality as the priority

Initiatives to improve customer experience through the use of DX and the promotion of originality

In the preservative field, Nippon Shinyaku aims to improve customer experience by strengthening interactive communication through the construction of an original system using DX, allowing the Company to both deliver the information needed by customers and timely receive their questions and requests for technical reviews.

Investigating unique human resources development program for the Functional Food Division

Based on the feedback on SPIRITS, the unique, next-generation leader development program for the Functional Food Division implemented in FY2022, and the digital human resources development program, Nippon Shinyaku will establish a new human resources development program to be implemented in FY2024.



Tetsuro Yoshida
Product Development Section
Protein Business Department

Supporting the healthy growth of children with our products

We are involved in development of sports supplement brand WINZONE. So far, we have brought to market 16 high-quality, safe and reliable products that top athletes want to get hold of in the three areas of endurance, joint care, and protein. Since last fiscal year, in a new initiative, we have been focusing on generation-specific nutritional issues as a priority task and we are developing applications that will help people to consume various proteins better. As the first step, we launched WINZONE Junior Protein this spring to solve the issue of inadequate consumption of protein at breakfast time by elementary and junior high school students. We believe it is significant for Nippon Shinyaku to supply this product that safely provides growing children with the nutrients they tend to lack. We will support the healthy growth of children through sales promotion campaigns and food education activities in collaboration with local governments, educational institutions, and other organizations.

Human Resources Development



Giving our all to solve social challenges brings both company and employee growth

Takashi Takaya
Director, Personnel, General Affairs, Risk Management, Compliance & Digital Transformation

Based on the idea that unique products are the product of unique people, Nippon Shinyaku respects the diversity of its employees and seeks to provide opportunities so that each and every one may take on challenges with a positive attitude and grow. The key message of our recruitment website is as follows: “Can you give your all for individuals?” Our employees believe and take pride in this message, and through action which embodies it, we are living up to the expectations of society.

The desire to give one’s all is what leads to action. The desire to give one’s all is the most powerful management resource. In accordance with this belief, in April 2023 we put a name on the desire to give one’s all, calling it the “NS Mind.” The NS Mind consists of three “alls,” principles that all employees, from the management team to the newest employee, should put into practice daily: “Give your all for yourself,” “give your all for others,” and “give your all for society.”

Nippon Shinyaku Academy (NS Academy) is a support system for autonomous career development. We also offer a variety of programs, providing support for developing expertise, MBA acquisition, PhD acquisition and studies abroad as complementary programs. Our HONKI Juku program for fostering the next generation of management leaders focuses on the management of tomorrow through dialogue with our management team. Employees can also make use of other systems, including those for second jobs, volunteering, and secondments, which provide opportunities to further cultivate sensibilities and diversity.

It is by no means easy to learn on one’s own initiative and build a career. We employ a variety of measures to increase the subjective happiness of employees on an individual level. We also constantly check on the health of individuals and organizational units through engagement and well-being surveys. Happy, unique, and individual human resources giving their all to solve social issues will promote sound company growth.

Materiality	Developing diverse human resources and realizing employee well-being	
Main Activities	FY2022 Activities	Issues and FY2023 Strategies
<ul style="list-style-type: none">Fostering autonomous human resources and global leaders who are motivated to growBuilding a flexible and resilient organization that can respond to changePromoting diverse work styles tailored to each individualRealizing a workplace that is comfortable and rewarding where psychological safety is ensured	<ul style="list-style-type: none">Instilled the NS MindCreated the NS MindLooked into the NS Academy systemRevised the Next-Generation Leader Challenge Program into HONKI JukuEstablished new programs to foster practical business skills and a global mindsetCreated new job descriptionsEvaluated the expertise needed for work tasks and expanded the professional system to provide appropriate employee treatmentIntroduced a second job systemPromoted 1-on-1 meetingsMade a portion of childcare leave paid	<ul style="list-style-type: none">Increasing the number of NS Academy participantsPromoting the human resources who have taken part in the Next-Generation Leader Challenge Program and HONKI Juku to middle management, executive, department manager, and other leadership positionsIncreasing the number of PROGOS English speaking test-takersIncreasing the number of participants in the global mindset trainingIncreasing the number of human resources able to flourish in global fieldsImplementing cross-departmental discussions on psychological safetyIntroducing engagement surveysExpanding the number of departments utilizing the flextime system

The NS Mind demonstrates the conduct, attitude, and awareness employees should set as a goal

In order to deliver our unique products as quickly as possible to as many people as possible, it is necessary for each and every employee to experience even greater growth and leverage their unique individuality and strengths in their work with each other. It is also essential for the entire company to come together as one team to maximize performance. For this purpose, we created the NS Mind, a list of principles which demonstrates the conduct, attitude, and awareness all employees should set as a goal. Through the NS Mind, we will aim for the growth of both employees and our Company to create an even better organization together.



The NS Mind: Three “alls” and seven actions

- <Give your all for yourself>
- 1. **Think and act as if it affects you personally**
Act with a sense of ownership toward any and all challenges.
 - 2. **Be better than you were yesterday**
Aspire each day to improve yourself as you engage in your work and self-development.
- <Give your all for others>
- 3. **Take the initiative and demonstrate leadership**
Be willing to speak up and get others involved.
 - 4. **Turn consideration into action**
Be considerate and create a highly psychologically safe environment.
 - 5. **When in doubt, share**
Share ideas, opinions, questions, knowledge, and experience to stimulate and inspire those around you.
- <Give your all for society>
- 6. **Think about the future of the Company and society**
Create a future that promotes the well-being of people.
 - 7. **Challenge yourself as a pioneer**
Have a dream for what you want to do as a member of Nippon Shinyaku and never give up on achieving it.

Human resources development policy

In order for Nippon Shinyaku to continue to grow sustainably, it needs to be a company employees choose, a company where employees feel self-fulfilled and that they are growing, a company where they want to continue to work. To that end, Nippon Shinyaku will be tackling four themes: Realizing employee treatment in line with roles, duties, and accomplishments; realizing self-directed career development and the placing of the right employee in the right position;

realizing a highly psychologically safe organization; and realizing flexible work styles. Accordingly, we will be establishing systems and an environment which enable all employees to flourish regardless of gender, nationality, age, or other personal characteristics. Additionally, in securing human resources, we engage in systematic mid-career recruitment, and the 4% of our employees who are mid-career hires provide us with their high levels of expertise. Going forward, we will be increasing our numbers of global human resources through both new graduate and mid-career recruitment.

Realizing employee treatment in line with roles, duties, and accomplishments	Realizing self-directed career development and the placing of the right employee in the right position	Realizing a highly psychologically safe organization	Realizing flexible work styles
<ul style="list-style-type: none">Job descriptionsReforming wage systemReducing number of years for promotionsRevising evaluation systems	<ul style="list-style-type: none">Competency surveysNS AcademyExpanding the professional systemWork experience in other departmentsSecond job system	<ul style="list-style-type: none">1-on-1 meetingsEngagement surveysInternal praise applicationLeadership assessments	<ul style="list-style-type: none">TelecommutingFlextimeStaggered working hoursSupporting work-life balance

■ **Realizing employee treatment in line with roles, duties, and accomplishments**

We have carefully considered our job descriptions establishing work content, authority, areas of responsibility, necessary skills and experience, objectives, and evaluation methods. Our goal is to make it easier for employees aiming for a specific position to create a self-development plan by clarifying the roles, duties, experience, and skills needed for positions, realizing employee treatment in line with roles and duties, and openly disclosing the required experience and skills. In addition, we have revised our evaluation systems to reflect employees taking on challenges in their work. We are also working on reducing the number of years required for promotions and reforming our wage system, which were previously based on age and experience.

■ **Realizing self-directed career development and the placing of the right employee in the right position**

Nippon Shinyaku has introduced competency surveys for its managerial positions so employees can get an objective analysis on the gap between where they are now and the role they should aim for. In addition, we looked into the NS Academy, a human resources development program whose goal is the success of diverse personnel and which supports employees’ autonomous career development. Nippon Shinyaku has established three types of human resources essential for its sustainable growth: those who promote “Change,” those who are “Global,” and those who are

Human Resources Development

“Professional.” The Company has further established programs for each type spanning four categories: “Career,” “Basic,” “Skill up,” and “Challenge.”

● Fostering future managers

We have revised our Next-Generation Leader Challenge Program, operated since 2007, into a program called HONKI Juku (Change/Challenge). By taking self-development programs and tackling management challenges provided by our management team, the aim of HONKI Juku is to give employees the knowledge, skills, and attitude needed by the next generation of management. In addition to providing self-development programs, we have expanded opportunities to engage in dialogue with the management team.

● Fostering global human resources

In accordance with our global expansion, we have also enhanced our training and support in order to foster global human resources. Through global mindset training (Global/Basic) and other training, we offer programs that cultivate the kind of mindset to face global challenges constructively and on a level footing. In FY2023, 68 new employees and 81 employees who have received a promotion have undergone such training, which is also mandatory for new employees. Our foreign language support program (Global/Skill up) supports employees' self-directed study of English and other foreign languages. In order to promote actual English usage abilities beyond mere study, we have introduced the PROGOS English speaking test (Global/Skill up), and to date 349 employees have taken this test.

In addition, we have also established study abroad support systems (Global/Challenge) to provide opportunities to the next generation of employees who will lead the Company to study at international universities and research institutions, gain an understanding of global business, and expand their knowledge. The aims of these systems are not only the acquisition of specialized knowledge and the building of

personal connections but also to support life in other countries and cultures, foster global human resources, and increase employee drive to take on new challenges. In addition to a system supporting study abroad at an institution of the employee's choice, we also offer a system which recruits interested persons to study abroad at an institution that Nippon Shinyaku has selected.

● Fostering human resources for DX

Nippon Shinyaku is focusing on creating an organization suited to the digital age and fostering human resources who will promote DX. Our efforts are supported by the two following pillars: “measures to enhance the IT and DX literacy of all employees,” and “selective DX specialist training,” in which there have been a total of 1,493 participants.

Our measures to enhance the IT and DX literacy of all employees (Professional/Skill up) include support for obtaining Di-Lite*¹-compliant certifications, internal DX webinars provided by both in-house and external instructors, and the introductory “Manan-DEGITA-ru” course for improving IT skills directly related to employee work. Our selective DX specialist training (Professional/Challenge) is divided into foundational and applied courses for three skill categories: data science, business, and data engineering. Each training session is implemented for half a year.

● Fostering human resources who will produce competitiveness

Nippon Shinyaku provides a system which supports employees in technical and research positions who wish to obtain a PhD with the aim of improving the Company's research and engineering capabilities. We also foster human resources aiming for middle management and executive positions with a support system, open to a few employees each year, for obtaining an MBA with the aim of strengthening our organization as a whole. Nippon Shinyaku has around 50 MBA-holders, and 36.2% of employees have a PhD or master's degree.

● Fostering human resources who determine their own careers

We provide career development training (Career) for employees aged 30, 40, 50, and 55. This program, provided to all employees when they reach critical ages, provides them with the opportunity to think about the work style that best fits them, how they can contribute to Nippon Shinyaku, and the future of their career.

We will also be expanding our professional system for evaluating not just management capabilities but also the expertise needed for one's position. Other programs we will be

expanding include our internal open recruitment system and work experiences in other departments to promote career planning and inter-departmental exchange. Through these means, we will be supporting diverse work styles at Nippon Shinyaku. In August 2022, we introduced a second job system for working outside Nippon Shinyaku. This system supports the autonomous growth of employees and helps them gain a diverse background as well as knowledge and skills they could not acquire internally, promoting employee growth.

■ Realizing a highly psychologically safe organization

Nippon Shinyaku is aiming to cultivate a work environment that promotes employee well-being. In addition to promoting 1-on-1 meetings to enhance communication between superiors and subordinates, we have also introduced an internal praise application for use between colleagues. Further, we implement leadership assessments which collate the results of anonymous answers by subordinates on the words and actions of superiors, providing feedback on strengths, weaknesses, and the degree to which a superior has been able to demonstrate their skills.

Nippon Shinyaku has focused on health and productivity management since 2018. In addition to annual stress checks, since 2003 we have also implemented programs to support employee engagement. Stress checks, however, are only one component of proper self-care, and it has been difficult integrating them into improving workplace engagement. In the spring of 2023, we introduced a new engagement survey*² with the aim of resolving organizational challenges at a deeper level and promoting the well-being of each individual employee. We are working to achieve a positive response rate*³ of at least 75% for each of the three engagement items*⁴ in the survey.

■ Realizing flexible work styles

With the aim of enabling flexible work styles, increasing productivity, and creating work-life balance, Nippon Shinyaku has introduced flextime, telecommuting, and staggered working hour systems. Our flextime system, already introduced in some departments, is scheduled to be expanded to additional departments in the future.

With the revisions to the Childcare and Caregiver Leave Act in April 2022, Nippon Shinyaku's president released an internal message encouraging the utilization of childcare leave so that all who desired could make use of such leave with peace of mind. In addition, Nippon Shinyaku now provides paid leave for a portion of childcare leave (up to 14 days total paid leave when taking childcare leave for five consecutive business days or more). As a result, the childcare leave uptake rate was 76.1% in FY2022. In addition to a 100% uptake rate among eligible women, the uptake rate among eligible men rose to 69.3%, up from 50% in FY2021.

A workplace where employees trust and understand each other and can take childcare leave with peace of mind is a workplace that is comfortable not only for employees raising children but all employees who may have personal circumstances necessitating leave-taking. In order to realize such a workplace, Nippon Shinyaku will create a culture of mutual acceptance of each other's situations and circumstances, and of helping each other.

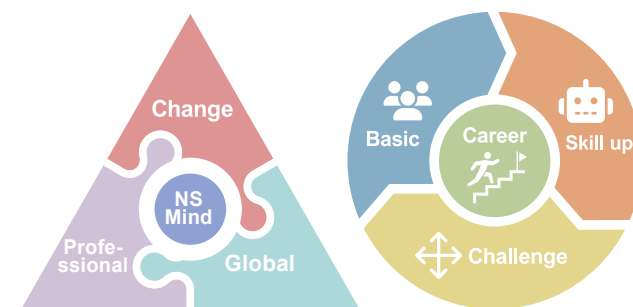
*1 Di-Lite: The scope of digital literacy all businesspersons should have as defined by the Digital Literacy Council of Japan.

*2 Nippon Shinyaku uses a survey provided by Qualtrics for its engagement surveys.

*3 The three engagement items in the survey are as follows:

- This company motivates me to contribute more than is normally required to complete my work.
- My work gives me a feeling of personal accomplishment.
- I would recommend this company to people I know as a great place to work.

*4 Positive response rate: The rate of those who answered “agree” or “strongly agree” on a five-point scale.



NS Academy



Shunya Kaji

Hospital Team
Chuo Sales and Marketing Branch
Tokyo Business Office
Sales and Marketing Department

Making full use of childcare leave with the support of my team members and a robust internal leave system

As a medical representative, I primarily work with university hospitals in Tokyo. When my first child was born, I didn't take off work, but after seeing how difficult childcare was, I felt like I should take childcare leave when my next child would be born. Later, my own brother took childcare leave, and I also learned about Nippon Shinyaku's own robust leave system, strengthening my decision to take leave when the time came. I was quick to tell the members of my team about my intention, and thanks to the cheerful support they gave me, I was able to use the childcare leave system smoothly and with peace of mind.

I was on leave for around a month, and I experienced firsthand the difficulty of raising children all day. This experience strengthened the bonds of my family and improved both my private and work life.

Diversity, Equity & Inclusion (DE&I)

Materiality	Developing diverse human resources and realizing employee well-being	
Main Activities	FY2022 Activities	Issues and FY2023 Strategies
<ul style="list-style-type: none"> Fostering a culture that recognizes individuals regardless of factors such as age, gender, values, or disability 	<ul style="list-style-type: none"> Conducted project activities by the Personnel Department and employees recruited from throughout the Company with the goal of employing people with disabilities and expanding their job opportunities In order to instill DE&I throughout the Company <ul style="list-style-type: none"> Held panel discussions with employees with disabilities and the Collaboration Department Simulated experience of people with developmental disabilities using VR Conducted Universal Manners (Level 3) training Conducted training on unconscious bias 	<ul style="list-style-type: none"> Promoting awareness of the importance of DE&I to human resources who have little experience collaborating in their own jobs or workplaces <ul style="list-style-type: none"> Publicizing the Collaboration Department Increasing the number of participants in Universal Manners training

Basic Approach to DE&I

Based on the idea that unique products are the product of unique people, Nippon Shinyaku respects diversity in terms of sex, age, nationality, and beliefs, and provides opportunities for individuals to take on challenges and grow in a positive manner. In order to create innovation and achieve sustainable growth, we are working to promote well-being and create an organizational climate in which employees with diverse values can thrive.

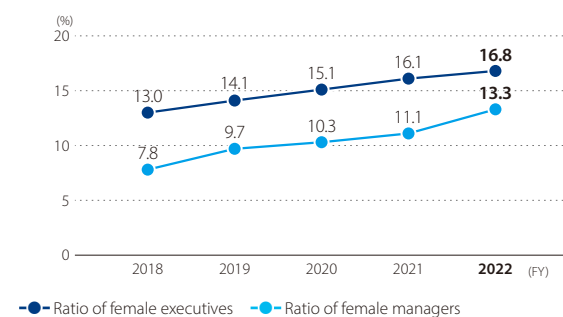
Supporting the advancement of diverse human resources

Since FY2019, Nippon Shinyaku has touted the goal of having 15% or more of female executives as part of its "General Employer Action Plan based on the Act on Promotion of Women's Participation and Advancement in the Workplace." That goal was met in FY2020, when female employees accounted for 15.1% of executive positions. In FY2022, that

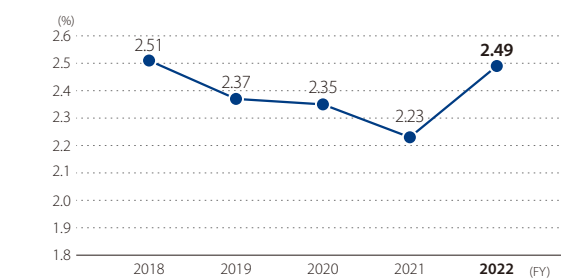
number rose to 16.8%, indicating that the number of female executives and female managers is growing every year. Having agreed to the Japan Business Federation (Keidanren)'s #Here We Go 203030 initiative—having females account for at least 30% of directors by 2030—we are aiming to create a workplace environment and organization that makes it possible for various types of human resources, including females, to improve their career.

As for employing people with disabilities, in FY2007, Nippon Shinyaku introduced the Dual System, which makes it possible for participants to learn while working, under the concept of diversity, equity, and inclusion. We are also working to expand employment and job opportunities in collaboration with work-transition support providers, government agencies, and local companies. We have not established any special-purpose subsidiaries, but we have set up collaborative departments to work with multiple people with disabilities and actively provide opportunities for them to grow together.

Ratio of female executives and female managers



Disabled employee ratio



Human Rights Initiatives

Materiality	Resolving social issues and coexisting with the community	
Main Activities	FY2022 Activities	Issues and FY2023 Strategies
<ul style="list-style-type: none"> Implementing in-house education and awareness-raising activities to promote understanding of human rights 	<ul style="list-style-type: none"> Conducted human rights risk survey for managers Conducted human rights due diligence training for all employees 	<ul style="list-style-type: none"> Establishing a system for human rights due diligence initiatives Raising awareness of human rights Having dialogue with third parties

Human Rights Initiatives

The Nippon Shinyaku Group has established the Nippon Shinyaku Group Human Rights Policy to fulfill its corporate respect for human rights based on the Code of Conduct for Nippon Shinyaku Group, which is a practical standard of conduct that all executives and employees should take in their business activities to meet the expectations of society and earn its trust.

Basic Approach to Human Rights

As a signatory to the United Nations Global Compact, we support the ten principles in the four areas of responsibility. We also understand the human rights expressed in the Universal Declaration of Human Rights and the principles related to fundamental rights set forth in the International Labour Organization (ILO) Declaration on Fundamental Principles and Rights at Work as minimum standards. In our business activities, we respect the human rights and personalities of individuals in accordance with the Guiding Principles on Business and Human Rights. In terms of pharmaceutical R&D, we will act with high ethical standards in accordance with the Declaration of Helsinki and build a relationship of trust with society.

WEB Click here for the full text of our Human Rights Policy
<https://www.nippon-shinyaku.co.jp/english/sustainability/esg/social/humanrights.php>

Organizational structure

The Sustainability Committee, chaired by the president, deliberates and reports twice a year on initiatives concerning respect for human rights, and important matters are reported

to the Board of Directors. The director in charge of business management & sustainability is responsible for human rights, and the Corporate Sustainability Department promotes initiatives to resolve issues.

In 2023, we established a Human Rights Subcommittee under the Sustainability Committee to further promote full-scale human rights due diligence, with the heads of related divisions as members. The subcommittee will hold discussions to identify internal and external human rights issues and promote human rights initiatives.

Going forward, we will assess and identify human rights risks both internally and externally in order to build a human rights due diligence mechanism in accordance with the United Nations Guiding Principles on Business and Human Rights. Also, we will evaluate our efforts to address the identified risks and their effectiveness, and disclose information appropriately.

Human rights risk assessment

In 2022, the Nippon Shinyaku Group conducted a human rights risk survey and other surveys targeting managers. We will continue to conduct surveys on a regular basis and expand the scope of the survey in order to identify human rights risks and take appropriate measures.

Training and awareness

The Nippon Shinyaku Group provides training on human rights to all employees. In addition to annual training on harassment, training on human rights due diligence was conducted as part of departmental compliance training in 2022. We also inform our business partners about our human rights policy, seeking their understanding and promoting their efforts.

Well-being Management

Materiality			Developing diverse human resources and realizing employee well-being				
Main Activities	FY2022 Activities		Issues and FY2023 Strategies				
<ul style="list-style-type: none"> Realizing a workplace that is comfortable and rewarding where psychological safety is ensured Maintaining and improving employee health 	<ul style="list-style-type: none"> Held health seminars (seven times, total of 3,400 participants) Held company-wide online lecture 		<ul style="list-style-type: none"> Maintaining well-being promotion activities Expanding measures to enable co-workers to increase their sense of unity 				

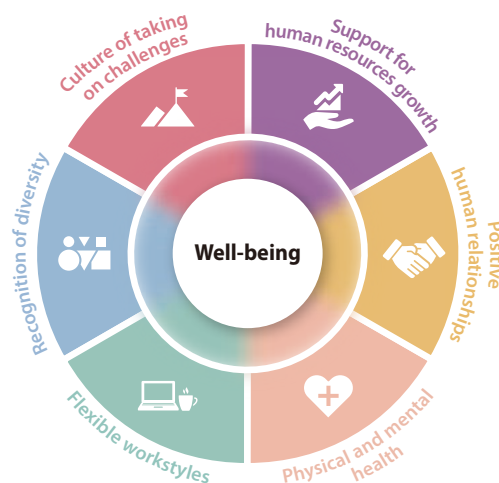
Approach to Well-being Management

Well-being refers to being in a positive state, physically, mentally, and socially. Nippon Shinyaku aims to be a company where employees can find happiness in their work. In other words, we seek to create a psychologically safe workplace where employees can be themselves. We believe well-being management is what enables each and every employee to find happiness in their work and realize our Business Philosophy, based on improvement of the working environment and promotion of health and productivity management. Nippon Shinyaku emphasizes six perspectives in promoting well-being management.

Six perspectives of well-being management

Maintaining the physical and mental health of employees is essential for well-being management. To achieve this, we engage actively in occupational health and safety activities, including prevention of workplace accidents and measures to address mental health to maintain a comfortable and safe working environment. We will also realize flexible workstyles through enhancement of systems such as flextime and telework.

In addition, by fostering a culture that recognizes diversity, we are building positive human relationships through connections between diverse people, and we will put in place well-being management to create an environment that is easy to work in.



Moreover, we will continue to help each and every employee to find job satisfaction by fostering a culture of taking on challenges and supporting the growth of human resources through the promotion of NS Mind and NS Academy within the Company.

Improving the Working Environment

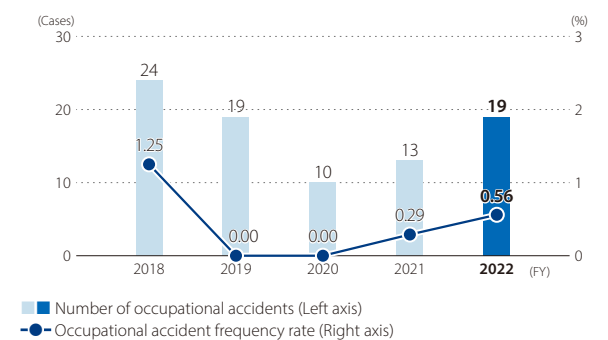
Basic Policy on Occupational Safety and Health

We will efficiently and effectively promote both basic safety and health activities and health and productivity management measures to maintain and enhance the health of employees. By doing so, we aim to protect the safety, security, and physical and mental health of all workers, create rewarding work environments, and continuously enhance the well-being of our employees.

Health and Safety Management Structure

The Company-wide Occupational Health and Safety (OH&S) Committee meets twice a year to decide on the policy for the fiscal year and evaluate and report on activities. We also promote company-wide health and safety activities, including the transmission of information from the Company-wide office to the OH&S Committee of each business location where meetings are held monthly.

Changes in number of occupational accidents and occupational accident frequency rate



* Occupational accident frequency rate = Number of fatalities and injuries from occupational accidents / Total number of actual working hours × 1,000,000

* Number of fatalities and injuries from occupational accidents: Number of fatalities and injuries from occupational accidents due to occupational injuries resulting in one or more days of absence from work and partial or total loss of body functions.

FY2022 measures to prevent the spread of COVID-19

Nippon Shinyaku implemented such measures as ensuring the thorough maintenance of basic infection controls, rules on mask wearing in line with government instructions, staggered working hours utilizing telecommuting and flextime, and urging self checks of the working environment during telecommuting. Going forward, as we do with regular influenza, we will continue to respond in line with the in-house procedures in the case of contraction of an infectious disease.

Promoting Health and Productivity Management

After the 2018 Nippon Shinyaku Health Declaration and 2020 Health Declaration, Nippon Shinyaku issued its Well-being Declaration 2021 in October 2021. In order to pursue well-being for employees and their families, the Health and Productivity Management Working Group (composed of the Well-being Promotion Section of the Personnel Department, the health insurance association, and the labor unions) has focused efforts on health seminars aimed at increasing health literacy and anti-smoking measures. In addition, we have assigned well-being supporters at our business sites to raise awareness of health and productivity management and collect opinions, and we promote health and productivity management in cooperation with them.

Aiming to Implement Well-being Management

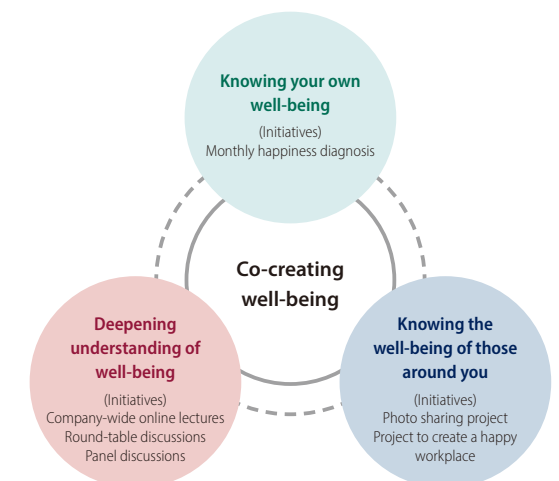
In 2021, we launched a project to promote well-being in the Personnel Department, with Professor Yukiko Uchida of the Institute for the Future of Human Society at Kyoto University as

an advisor. In April 2022, we changed the name of the department with responsibility for the project from the Health Promotion Office, Personnel Department to the Well-being Promotion Section, Personnel Department. In the area of internal awareness, we have accelerated full-scale well-being promotion activities with the aim of co-creating well-being based on three axes.

To mark the first anniversary after we issued Well-being Declaration 2021, we created an original sticker, which can also be described as the symbol of the activities. In addition, at a company-wide online lecture, after listening to Professor Yukiko Uchida's lecture, we had all employees declare what they would like to try doing for themselves and the people around them to enjoy working, creating an opportunity for employees to think about well-being as something that involves them personally.

Through the well-being promotion project, we will explore what it means to be in a positive state and implement measures to nurture connections between people and a spirit of altruism, which have a significant impact on well-being.

Three axes of well-being



Chihiro Katagiri
Well-being Promotion Section
Personnel Department

Contributing to well-being for each and every employee through dialogue

We launched the Well-being Promotion Project based on the desire for each and every employee to achieve well-being through their work and have been engaging in activities since 2021. Well-being is created by the Company and all the employees working together. Through activities to promote well-being internally, I found that dialogue is important. Sharing well-being time at company scale through the participation of many employees, which included creating the sticker and the well-being photo sharing project, brought me great happiness. In the future, I will continue to value dialogue in order to co-create well-being for each and every employee.

Co-creating Value with the Environment

Materiality	Strengthening efforts to protect the global environment	
Description of Main Activities	FY2022 Activities	Issues and FY2023 Strategies
<ul style="list-style-type: none">Promoting greenhouse gas reductionsPromoting recycling of resources (water, waste, etc.)	<ul style="list-style-type: none">Received third-party verification of CO2 emissions and energy consumptionInstalled a solar power generator (Discovery Research Laboratories in Tsukuba)Began the switch to hydroelectric power (Odawara Central Factory)	<ul style="list-style-type: none">Promoting the switch to renewable energy (Head Office area)Expanding installations of solar power generators (Head Office area and Odawara Central Factory)Strengthening water resource management initiatives
<ul style="list-style-type: none">Continuing activities to protect and cultivate endangered species at the Yamashina Botanical Research Institute	<ul style="list-style-type: none">Futaba aoi dedications: Aimed to be the number one company in the number of dedications of futaba aoi (<i>Asarum caulescens</i>) to Kamigamo Shrine. Also began examining methods of propagation by suckering in FY2022.Conservation of <i>Chrysanthemum seticuspe</i>: Exhibited at the Green-Water Promenade of Kyoto Station and at the Kan-in no Miya Residence in the Imperial Palace. Provided seedlings and participated in replanting activities.Conducted an initial survey of vegetation on the mountain and forests around Daigoji Temple.	<ul style="list-style-type: none">Futaba aoi dedications: Continued cultivating suckers from Kamigamo Shrine and experimenting with propagation using suckers.Preservation of <i>Chrysanthemum seticuspe</i>: Conducting plant education activities through the propagation and exhibition of <i>Chrysanthemum seticuspe</i>.Continuing to survey the mountain and forests around Daigoji Temple.

Environmental Management

Nippon Shinyaku is aware of its responsibility toward the environment and has established a Basic Environmental Policy to reduce its environmental impact in all areas of its business activities. The Environment Committee, chaired by the Director in charge of Business Management & Sustainability, was established to put this policy into practice and determines the direction and targets of our environmental preservation activities.

WEB About environmental initiatives at Nippon Shinyaku
<https://www.nippon-shinyaku.co.jp/english/sustainability/esg/environment/>

Nippon Shinyaku's Basic Environmental Policy

<p>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.</p> <p>1. Environmental commitment We will effectively operate a Company-wide organization responsible for environmental issues and establish clear targets for our collective pursuit of environmental conservation initiatives.</p> <p>2. Environmental preservation We will accurately judge the impacts of our business activities on the environment (including global warming, resource depletion, and environmental pollution) and continuously improve our environmental preservation activities (conserving energy and reducing greenhouse gas [GHG] emissions, water usage, and waste) in order to enable sustainable and efficient use of resources and prevent pollution (by appropriately managing and reducing wastewater and gaseous emissions).</p> <p>3. Conservation of biodiversity We will pay due consideration to the conservation of biodiversity in our business activities.</p> <p>4. Legal compliance We will comply with the environmental laws and regulations of each country or region where we operate, our internal environmental rules and all other applicable rules to fulfill our social responsibility.</p> <p>5. Education and training We will educate and train all directors and employees so that they can recognize the importance of environmental conservation and act in a responsible manner.</p> <p>6. Disclosure We will proactively disclose information about our environmental preservation activities and communicate with our local communities and other stakeholders to build relationships of trust with them.</p>
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The 7th Nippon Shinyaku Environmental Targets Plan (FY2023-2025)

Item	Targets
Climate change alleviation	Greenhouse gas emissions (Scope 1, 2) by FY2030 by 42% from the FY2020 benchmark Greenhouse gas emissions (Scope 1, 2) by FY2025 by 21% from the FY2020 benchmark
Water resources management	Reduce water use intensity by 10% from the FY2021 level by FY2025
Waste management	Reduce the final amount of landfilled waste by 75% from the FY2005 level by FY2025 Set the target waste plastic recycling rate for FY2025 at 65% or above Set the target waste recycling rate for FY2025 at 60% or above
Chemical substance management	Promote appropriate management of chemical substances, including those designated in the Pollutant Release and Transfer Register (PRTR) system provided for by the Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement, and constantly reduce releases of such substances in the environment
Environmental management	Continue the certification of the environmental management systems (ISO 14001 and KES Step 2) so as to effectively improve environmental performance
Biodiversity	Promote biodiversity conservation activities

Disclosure Based on the TCFD Recommendations

In December 2021, Nippon Shinyaku declared its support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD)*. In addition to working to address already identified risks from the perspective of risk management, we conducted a scenario analysis of climate-related risks and opportunities in line with the framework of the TCFD recommendations.



* TCFD: Abbreviation of Task Force on Climate-related Financial Disclosures. Established in 2015 by the Financial Stability Board (FSB) to develop recommendations for more effective climate-related disclosures to be made by companies to investors, lenders, and insurance underwriters.

Governance

The Director in charge of Business Management & Sustainability serves as Officer in charge of response to climate issues. This Director chairs the Environment Committee, which meets four times a year to ensure the implementation of Nippon Shinyaku's Basic Environmental Policy, which was formulated by the Board of Directors. The committee formulates other environmental policies, promotes environmental preservation and other initiatives, and checks the results of environmental preservation activities, including the annual CO2 emissions reduction.

The same Director is also a member of the President-chaired Sustainability Committee, which meets twice a year, so that Group-wide sustainability activities will be further enhanced. The Nippon Shinyaku Group has identified tackling climate change as one of its material issues. The details and progress of

the relevant activities are reviewed by the Sustainability Committee. The results of the Environment Committee and Sustainability Committee's investigations are reported at least once a year to the Board of Directors.

Scenario analysis

Recognizing the enormous impact climate-related risks and opportunities will yield on the company's business strategies, Nippon Shinyaku has identified the risks and opportunities of climate change and evaluated their importance according to the following process. This analysis and evaluation into climate change-related risks and opportunities was conducted utilizing a 1.5° C warming scenario and a 4° C warming scenario. First, climate-related risks and opportunities were comprehensively sampled. Next, the sampled climate risks and opportunities were sorted according to their relationship to the company's pharmaceuticals and functional food businesses. Finally, their importance was evaluated based on two criteria: degree of impact on the company, and probability of occurrence.

Strategy

Nippon Shinyaku is continually working to improve its environmental conservation activities (conserving energy and reducing CO2 emissions) based on its Basic Environmental Policy in order to achieve carbon neutrality by 2050. The company's long-term goal is to realize net-zero CO2 emissions by FY2050. In addition, Nippon Shinyaku is also monitoring climate-related risks across its entire supply chain. Nippon Shinyaku views the transition to a low-carbon economy as an opportunity, and recognizes the reduction of costs through energy conservation and recycling, and the development of relevant products as means to increase its competitiveness.

Co-creating Value with the Environment

Identified Risk/Opportunities and Measures

Category	Impact on Nippon Shinyaku	Measures	Period		
			Short-term	Mid-term	Long-term
			- 2025	2026-2030	2031 -
Risks	Transition risks	Policies and laws		●	
		Delay in response to global environmental regulations		●	
	Markets	Increases in market prices of procured goods due to increases in demand for raw materials (pharmaceuticals) Risk of decreases in demand due to increases in product prices in accordance with increased market prices of procured goods (functional foods)		●	
	Evaluation	Stoppage of plant operation and business activities due to depletion of raw materials and other resources			●
	Physical risks	Acute risks		●	
		Increased frequency of damage to facilities and increased repair costs due to abnormal weather and weather-related disasters Suspension of business activities due to damage to associated facilities, including those of the company as well as collaboration research companies		●	
Opportunities	Resource efficiency/energy	Risk of need to move plants and other sites due to impact of rising sea levels		●	
		Depletion of water resources and water intake limits due to changes in rainfall patterns (reduction in profits due to reduced production capacity)			●
	Resilience	Insufficient raw material procurement due to climate change		●	
		Reduction in production costs through a variety of improvements to resource efficiency, including energy conservation, reduced water utilization, and waste disposal		●	

Risk management

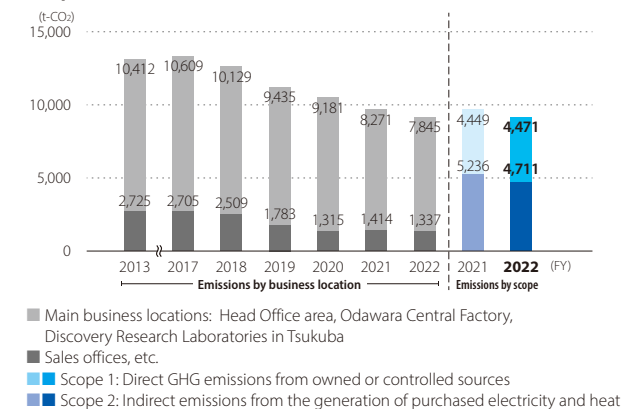
The Nippon Shinyaku Group has in place Basic Risk Management Rules, with the Director who is the Head of Personnel, General Affairs, Risk Management, Compliance & Digital Transformation acting as the Risk Management Officer, and a department dedicated to overseeing risk management. We have identified various possible risks, including climate change-related ones. Each department has devised measures to prevent the actualization of those risks and to respond to any realized risk. Further, every year, action plans are formulated to address the risks selected as highly serious for the entire Group or each department and enhance measures to prevent their actualization. The results of these activities are reported to the Risk & Compliance Committee and then to the Board of Directors at the end of each fiscal year so that activities in subsequent years will be improved.

WEB FY2023 activity themes and risk management goals
<https://www.nippon-shinyaku.co.jp/english/sustainability/esg/environment/tcfd.php#anchor04>

Indicators and targets

Nippon Shinyaku has established a greenhouse gas reduction target of reducing its greenhouse gas emissions (Scope 1 and 2) by FY2030 by 42% from the FY2020 benchmark. As a climate-related opportunity the Company has also established the ratio of hybrid vehicles for our sales activities as a key performance indicator. Further, we will be striving to assess our capital outlays and allocation by using as indicators investments in environmentally conscious facilities and facilities which contribute to reduced greenhouse gas emissions.

Scope 1 and 2 emissions volume (FY2022 results)



Initiatives to Reduce CO₂ Emissions

1. Switching to renewable energy

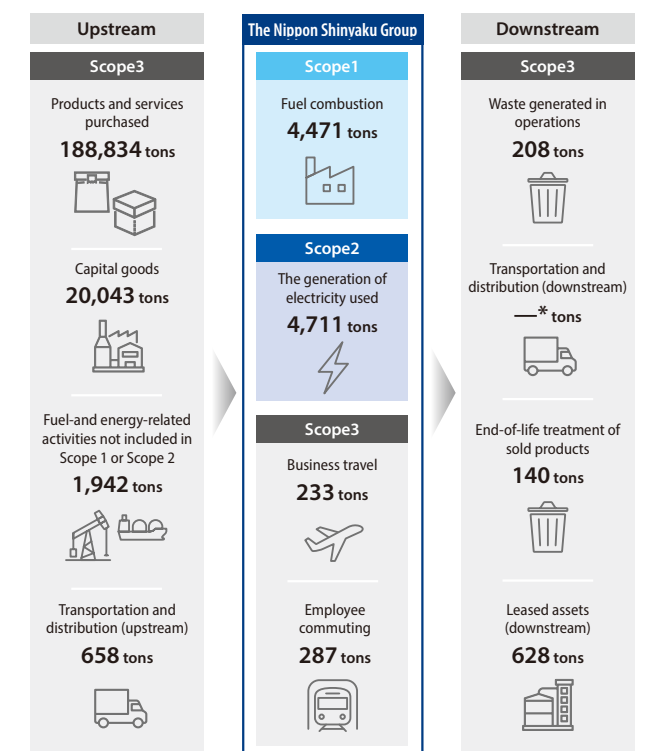
Nippon Shinyaku aims to reduce CO₂ emissions to zero by FY2050, with a target of 6,088 t-CO₂ in FY2030 (a 42% reduction from the FY2020 benchmark).

In April 2021, we began the switch to renewable energy, which is expected to reduce CO₂ emissions by 50% in the Head Office area. In November 2022, the Odawara Central Factory began switching to hydroelectric power, which is expected to reduce their CO₂ emissions by 6% in the current fiscal year. In addition, in April 2022, a solar power generator was installed at the Discovery Research Laboratories in Tsukuba, which is expected to reduce the CO₂ emissions of the entire premises by 12%. We will continue to consider switching to and expanding our renewable energy sources, including solar power generators.

2. Introducing hybrid company-owned vehicles for 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 company-owned vehicles will be entirely replaced by hybrid cars over a four-year period starting from

Supply chain emissions (FY2022 results)



- Scope 1** Direct emissions from owned or controlled sources (in-house use of fuel and industrial processes)
- Scope 2** Indirect emissions from the generation of purchased electricity and heat
- Scope 3** Indirect emissions, other than Scope 1 and Scope 2 emissions, from the supply chain

* Emissions in FY2022 have not yet been calculated due to a partial lack of data disclosure from relevant pharmaceutical wholesalers at the time of calculation.

Co-creating Value with the Environment

FY2020, except in heavy snowfall areas. In FY2022, hybrid cars already accounted for 80% of the company's fleet of sales vehicles.

As in the previous fiscal year, we continue to reduce energy consumption through equipment improvement, promote energy conservation following the guidelines for electricity conservation and saving energy, and educate employees on the importance and necessity of environmental preservation through in-house educational programs.

■ Received third-party verification

To improve the reliability of our environmental information, we received verification from a third party, SGS Japan Inc., based on verification standards (ISO 14064-3:2019 and SGS Japan's verification procedures). The verification covers Scope 1 and Scope 2 and energy consumption.

WEB Independent Third-Party Verification Statement
<https://www.nippon-shinyaku.co.jp/english/sustainability/esg/environment/climatechange.php#anchor05>

Promoting the Recycling of Resources

■ Basic attitudes and targets

Recognizing the limits of resources derived from natural capital, we at Nippon Shinyaku are constantly striving to reduce the amounts of resources we use, adopting various methods, including reuse and common use. We are also focusing our effort on the active use of recycled raw materials to ensure that the waste resulting from our activities is recycled or reused. We are working to reduce the quantities of waste generation and waste disposal in landfills, which are general indicators for the abovementioned efforts. We appropriately manage the quality of used water for discharge, including cooling water used at production sites, in compliance with applicable laws and regulations so that water sources will be safeguarded from pollution.

We have set and promote a long-term target of increasing the percentage of recycled waste plastic to 65% (in conformity with the goals set in the Voluntary Action Plan on the Environment – Creating a Sound Material-Cycle Society adopted by the Federation of Pharmaceutical Manufacturers' Associations of Japan) by FY2030.

■ Initiatives for resource recycling

1. Appropriate treatment and utilization of waste materials

We recycle metals and collect and sort out plastic waste in compliance with the Waste Disposal and Public Cleansing Act*¹ and applicable Kyoto City ordinances.*²

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*³ environmental management system standard.

*1 Law concerning waste disposal and public cleansing

*2 City of Kyoto's ordinances on reduction and proper treatment of waste

*3 Abbreviation for Kyoto Environmental Management System Standard, enforced by the specified non-profit corporation KES Environmental System since 1999. The number of registered companies exceed 5,000.

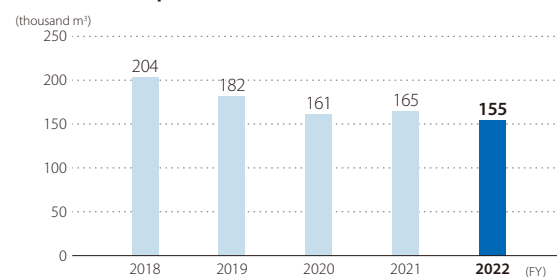
2. Water consumption and risk assessment

Water consumption in FY2022 was 155 thousand m³ and Nippon Shinyaku was not involved in any cases of finable violations against laws or regulations on drawing or discharging water.

In the assessment of water stress at the three main business locations using WRI AQUEDUCT (3.0)*⁴, the Odawara Central Factory and the Discovery Research Laboratories in Tsukuba fell into a medium water risk area, and no business locations fell into a high water risk area.

*4 WRI AQUEDUCT(3.0): A set of water risk assessment tools developed and presented by the World Resources Institute (WRI)

Water consumption (main business locations*)



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

In addition, as in the previous fiscal year, we continue to promote the reduction of package waste and office paper, and have joined the Plastic Smart campaign launched by the Ministry of the Environment of Japan.

Appropriate 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

Business operators that handle one ton or more of any designated Type 1 chemical substances per year under the Pollutant Release and Transfer Register (PRTR) method defined under the Act on Specific Chemical Substances are required to file notices of these chemicals. We report that we are appropriately managing them.

■ Management of Highly Active Substances at Odawara Central Factory

The manufacturing plant for highly active solid formulations 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.

Conservation of Biodiversity

The Yamashina Botanical Research Institute conserves approximately 3,000 varieties of plants, including 160 species that are the botanical origins of herbal medicines recorded in the Japanese Pharmacopoeia, 480 rare plant species, including 0.7% of the plants regulated by CITES, such as *Welwitschia mirabilis* and aloes, 12% of the plants on the Japanese Red List of the Ministry of the Environment, and 5% of the plants in the Red Data Book of Kyoto Prefecture. Nippon Shinyaku is committed to these ex situ conservation efforts as a materiality issue.

■ Botany education activities

The Yamashina Botanical Research Institute routinely holds tours by appointment, tours for university students studying pharmacology and agriculture and pharmacists, indigo dyeing workshops for elementary school students, public holiday tours, and other events designed to raise awareness of conserving the diversity of useful plants.



■ Conservation activities for plants that have a place in traditional Kyoto culture

We conserve and propagate plants that have a place in traditional Kyoto culture, such as futaba aoi (*Asarum caulescens*) and *Chrysanthemum seticuspe*. Through the Aoi Project, a general incorporated foundation, we have dedicated 140 pots of futaba aoi to Kamigamo Shrine and provided seedlings to Kyoto City's Kikutani Forest of Flowering Chrysanthemums.

■ Survey of plants in the mountain and forests around Daigoji Temple, a World Cultural Heritage site

In June 2021, the G7 Nature Compact committed to the "30 by 30" initiative, whereby national governments designate more than 30% of land and sea areas as protected areas by 2030. As a result, attention is focusing on temple and shrine forests as areas other than protected areas that can contribute to biodiversity conservation. Focusing on the Daigoji Temple forest in the southern part of Kyoto City, Nippon Shinyaku has conducted eight surveys since April 2022 and identified 157 species of higher plants in 78 families.

■ Ex situ conservation of the Japan-designated Natural Monument, ayumodoki

The ayumodoki (*Parabotia curtus*) is a freshwater fish endemic to Japan that has been drastically reduced due to environmental changes in its habitat and is now distributed only in the Kameoka Basin and Okayama Prefecture. Yamashina Botanical Research Institute collaborated with the Ministry of the Environment's conservation and propagation project and succeeded in raising ayumodoki naturally in artificial ponds within its park grounds. We will continue to help conserve valuable wildlife as part of our biodiversity conservation activities.

Stakeholder Engagement

Materiality	Strengthening governance	
		 
Main Activities	FY2022 Activities	Issues and FY2023 Strategies
<ul style="list-style-type: none">Strengthening IR activities for investorsImplementing information disclosure to stakeholders	<ul style="list-style-type: none">Held R&D briefings and implemented overseas IR activitiesPublished the integrated report and news releases in a timely manner	<ul style="list-style-type: none">Enhancing integrated report and website disclosure

Communication with Stakeholders

Nippon Shinyaku's business is supported by a variety of stakeholders. Therefore, the Company believes it is important to listen to and engage in dialogue with stakeholders, including shareholders, employees, society (local communities, business partners, etc.), customers (patients, consumers, medical professionals), and the environment. By reflecting the requests and opinions obtained through such dialogue in its business activities, Nippon Shinyaku will grow as a company and create and provide new value to society.

Nippon Shinyaku's Stakeholders



Stakeholder Relations		Dialogue and Means, Frequency
Shareholders	Nippon Shinyaku will strive to pay a return to shareholders by securing appropriate profits through management that is conscious of the cost of capital. The Group is intent on meeting the expectations of shareholders and investors by promoting constructive communication through fair management that emphasizes timely and honest disclosure of corporate information and proactive dialogue.	<ul style="list-style-type: none">Number of dialogues with institutional investors and analysts: approx. 180Participation in events sponsored by securities corporations: 9Financial results briefings (May, November)Financial results conference calls (August, February)General Meeting of Shareholders (June)R&D briefing (December)Overseas IR events and large meetings (September)
Employees	Based on its Management Policy, "Employees: Develop Each Employee," Nippon Shinyaku has established an education and training system aimed at developing the kind of human resources it seeks: people who think and act on their own initiative. It believes that each employee thinking, acting, and proactively taking on challenges on their own initiative leads to personal growth, which in turn leads to the growth of the Company.	<ul style="list-style-type: none">Training for employees, opportunities for dialogue with directorsEmployee stress check, engagement surveyInternal Compliance Reporting System (whistleblowing hotlines)
Society	As a corporate citizen, Nippon Shinyaku will maintain close communication and exchange with society and actively engage in social contribution activities. It will maintain mutual trust and sound and proper relationships with business partners and aim to grow together with them.	<ul style="list-style-type: none">On-site classes on food educationYamashina Botanical Research Institute: 130 tours, 1,335 visitorsNippon Shinyaku Sparkling Future Mobile Library: participated in 27 events; lent out 5,140 picture booksConducted surveys of suppliers (CSR, stable supply, sustainability procurement policy)
Customers	In the Pharmaceuticals business, Nippon Shinyaku places the highest priority on patients who suffer from illnesses and makes efforts to provide information to ensure that patients are properly medicated by medical professionals. In the Functional Food business, the Company seeks to leverage its advanced technical expertise as a maker of pharmaceuticals to supply high-value-added products that meet customer needs.	<ul style="list-style-type: none">Number of inquiries about pharmaceuticals Total 10,730 (8,732 from medical professionals, 783 from wholesalers, 1,093 from general consumers, 122 from others)Disease awareness via the Company's websiteOnline seminars available to the public (pulmonary hypertension, muscular dystrophy)Patient exchange eventsBooths at marathons in Japan, etc.
Environment	Nippon Shinyaku always strives to protect, sustain, and improve the environment through eco-considerate business activities, and aims for growth in harmony with the environment.	<ul style="list-style-type: none">Events designed to educate about botany at the Yamashina Botanical Research InstitutePreservation activities for plants related to Kyoto's culture

Dialogue with Shareholders

In FY2022, in addition to financial results briefings and conference calls, Nippon Shinyaku held a two-part R&D briefing for shareholders and investors. In the first part, a medical specialist explained the treatment of Dravet syndrome and future prospects in relation to Fintepla, a treatment for seizures associated with Dravet syndrome that was launched in Japan in November 2022. In the second part, presentations were made on the progress of the nucleic acid drug pipeline, as well as initiatives for new modalities of next-generation antisense nucleic acids, gene therapy, and cell therapy, which are attracting a great deal of attention. In addition, President Nakai has been attending financial results briefings, shareholder and investor meetings, overseas IR events and large meetings, and will continue to regularly interact with shareholders and investors to explain the Company's growth strategies in the short, medium, and long term.



WEB Other Briefings
https://www.nippon-shinyaku.co.jp/english/ir/ir_library/other_presentation/

Dialogue with Society

In order to interact with the local community and society and provide opportunities for children to read, the Company regularly exhibits the Nippon Shinyaku Sparkling Future Mobile Library at events and children's centers in Kyoto. It also brought the Mobile Library to Purple Day, an epilepsy awareness event held in Osaka on March 26. Purple Day is a campaign to support epilepsy patients and promote understanding of the disease by wearing purple, the color of awareness for epilepsy. On the day of the event, staff members also wore purple while lending out picture books. Nippon Shinyaku also has a volunteer program available for employees to freely participate in social contribution activities, which it will continue implementing going forward.



WEB Nippon Shinyaku Sparkling Future Mobile Library (in Japanese)
<https://kodomo-bungaku.jp/miraigo/>

Dialogue with Customers

The Pharmaceutical Consultation Office receives more than 10,000 inquiries a year, mainly by phone and the inquiry form on its website. Nippon Shinyaku strives to promote the proper use of pharmaceuticals by responding to these inquiries on a daily basis, making full use of information technology, such as the latest AI-based telephone answering system. In addition, information and opinions received here are promptly conveyed to the relevant departments and utilized to improve quality and safety.

In recent years, the Company has been enhancing its website so that customers can actively obtain a variety of information. Nippon Shinyaku will continue to place utmost priority on responding promptly and accurately to gain the trust of a wide range of stakeholders, including patients and their families, physicians, pharmacists, and other medical professionals.



WEB Feedback & Inquiries
<https://www.nippon-shinyaku.co.jp/english/inquiry/input.php>

Coexistence with Local Communities

Materiality			Resolving social issues and coexisting with the community		
Main Activities	FY2022 Activities	Issues and FY2023 Strategies			
<ul style="list-style-type: none"> Enhancing the public research grant system to support medical and scientific research Implementing social contribution activities rooted in each region, including preserving Kyoto culture Providing educational and mental well-being support for children through activities such as sports and reading opportunities 	<ul style="list-style-type: none"> FY2022 public research grants: 10 Publications of quarterly PR magazine "Kyo": 4, calendar: 1 The Nippon Shinyaku Sparkling Future Mobile Library: participated in 22 events 	<ul style="list-style-type: none"> Raising awareness of and increasing participation in public research grants and social contribution activities 			

Contributing to Medical and Scientific Research and Development of Local Communities

Nippon Shinyaku thinks that it should play two roles —the first is providing outstanding drugs to the world as a pharmaceutical company, and the other is contributing to the development of general society and local communities as a member of each.

Public research grant system

As part of its centenary celebrations, and to contribute to the advancement of science in the fields of medicine and pharmacology, Nippon Shinyaku has launched a public research grant system. Under the system, it aims to support young researchers by offering grants to successful applicants.

Preservation and maintenance of Kyoto culture

For more than half a century, Nippon Shinyaku has created an annual calendar using works of art created with dyes using a traditional Kyoto technique called stencil dyeing, and through this, introduced various aspects of Kyoto, including its scenery and landscapes in the various seasons and historical events. The Company also publishes a quarterly PR magazine titled "Kyo," also using works of art created with dyes for the cover, that showcases the huge appeal of Kyoto—from the city's many shrines, temples, and other cultural assets to its cuisine, traditional techniques, and local products.

Providing support for children through activities such as sports and reading opportunities

Educational support through sports

Working with municipal governments and baseball associations, for many years the Nippon Shinyaku baseball team has organized baseball clinics for players of various ages, including elementary,

junior high, and high school students. In recent years, the Company has been holding sports clinics for preschool children in the vicinity of Kyoto to experience the joy of exercise. In November 2022, Nippon Shinyaku visited Kyoto Seibo Gakuin Nursery School in Fushimi Ward, Kyoto, and conducted sports clinics, including tee-ball classes. At the Nippon Shinyaku Children's Challenge Cup, held at Wakasa Stadium Kyoto in December 2022, the Company conducted athletic performance measurements—something most preschool children never get to experience—nutrition education activities, and other activities.

In addition, besides our hardball baseball activities, we organized e-sports contests accessible online and on site for children with disabilities with the use of an eye-tracking application in August 2022. Going forward, we will carry on with these initiatives and contribute to the development of local communities through social contribution activities.

Supporting children by providing opportunities for reading and other activities

The Nippon Shinyaku Children's Literary Awards, with the support of the Japan Juvenile Writers Association, call for entries in the two categories of stories and artworks, and make copies of selected top works in each category. The produced picture books are then donated to medical institutions, such as children's hospitals, and public facilities, which makes it possible for many children to read the books.

Moreover, the Company started the Nippon Shinyaku Sparkling Future Mobile Library in 2019 as part of its centenary celebrations to bring exciting library experiences to children. The library van carries around 1,000 physical and digital books, including the Nippon Shinyaku Children's Literary Award-winning titles. Along with employee volunteers, the library visits elementary schools and special needs schools.



Message from the Chairman



As Chairman,
I work to further
enhance governance.

S. Maekawa

Shigenobu Maekawa
Representative Director, Chairman

Nippon Shinyaku's corporate activities revolve around its business philosophy of "Helping People Lead Healthier, Happier Lives." In order to grow into our vision of company with a meaningful existence in the healthcare field, we are working to further enhance our corporate value by enhancing sustainability initiatives. To make a sustainable society a reality, we must contribute to solving a variety of social issues and be trusted by society. I believe that dealing with issues of materiality is essential to a company, and that it is the foundation of corporate management. In March 2023, we revised our issues of materiality based on the changing business environment.

People who think and act by themselves and actively take on challenges are indispensable to the sustainable growth of Nippon Shinyaku, and we are developing an environment where they can grow and flourish, aiming to build a flexible, resilient organization that can adapt to change. Turning to environmental efforts, under the Nippon Shinyaku Basic Environmental Policy, we are introducing and expanding the use of solar power facilities and other renewable energy sources to reduce CO₂ emissions. Further, through activities to conserve rare species, we are also actively contributing to the preservation of biodiversity.

In promoting these initiatives, I believe that securing management transparency and being accountable to all our stakeholders is one of our most important management issues, and as Chairman, I will continue working to further enhance our corporate governance system. Through Board of Directors meetings as well as the Management Policy Review Group, training and debriefing conferences, and a variety of other opportunities, Nippon Shinyaku's directors engage in the healthy exchange of opinions. In FY2022, we engaged in numerous discussions on R&D, capital investment, the revision of our personnel system, and other matters which will contribute to Nippon Shinyaku's sustainable growth. Of particular note, Nippon Shinyaku's external directors actively ask questions and provide answers to our executive directors based on their personal experience and expertise. They also engage in discussions with a medium- to long-term business perspective. Accordingly, I judge that the effectiveness of our Board of Directors is secured.

Going forward, I will continue striving to strengthen Nippon Shinyaku's corporate governance, and to secure further transparency and reliability through proactive disclosure and dialogue with all our stakeholders. I hope that you will extend Nippon Shinyaku your continued support and understanding.

Corporate Governance

Materiality	Strengthening governance	
Main Activities	FY2022 Activities	Issues and FY2023 Strategies
<ul style="list-style-type: none"> Strengthening governance including at Group companies 	<ul style="list-style-type: none"> Enhanced items disclosed in the Corporate Governance Report Implemented company-wide activities to raise awareness about compliance 	<ul style="list-style-type: none"> Further strengthening governance Further ensuring compliance



Basic Approach

The Nippon Shinyaku Group recognizes that ensuring management transparency and fulfilling accountability to all stakeholders is one of management's most important tasks in order to raise corporate value through social contributions. The effective functioning of corporate governance is essential for the realization of material issues, which include strengthening governance. Based on the Business Philosophy, Management Policy, and Guidelines for Action, Nippon Shinyaku promotes initiatives to further enhance the corporate governance system, including improving management transparency and fairness and implementing prompt decision making, with the aim of achieving sustainable growth and enhancement of social value as well as corporate value over the medium to long term.

Furthermore, in 2015, the Company formulated its basic approach and basic policy governing corporate governance as the Corporate Governance Basic Policy, which it has reviewed regularly. In June 2023, the Corporate Governance Report included Disclosure Based on the Principles of the Corporate

Governance Code as well as the disclosure of Reasons for Non-compliance with the Principles of the Corporate Governance Code. Nippon Shinyaku will continue striving to strengthen corporate governance in order to achieve the sustainable enhancement of corporate value.

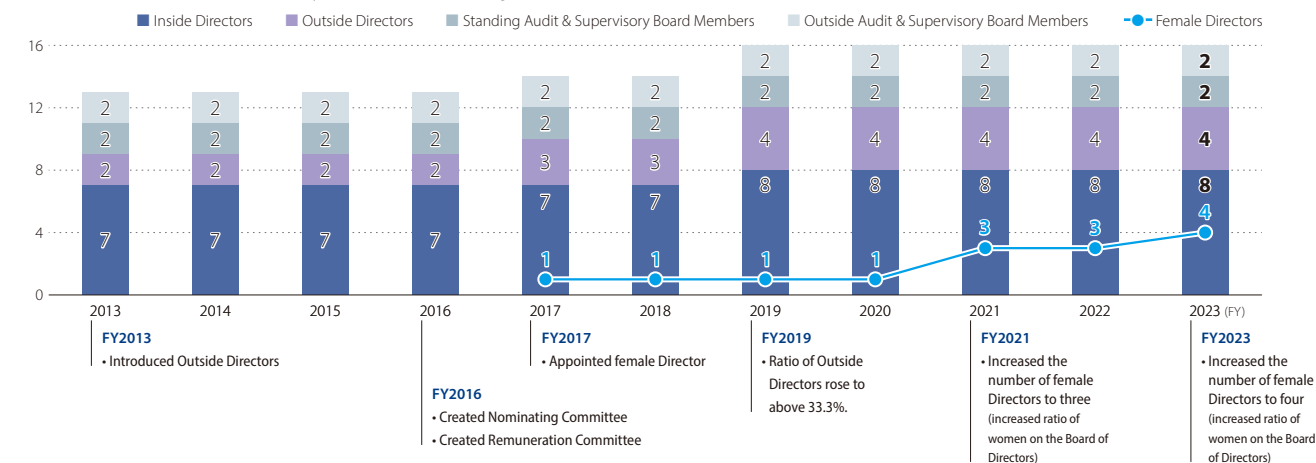
WEB Corporate Governance Basic Policy
Corporate Governance Report
https://www.nippon-shinyaku.co.jp/english/ir/esg_management/governance.php

Initiatives for Strengthening Governance

Nippon Shinyaku takes steps to enhance governance, including at Group companies, by ensuring compliance. Going forward, the Company will constantly examine the status of initiatives and make improvements in light of amendments to laws and regulations, revisions of the Corporate Governance Code, social conditions, and other factors, in order to further increase the effectiveness of corporate governance.

Steps taken to strengthen corporate governance

(number of officers is as of conclusion of each year's Annual General Meeting of Shareholders)



Corporate Governance System

Nippon Shinyaku has adopted the structure of a Company with an Audit & Supervisory Board as its corporate governance system. The Board of Directors is composed of twelve Directors, four of whom are Outside Directors, and the Audit & Supervisory Board is composed of four Members, two of whom are Outside Members.

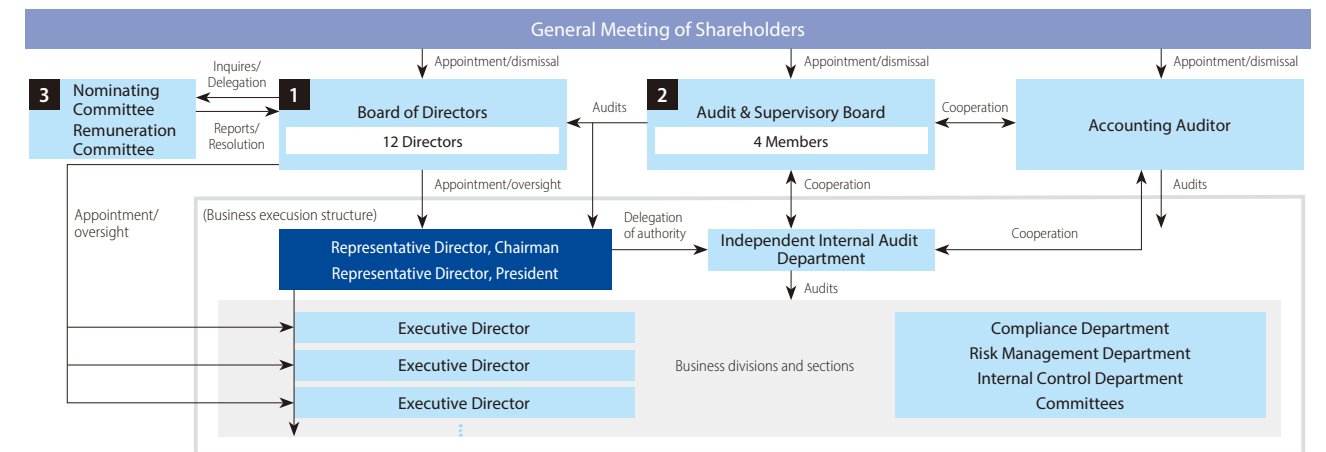
To clarify management responsibility and establish the optimal management system in response to changes in the business environment in a flexible manner, the term of office of the Directors is one year. By having four Outside Directors, the Company further strengthens oversight of the Directors'

execution of duties and further enhances the transparency and objectivity of management. Furthermore, the Audit & Supervisory Board Members attend all Board of Directors' meetings and other important meetings on business to accomplish the management oversight function of the Audit & Supervisory Board.

Nippon Shinyaku enhances the effectiveness of meetings of the Board of Directors and the Audit & Supervisory Board by sending materials on the respective agenda items and matters to be reported to the Outside Directors and Outside Audit & Supervisory Board Members in advance of meetings.

Organization for corporate governance (as of June 29, 2023)

Headed by the Company's Chairman and consisting of 12 members including four Outside Directors, the Board of Directors holds a meeting once a month in principle and resolves and reports on material business matters.



	1 Board of Directors	2 Audit & Supervisory Board	3 Nominating Committee and Remuneration Committee
Attendees	All Directors and Audit & Supervisory Board Members	All Audit & Supervisory Board Members	Shigenobu Maekawa (Representative Director, Chairman) Miyuki Sakurai (Outside Director) Yoshinao Wada (Outside Director)
Role	<ul style="list-style-type: none"> Performing the oversight function for management in general and ensuring fairness and transparency of management Determining policies governing the appointment and dismissal of Directors and Audit & Supervisory Board Members Evaluating serious risks and formulating countermeasures Making decisions, such as the execution of important business operations 	<ul style="list-style-type: none"> Playing a role in corporate oversight in coordination with the Board of Directors Supervising the execution of duties by the Board of Directors and working to establish the corporate governance system Actively expressing opinions based on their own specialized knowledge and vast experience 	<p>Nominating Committee</p> <ul style="list-style-type: none"> Deliberating on matters related to the appointment and dismissal of Directors and Audit & Supervisory Board Members and reporting to the Board of Directors <p>Remuneration Committee</p> <ul style="list-style-type: none"> Deliberating on proposals for the General Meeting of Shareholders related to remuneration of Directors and Audit & Supervisory Board Members and basic policies governing remuneration for Directors, and reporting to the Board of Directors Deliberating and making decisions on the details of remuneration for individual Directors based on the responsibility delegated by the Board of Directors
Meetings held in FY2022	15 (12 regular meetings, 3 extraordinary meetings)	18	3 (Nominating Committee: 1; Remuneration Committee: 2)

Inside Directors
 Outside Directors
 Standing Audit & Supervisory Board Members
 Outside Audit & Supervisory Board Members
 Chairperson

Corporate Governance

Meetings held in FY2022

Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.
Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors	Board of Directors
Audit & Supervisory Board	Board of Directors	Audit & Supervisory Board	Audit & Supervisory Board	Audit & Supervisory Board	Audit & Supervisory Board	Board of Directors	Audit & Supervisory Board	Audit & Supervisory Board	Audit & Supervisory Board	Audit & Supervisory Board	Audit & Supervisory Board
Audit & Supervisory Board	Audit & Supervisory Board	Audit & Supervisory Board				Board of Directors					Audit & Supervisory Board
Remuneration Committee	Audit & Supervisory Board	Remuneration Committee				Audit & Supervisory Board					Audit & Supervisory Board
	Audit & Supervisory Board										Nomination Committee

Status of Operations of the Board of Directors

In addition to the resolutions provided for by laws and regulations, the Articles of Incorporation, and the Rules of the Board of Directors, meetings of the Board of Directors also focus on strategic discussions of basic management policies.

In FY2022, the Board of Directors held lively discussions aimed at achieving the sustainable growth of the Company, with a focus on matters relating to important business, matters relating to financial results, and matters relating to organization and personnel. For matters relating to important business, the Board of Directors mainly held discussions on whether to proceed to clinical trials for products developed in house and in-licensed products and whether to conclude agreements on in-licensed and out-licensed products. For matters relating to financial results, the Board of Directors set aside time on the agenda for deliberating and discussing, in addition to explaining, the quarterly financial reports, which are important for implementing management strategy, to deepen the overall understanding of Directors. For matters relating to organization and personnel, in addition to the establishment, modification, and abolition of important organizations, the Board of Directors held discussions on the development of the internal control system and other important matters related to organizations and personnel.

Main themes of deliberation

Category	Number of discussions
Matters relating to the General Meeting of Shareholders	1
Matters relating to the directors	5
Matters relating to the Nominating Committee	1
Matters relating to the Remuneration Committee	4
Matters relating to financial results	14
Matters relating to shares	3
Matters relating to corporate governance	2
Matters relating to organizations and personnel	11
Matters relating to important business (research and development, capital investment, management, etc.)	42
Matters relating to subsidiaries	3
Other matters	4

Example of deliberations

● Conclusion of distribution partnership agreement with Capricor Therapeutics, Inc.

Executive Directors proposed an agenda item on the conclusion of a partnership agreement for distribution in Japan of CAP-1002, a cell therapy for Duchenne muscular dystrophy under development in the United States by Capricor Therapeutics.

Lively discussions took place in response to the proposal, as members of the Board of Directors, including Outside Directors and Audit & Supervisory Board Members, gave their opinions on product characteristics, U.S. non-clinical and clinical trial data, patent information, the competitive situation, business value, and contract terms from a wide range of perspectives based on their respective areas of expertise.

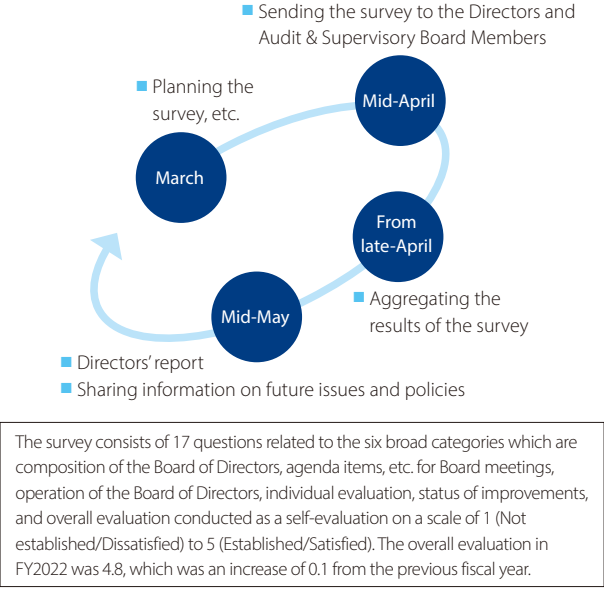
After these discussions, the Chairman placed the matter before the Board, and the proposal was approved following deliberation.

Evaluation of Effectiveness of the Board of Directors

■ Initiatives to enhance effectiveness of the Board of Directors

Once each year, Nippon Shinyaku evaluates the Board of Directors at a Board of Directors meeting in an effort to bring about improvements that will enhance its effectiveness. In order to analyze and evaluate the overall effectiveness of the Board of Directors, in FY2022 the Company implemented a self-evaluation survey for all Directors. As a result, it was able to confirm that within the Board of Directors, each executive Director and Outside Director continued to actively make remarks, that open-minded and constructive discussions were pursued from a wide perspective, and that appropriate judgment was being performed by the management, and therefore determined that the overall effectiveness of the Board of Directors was properly maintained. Based on the results of this analysis and evaluation, the Board of Directors will focus on further invigorating and enhancing the discussions at the meetings of the Board of Directors, and continue to ensure and improve the effectiveness of the Board of Directors moving forward.

Method for evaluating effectiveness



In FY2022, the following initiatives were taken to address the issues raised in the FY2021 survey.

- Enhancing the content of materials and prior explanations for Board meetings**
The Board of Directors worked to further enhance the content of materials for Board meetings, which has been an issue since FY2020. In addition, for items on the agenda related to the research and development pipeline which require specialized knowledge, the Board provided prior information that contributed to deliberations, such as information on a drug's mechanism of action or the target disease.
- Enhancing discussions at Board meetings**
Since deepening the members' understanding of the content of proposals and reports is important for exercising the oversight function of the Board of Directors, in addition to ensuring distribution of materials in advance of meetings, the Board of Directors provided training and other activities for Board members outside of meetings to deepen their knowledge as a prerequisite for discussion. The Board also ensured more time for discussion by enhancing the content of materials and prior explanations, and simplifying explanations on the day of meetings to stimulate discussions.
- Reviewing the management of the Board**
As a rule, the Board of Directors meetings are held with all the Directors assembled. However, the Board also introduced a hybrid format using face-to-face and online meetings. In doing this, the Board took measures to ensure that the facial expressions

of all members were shown, creating an environment that facilitates lively discussions as in face-to-face meetings.

- Future issues**
- By selecting matters submitted to the Board of Directors more carefully, discussions on medium- to long-term management issues will be enhanced in addition to short-term management issues with high importance and priority.
 - Proceedings will be reviewed in order to facilitate positive comments that contribute to discussions.

Officers' Remuneration System

The Remuneration Committee considers remuneration for Directors so as to ensure its appropriateness, fairness and proper balance in an effort to further increase Directors' motivation to seek the sustainable growth of the Company and enhancement of social and corporate value.

- Basic policy
- Our basic policy regarding the remuneration of Directors is that it shall effectively serve as an incentive for Directors to seek the sustainable enhancement of corporate value, that the details surrounding it shall be fair and rational enough for the Company to fulfill its accountability to shareholders and employees, and that the level of each individual Director's remuneration shall be adequately determined by taking into account the responsibilities of their positions.
- Structure of remuneration
- Remuneration of Directors (excluding Outside Directors)**
- Monthly remuneration: Determined by evaluating the performance of each Director and adding the amount to a fixed amount corresponding to their position. Such fixed amount corresponding to their position has been pre-determined by considering a comprehensive range of information, including survey data from external institutions and levels of remuneration for their counterparts at competitors.
- Bonuses: Cash remuneration reflecting performance indicators is paid to raise awareness toward improving business performance for each period. Bonus amounts are determined by considering the performance evaluation for each Director and calculating the amount based on the consolidated operating profit for each period.

Remuneration of Outside Directors and Audit & Supervisory Board Members

Remuneration of Outside Directors and Audit & Supervisory Board Members comprises fixed remuneration only.

Corporate Governance

■ Remuneration-related governance

Remuneration for individual Directors is determined through deliberations by the Remuneration Committee as entrusted by the Board of Directors within the limit of the amount of executive remuneration approved by resolution of the General Meeting of Shareholders.

Remuneration system for Directors (excluding Outside Directors)

Fixed monthly remuneration: bonuses (performance-linked remuneration) = roughly 1:1 (based on business performance)	
Total remuneration	
Fixed remuneration	Variable remuneration
¥255 million	¥223 million

Total remuneration for each officer category

Subtotals for each type of remuneration and numbers of recipients

Officers category	Total remuneration (millions of yen)	Subtotals for each type of remuneration (millions of yen)		Number of recipients
		Fixed remuneration	Performance-linked remuneration	
Directors (incl. Outside Directors)	478 (40)	255 (40)	223 (—)	12 (4)
Audit & Supervisory Board Members (incl. Outside Audit & Supervisory Board Members)	53 (19)	53 (19)	—	4 (2)
Outside Officers	60	60	—	6

Succession Plan

■ Succession Plan

Nippon Shinyaku recognizes that it is important to train successors from various perspectives based on the future vision of the Company. We run HONKI Juku selective training programs which are classified into Leader, Management, and Executive according to the position and number of years at the Company of trainees.

The Leader program targets the younger group from age 25 to 35 to quickly uncover and pick out leader candidates. The Management program provides lectures on management basics and middle management for executives from age 36 to 45 to acquire the perspective of a department manager. The Executive program aims for acquisition of practical management knowledge to train the next generation of management candidates. Through these efforts, we constantly secure motivated and outstanding human resources, striving to develop and acquire the human resources to lead the Company in the future.

■ Training for Officers

Nippon Shinyaku holds training and debriefing sessions attended by all Directors, 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. Audit & Supervisory Board Members can also attend these sessions. New Directors and new Audit & Supervisory Board Members receive new officer training offered internally upon their assumption of office. In this manner, Nippon Shinyaku provides the necessary training opportunities for Directors and Audit & Supervisory Board Members, covering any expenses incurred.

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 Chairman, evaluate the state of internal controls for financial reporting.

Director and Audit & Supervisory Board Member Skills Matrix

Nippon Shinyaku requires the Directors to possess qualities that include experience and knowledge in a wide range of areas, excellent character, high ethical standards, and extensive business-related experience and knowledge suitable for

Six actions under the 6th Five-Year Medium-term Management Plan	Related risks
Creation of new value through R&D	R&D
Development of global business	Global business
Increase in corporate value by strengthening ESG management	ESG/Social contribution
Creation of organizational climate in which every employee can flourish	Personnel/HR development
Active use of AI and adoption of IT	IT/information management
Further strengthening of management base	Management strategy R&D Sales/Marketing Production/Quality

leading management in the global expansion of business. In addition, based on consistency with the Company's management strategy, Nippon Shinyaku has identified the skills

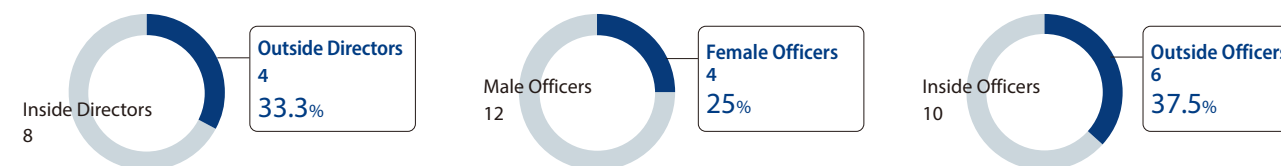
considered necessary for promoting and achieving the “six actions” under the 6th Five-Year Medium-term Management Plan, which it has set out as disclosure items in the skill matrix.

Skills Matrix of Directors and Audit & Supervisory Board Members

Category	Name	Attendance at meetings of Board of Directors/Audit & Supervisory Board (shown in right column)	Skills and Experience									
			Corporate management/Management strategy	Global business	Finance/Accounting	Legal affairs/Risk management	Research & Development	Sales/Marketing	Production/Quality	Personnel/HR development	ESG/Social contribution	IT/Information management
Inside Directors	Shigenobu Maekawa	15/15	●	●	●	●					●	●
	Toru Nakai	15/15	●	●	●			●				
	Shouzou Sano	15/15						●				
	Takashi Takaya	15/15	●			●		●		●	●	●
	Takanori Edamitsu	15/15	●		●	●						
	Kazuchika Takagaki	15/15					●					
	Hitoshi Ishizawa	15/15						●				
Outside Directors	Hitomi Kimura	15/15		●			●		●			
	Miyuki Sakurai	15/15				●						
	Yoshinao Wada	15/15					●			●		
	Yukari Kobayashi	15/15	●	●	●			●		●		●
Standing Audit & Supervisory Board Members	Mayumi Nishi	—					●					
	Kenji Kuwabara	15/15		●			●					
	Hirotsugu Ito	—						●				
	Tsuyoshi Kondo	15/15				●						●
Outside Audit & Supervisory Board Members	Hiroharu Hara	—			●							

* The above list does not represent all the expertise and experience of the Directors and Audit & Supervisory Board Members

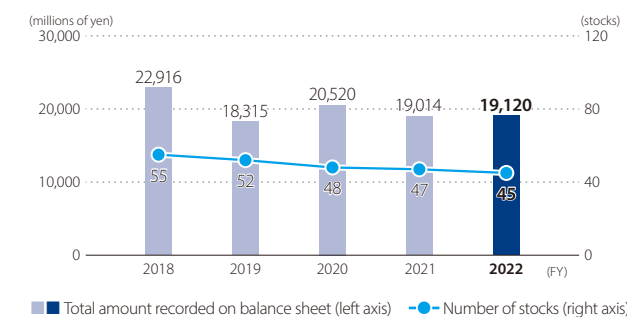
Composition of Board of Directors



Cross-shareholding Status

The Board of Directors will inspect and confirm the rationality and economic significance of the purpose of holding each individual cross-shareholding, taking into consideration the capital requirements, the market environment, etc., and the Company will in turn proceed to reduce cross-shareholdings in which the significance of retention is immaterial. Regarding the exercise of voting rights pertaining to cross-shareholdings, we will judge the situation based on whether or not it contributes to improving the corporate value of the Company or the issuing company, and will respond appropriately. In FY2022, the Company reduced cross-shareholdings in two listed stocks (sales amount: ¥743 million).

Status of cross-shareholdings



Compliance

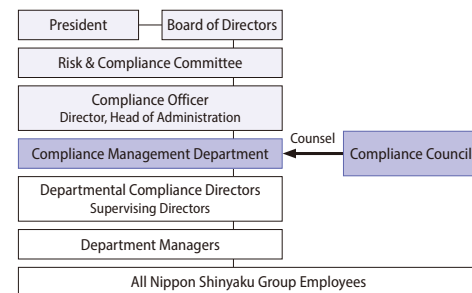
Materiality	Strengthening governance	
Main Activities	FY2022 Activities	Issues and FY2023 Strategies
<ul style="list-style-type: none"> Enhancing compliance Promoting fair and transparent business 	<ul style="list-style-type: none"> Implemented compliance training and awareness-raising initiatives for all employees 	<ul style="list-style-type: none"> Continuing compliance training and awareness-raising initiatives for all employees



Framework for Compliance

The Nippon Shinyaku Group has Compliance Operating Rules and has established a Compliance Management Department headed by the Director in charge of compliance. Our Compliance Council was established to support and provide counsel on enhancing our approach to compliance. In each department, the Director who serves as its head is responsible for its compliance initiatives, which are carried out by the managers therein.

Compliance Framework Chart



Compliance promotion and awareness-raising initiatives

The Compliance Management Department plans and drafts compliance promotion and awareness-raising activities with the aim of instilling and raising compliance awareness among all employees. In addition, a compliance awareness survey is conducted annually for all Group employees, and the results are disclosed within the Group. Specific training is provided to departments with relatively low scores to prevent the occurrence of compliance incidents.

■ Implementing training based on the Code of Conduct for Nippon Shinyaku Group

The Code of Conduct for Nippon Shinyaku Group clearly stipulates respect for human rights, compliance with laws, regulations, and internal rules, and the practice of fair, transparent, and free competition, and is updated as necessary to reflect changes in laws, regulations, and the business environment

surrounding the Group. In addition to providing training on the Code of Conduct to all global employees when they join the Company, we also conduct compliance training and e-learning training programs for all employees throughout the year.

Main training and awareness-raising activities (FY2022)

Training and awareness-raising activity	For	Details	Frequency
Transmission of messages from top management	All employees	Transmission of messages from the President requesting more thorough compliance	Twice annually
Compliance training for the management team	All officers	Implementation of training to the management team on compliance-related topics	Annually
Departmental compliance training	All employees	Departmental training on company-wide common themes and department-specific themes	Monthly
Compliance bulletins	All employees	Transmission of compliance-related timely information via the intranet	Every other month
E-learning	All employees	Provided to all employees as a means to review their learning from the departmental training and intranet communication	As needed
Training for new recruits	New hires	Training centered on the Code of Conduct for Nippon Shinyaku Group conducted on the importance of compliance, including the concept of compliance and matters to be observed	As needed
Training for newly appointed managers	Newly appointed managers	Training implemented for new managers to learn the roles of managers and knowledge related to compliance	Twice annually

■ Establishing hotlines

The Nippon Shinyaku Group has established and operates the Hotline for employees of the Group and Directors and employees of business partners, which allows anonymous reporting and consultation. We have also set up an online contact point to receive questions and comments from various stakeholders, including those related to human rights and harassment. We implement thorough measures to appropriately protect whistleblowers in line with the Whistleblower System Operating Rules, which clearly provide for confidentiality and other necessary measures and the prohibition of treating them disadvantageously. The reporting and consultation results for FY2022 are as follows.

Law and Company Rules	9 cases
Personnel (Treatment and Systems)	3 cases
Work Environment	7 cases
Other	5 cases
Total	24 cases

Risk Management

Materiality	Strengthening governance	
Main Activities	FY2022 Activities	Issues and FY2023 Strategies
Understanding critical risks and strengthening the management and response system for each risk	<ul style="list-style-type: none"> Identified critical risks and countermeasures Requested the departments responsible for each risk to prepare an action plan, and compiled them Conducted risk management self-checks and training Studied risk management operation methods based on risk management under the new risk classification Established and operated a zero trust network Strengthened information security literacy of employees Enhanced NS-CSIRT* activities through information sharing, drills, etc. <p>* NS-CSIRT: NS-Computer Security Incident Response Team</p>	<ul style="list-style-type: none"> Smoothly transitioning to and stably operating risk management activities based on the new risk classification Continuously formulating action plans for critical risks Strengthening information security education for Group companies Enhancing IT-BCP



Basic Approach to and Initiatives related to Risk

Along with strengthening our risk management framework, we aim to achieve solid growth for the Nippon Shinyaku Group and enhance corporate value through our ongoing risk management activities. We have 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. Each year we identify highly critical risks and set action plans for the year, strengthening preventative measures. The results of these efforts, along with critical risks for the next fiscal year are reported to and deliberated on by the Risk & Compliance Committee. The Board of Directors receives reports on the contents and supervises the implementation and effectiveness of risk management.

When an incident does occur, the Director in charge of risk management determines the effect the incident will exert on business operations and decides how to respond according to its level of importance. If it is deemed that the incident will have a serious effect on business operations, a

temporary crisis management office will be established to prevent the situation from worsening and respond in a timely manner. Once the incident is dealt with, measures are devised to prevent recurrence and are implemented by the relevant departments. In addition, we conduct annual self-checks for all employees to raise awareness.

WEB About risk management at Nippon Shinyaku
<https://www.nippon-shinyaku.co.jp/english/sustainability/esg/governance/compliance.php>

Enhancing Information Security

Nippon Shinyaku has established a policy and basic rules that indicate its approach to information security. The ISMS*¹ Committee, established based on the basic rules, reviews various rules in response to changes in the social environment and advances in information technology in order to protect the Nippon Shinyaku Group's information assets from various risks. Specifically, in addition to an SOC*² that conducts 24/7 surveillance and operation of the Group's networks and computers, we enhanced network security in FY2022 based on the zero trust security concept. As countermeasures against information security risk related to human factors, we conduct training to ensure that employees are aware of the importance of information security, and regularly conduct drills against targeted e-mail attacks.

*1 Information Security Management System

*2 Security Operation Center

FY2022 Group critical risks: activity themes

Leaks of confidential information (information mismanagement)
Breaches of labor laws
Harassment (sexual harassment, power harassment, etc.)
Earthquakes, volcanic eruptions, tsunamis, storm and flood damage, lightning strikes
Falsification or leaks of electronic data from cyber attacks

Dialogue with Outside Directors

With a view to achieving sustainable growth on a global scale, the Outside Directors shared with us their candid views on topics such as ideal leaders, the kind of human resources needed by Nippon Shinyaku, and the issues the Company should address going forward.

Strategically developing “human resources with an edge” for taking on global expansion

Sakurai: The Nominating Committee and Remuneration Committee has discussed the drafts presented, received reasonable and convincing explanations, and reported that it has no objections. However, the method of selecting candidates and the policy for determining their remuneration will remain fuzzy until the committee considers the kind of person sought in the human resources who will take on management of the Company and the policy for their



development—not as isolated points of consideration but as a strategically drawn line. I made this point at the last Nominating Committee meeting.

Kobayashi: I also believe that there needs to be a company strategy for decisions about human resources and their remuneration. The Company’s overall position on human resources is being discussed in preparation for the formulation of the 7th Medium-term Management Plan. There should be strategic discussions suited to its position. For example, there will be more risk than ever before in achieving the global expansion that Nippon Shinyaku has in view. It would be difficult for one top executive to address all of this risk solitarily. A wide breadth of knowledge is essential. The contribution of the Board of Directors will improve dramatically once all Directors can see and discuss business from the same perspective as management.

Sakurai: The top management of a company must have the management knowledge to steer the company’s responses to changes in the external environment, the strong leadership skills to respond flexibly and quickly, and the charisma to get others involved. For the Board of Directors to support this, it is first necessary to discuss the skills matrix. I feel that the skills required of Nippon Shinyaku’s Directors should be examined and itemized, and that the Directors in charge of each division should take a bird’s eye view of the entire Company, not just the division they are in charge of, and have candid discussions from both of these perspectives.

Wada: If that can be achieved, it will lead to a group leadership system where the top executives are not the only ones thinking about management. Today, there are many companies where people with scientific backgrounds study management and serve as presidents. In the future, Nippon Shinyaku might also have top executives who experienced

technological evolution firsthand. However, even if we promote in-house development of top management, they will not necessarily always be coming from inside the Company forever. I hope that the Company will look 10 to 30 years into the future from various perspectives and decide on guidelines and strategies concerning human resources in a highly transparent manner.

Kobayashi: No topic at Board meetings is more time-consuming than the topic of human resources strategy. Nippon Shinyaku employees are highly praised as “good people” both internally and externally. While retaining those good qualities, I believe that they need to adapt to changes in the environment and become versatile human resources.

Sakurai: There has been a lot of talk at recent Board meetings about the need for “human resources with an edge,” or in other words, “human resources of a different nature.” Even in the Company, a radical reform of the personnel system is underway, and I sense that employees are expected to break out of the “good people” box and grow more as individuals.

Wada: I expect that many employees will be inspired by the process of mid-career hiring that is now being actively promoted, bringing in different ways of thinking and a



willingness to change. Job-based employment is also being introduced as part of the personnel system reform. I agree with President Nakai that it is important to write a job description that leads to employees’ growth. I believe that job-based employment may lead to “human resources with an edge” because, in accomplishing your assignments, you must have the ability to see for yourself which parts of the job should take priority and which parts you should let slide depending on the situation.

Kobayashi: Alternatively, it can also be a clue for employees to start thinking about their own careers. The Company must clarify what kind of human resources it needs, develop a system that allows for fair evaluation, and promote the training of human resources. Employees have the right to choose their own careers, and they have the option to choose the environment that suits them best.

Sakurai: In terms of evaluation, the current remuneration system for Directors may also need to be examined. I hope that such discussions will be had when formulating the 7th Medium-term Management Plan, including the possibility of incorporating shareholder compensation for performance-linkage over the medium to long term.

Aiming to be an essential company, a turning point for further growth

Wada: In formulating the 7th Medium-term Management Plan, we must consider how to proceed with the urgent issues of R&D, expansion of pipelines, and ensuring compliance on a global scale. In terms of global operations, we have only just begun to put the necessary systems in place, and I believe there are risks in this regard.

Kobayashi: In expanding business globally, we need to understand that values, business practices, and attitudes toward security vary from country to country and region to region, and the Board of Directors also needs to focus even more on risk management. I feel that another issue is that it is difficult for people outside the Company to see into internal discussions. For example, it is easier to make constructive suggestions when you share information, including histories, on the strategic discussions and prioritization at the time of the Medium-term Management Plan drafting. Since many of these suggestions have already been implemented, I feel that they are being taken seriously and we are headed toward improvement. Moreover, we are having heated discussions about how quickly we can reconfigure our business and improve our competitiveness in response to changes in the



market. As Outside Directors, we would like to help make that happen as soon as possible.

Sakurai: The three commitments made by President Nakai after 10 consecutive years of growth (➡ P. 6 Message from the President) indicate that Nippon Shinyaku is at a turning point toward further growth. We hope that stakeholders will trust in the appeal of this Company, which aims to bring health beyond borders to as many patients as possible, as quickly as possible, and to enable each and every employee to grow with satisfaction in their jobs.

Wada: Nippon Shinyaku aims to be a company with a meaningful existence in the healthcare field and an essential company for patients and medical professionals. We are now at the stage of taking the next step toward achieving this goal, which we believe will lead to the growth of the Company.

Miyuki Sakurai Outside Director

Registered as an attorney-at-law in 1992. Has served in positions that include Joint Owner at the Hanamizuki Law Office and auditor at Osaka University, and has been an Outside Director at Nippon Shinyaku since 2017.

Yoshinao Wada Outside Director

Has served for many years in diagnosis and treatment as a doctor, has served in positions that include Director of the Research Institute at the Osaka Medical Center for Maternal and Child Health and Guest Professor at the Graduate School of Osaka University, and has been an Outside Director at Nippon Shinyaku since 2019.

Yukari Kobayashi Outside Director

Has served in positions including Corporate Officer at Microsoft Japan Co., Ltd. and Representative Partner at Amanda Life Consulting LLC., and has been an Outside Director at Nippon Shinyaku since 2021.

Message from the Newly Appointed Outside Director



Mayumi Nishi
Outside Director

Obtained pharmacist license in 1980 and medical license in 1991. After working at Aichi Cancer Center Research Institute, Kyoto Prefectural University of Medicine, and obtaining a Doctor of Medicine from the same university, has served as a professor at Nara Medical University in 2009, and has been a professor emeritus at Nara Medical University since April 2023 (current position). Appointed as an Outside Director of Nippon Shinyaku in June 2023.

My name is Mayumi Nishi, and I have just assumed the position of Director. I am very humbled to be able to take on this important responsibility. After graduating from pharmacy school, I worked at a cancer research institute, but my desire to study medicine grew stronger, so I re-entered medical school. After graduating from medical school, I spent several years in clinical practice, and then went on to do basic research in neuroendocrinology. I spent over 30 years researching and teaching anatomy at Kyoto Prefectural University of Medicine and Nara Medical University.

I believe that my involvement in research and development for drug discovery, based on my experience in pharmacy and medical school, is desirable with regards to the governance of Nippon Shinyaku. I have been involved in neuroscience research in a broad sense. There are many intractable and rare diseases of the nervous system for which there are still no effective treatments, and I hope that Nippon Shinyaku will further promote drug discovery in this field by utilizing its past research and development achievements. I believe that pharmaceutical companies are now at a major turning point, particularly in AI-based drug discovery. I also believe that Nippon Shinyaku is faced with the need to further strengthen its collaboration with universities and research institutions to promote highly original drug discovery. I think that the network of researchers I have cultivated could be utilized in this regard.

I would like to express my gratitude to all of our stakeholders for their continued support and cooperation as I strive to further develop Nippon Shinyaku by leveraging my perspectives as a researcher and physician, as well as the personal networks I have built through academic conferences and other activities.

Management Team

(Current as of June 29, 2023)

Inside Directors



Shigenobu Maekawa

Representative Director,
Chairman

Number of shares of the Company held
53,200 Shares

Apr. 1976 Joined the Company
Mar. 1992 Transfer to Japan Federation of Employers' Associations
Apr. 2002 Department Manager, Corporate Planning Department, Corporate Strategy Office
Apr. 2004 Corporate Officer
Jun. 2005 Director
Jun. 2005 Corporate Planning, Finance & Accounting, and Information system, and Department Manager, Corporate Planning Department
Jun. 2006 Managing Director
Apr. 2007 General Manager, Corporate Planning, Finance & Accounting, and Information system
Jun. 2007 Representative Director, President
Jun. 2021 Representative Director, Chairman (current position)
Jun. 2023 Outside Director of KYOCERA Corporation (current position)
<Significant concurrent positions>
Chairman, Kyoto Employers' Association
Outside Director, KYOCERA Corporation (Scheduled)



Toru Nakai

Representative Director,
President

Number of shares of the Company held
10,500 Shares

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



Shouzou Sano

Managing Director,
Sales and Marketing

Number of shares of the Company held
6,900 Shares

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



Takashi Takaya

Director, Personnel,
General Affairs, Risk Management,
Compliance & Digital Transformation

Number of shares of the Company held
4,900 Shares

Apr. 1984 Joined the Company
Apr. 2005 Department Manager, Marketing Department, Sales and Marketing
Apr. 2009 Department Manager, Marketing Department, Sales and Marketing Planning Division, Sales and Marketing
Apr. 2010 Department Manager, Marketing and Planning Department, Sales and Marketing Planning Division, Sales and Marketing
Apr. 2011 Head of Sales and Marketing Planning Division, Sales and Marketing
Apr. 2012 Corporate Officer; Head of Sales and Marketing Planning Division, Sales and Marketing
Jun. 2018 Director (current position)
Jun. 2018 General Manager, Administration
Apr. 2022 General Manager, Personnel, General Affairs, Risk Management, Compliance & Digital Transformation (current position)



Takanori Edamitsu

Director, Business Management
& Sustainability

Number of shares of the Company held
4,400 Shares

Apr. 1989 Joined the Company
Aug. 2011 Department Manager, Corporate Planning Department
Apr. 2013 Corporate Officer; Department Manager, Corporate Planning Department
Jun. 2018 Director (current position)
Jun. 2018 General Manager, Business Management
Apr. 2022 General Manager, Business Management & Sustainability (current position)



Kazuchika Takagaki

Director, Research & Development

Number of shares of the Company held
3,500 Shares

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



Hitoshi Ishizawa

Director, Functional Food

Number of shares of the Company held
4,700 Shares

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



Hitomi Kimura

Director, General Manager,
Resource Procurement,
Production & Assurance

Number of shares of the Company held
1,700 Shares

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

Nippon Shinyaku Today

A New Way of Life

In Pursuit of Originality

ESG as the Foundation for Growth

Corporate Data

*** For the reasons for the appointment of Directors and Audit & Supervisory Board Members, please visit the following website:**
https://www.nippon-shinyaku.co.jp/english/company_profile/profile/executive_officer/index.php

Outside Directors



Miyuki Sakurai

Outside Director

Number of shares of the Company held
600 Shares

Apr. 1992 Completed training program at Legal Training and Research Institute of Japan
Apr. 1992 Registered with Osaka Bar Association
Apr. 1992 Joined Nishimura Law and Accounting Office
May 2003 Joint Owner, Hanamizuki Law Office (current position)
Mar. 2015 Auditor, Nissay Life Foundation (current position)
Apr. 2016 Auditor, Osaka University (current position)
Jun. 2017 Director, the Company (current position)
Jun. 2020 Member of the Board, NIPPON SHOKUBAI CO., LTD. (current position)
Jun. 2022 Outside Auditor, MBS MEDIA HOLDINGS, INC.
<Significant concurrent positions>
Joint Owner, Hanamizuki Law Office
Member of the Board, NIPPON SHOKUBAI CO., LTD.
Outside Auditor, MBS MEDIA HOLDINGS, INC.



Yoshinao Wada

Outside Director

Number of shares of the Company held
200 Shares

Jul. 1975 Joined Osaka University Hospital
Nov. 1981 Department of Maternal Medicine, Osaka Medical Center for Maternal and Child Health
Oct. 1989 Obtained the degree of Doctor of Medicine (Osaka University)
Apr. 1991 Department Manager, Department of Molecular Medicine, Research Institute, Osaka Medical Center for Maternal and Child Health
Apr. 1998 Director, Research Institute, Osaka Medical Center for Maternal and Child Health
Apr. 2011 Department Manager, Department of Maternal Medicine; Director, Research Institute; Osaka Medical Center for Maternal and Child Health
Apr. 2014 Chief Department Manager, Department of Maternal Medicine; Director, Research Institute; Osaka Medical Center for Maternal and Child Health
Apr. 2016 Part-time physician, Department of Maternal Medicine, Osaka Medical Center for Maternal and Child Health
Apr. 2017 Part-time physician, Department of Maternal Medicine, Osaka Women's and Children's Hospital (current position)
Apr. 2018 Visiting Professor, Yokohama City University
Jun. 2019 Director, the Company (current position)
<Significant concurrent positions>
Part-time physician, Department of Maternal Medicine, Osaka Women's and Children's Hospital



Yukari Kobayashi

Outside Director

Number of shares of the Company held
100 Shares

Apr. 1987 Joined IBM Japan, Ltd.
Jul. 2002 Senior Manager, Overall Management of System Products Marketing, IBM Japan, Ltd.
Jan. 2007 Director in charge of Public Sector, Global Business Service, IBM Japan, Ltd.
Jan. 2007 Executive Officer, IBM Business Consulting Services KK
Mar. 2016 Growth Leader for Mercer Far East Zone; Chief of staff, Mercer Japan Ltd.
Jan. 2018 Director, Mercer Investment Solutions Ltd.
Feb. 2018 COO, Mercer Japan Ltd.
Sep. 2018 Corporate Officer; Corporate Strategy Management Lead, Area Transformation Lead, and Chief of Staff, Microsoft Japan Co., Ltd.
Mar. 2020 Representative Partner, Amanda Life Consulting LLC. (current position)
Jun. 2021 Director, the Company (current position)
Apr. 2022 Outside Director, Panasonic Connect Co., Ltd. (current position)
Mar. 2023 Outside Director, Bridgestone Corporation (current position)
<Significant concurrent positions>
Representative Partner, Amanda Life Consulting LLC.
Outside Director, Panasonic Connect Co., Ltd.
Outside Director, Bridgestone Corporation
CEO, JC1 LLC (Scheduled)



Mayumi Nishi

Outside Director

Number of shares of the Company held
0 Shares

Apr. 1980 Joined Department of Biology, Aichi Cancer Center Research Institute
Apr. 1980 Obtained pharmacist license
Apr. 1991 Joined Department of Anesthesiology, Kyoto Prefectural University of Medicine
May 1991 Obtained medical license
Mar. 1997 Obtained the degree of Doctor of Medicine (Kyoto Prefectural University of Medicine)
Apr. 1997 Teaching Associate, Department of Anatomy I, Kyoto Prefectural University of Medicine
Jun. 1998 Lecturer, Department of Anatomy I, Kyoto Prefectural University of Medicine
Apr. 2003 Lecturer, Graduate School of Medical Science, Kyoto Prefectural University of Medicine
Apr. 2005 Assistant Professor, Department of Anatomy and Neurobiology, Graduate School of Medical Science, Kyoto Prefectural University of Medicine
Apr. 2007 Associate Professor, Department of Anatomy and Neurobiology, Graduate School of Medical Science, Kyoto Prefectural University of Medicine
Aug. 2009 Professor, Department of Anatomy and Cell Biology, Nara Medical University
Apr. 2010 Visiting Professor, Graduate School of Medical Science, Kyoto Prefectural University of Medicine
Apr. 2023 Professor Emeritus, Nara Medical University (current position)
Jun. 2023 Director, the Company (current position)
<Significant concurrent positions>
None

Audit & Supervisory Board Members



Kenji Kuwabara

Standing Audit &
Supervisory Board Member

Number of shares of the Company held
6,800 Shares

Apr. 1983 Joined the Company
Oct. 2004 Department Manager, Biological Research Department, Discovery Research Labs., Research & Development
Apr. 2008 Department Manager, Nucleic Acid Business Promotion Department, Nucleic Acid Business Division, Research & Development
Jan. 2010 Department Manager, Discovery Research Laboratories in Tsukuba, Discovery Research Labs., Research & Development
Apr. 2012 Department Manager, Alliance & Business Planning Department, Business Development Division, Research & Development
Apr. 2016 General Manager, Beijing Representative Office
Apr. 2019 General Manager, Beijing Representative Office, Global Business Division
Jun. 2019 General Manager, Beijing Representative Office, Global Business
Apr. 2020 Deputy Head, Global Business
Jun. 2020 Standing Audit & Supervisory Board Member (current position)



Hirotsugu Ito

Standing Audit &
Supervisory Board Member

Number of shares of the Company held
2,100 Shares

Apr. 1986 Joined the Company
Apr. 2015 Department Manager, Keiji Hokeniku Branch Office, Western Japan Division, Sales and Marketing
Apr. 2017 Department Manager, Kyushu Branch Office, Sales and Marketing
Apr. 2019 Department Manager, Chushikoku Branch Office, Sales and Marketing
Apr. 2021 Department Manager, Nagoya Branch Office, Sales and Marketing
Apr. 2022 Department Manager, Information Service Supervisory Department
Jun. 2023 Standing Audit & Supervisory Board Member (current position)



Tsuyoshi Kondo

Outside Audit & Supervisory
Board Member

Number of shares of the Company held
1,000 Shares

Apr. 1993 Completed legal training at The Legal Training and Research Institute of Japan
Apr. 1993 Qualified as a lawyer
Apr. 1993 Worked for Kondo Chiaki & Tsuyoshi Law Office
Apr. 2001 President of Kondo Law Office (current position)
Apr. 2003 Registered as a patent attorney
Apr. 2010 Specially appointed professor, Graduate School of Law, Kansai University (current position)
Jun. 2016 Outside Audit & Supervisory Board Member (current position)
Jan. 2018 Outside Director, Senshu Electric Co., Ltd. (current position)
<Significant concurrent positions>
President of Kondo Law Office
Outside Director, Senshu Electric Co., Ltd.



Hiroharu Hara

Outside Audit & Supervisory
Board Member

Number of shares of the Company held
100 Shares

Apr. 1983 Joined Osaka Regional Taxation Bureau
Jul. 2012 District Director, Shingu Tax Office, Osaka Regional Taxation Bureau
Jul. 2015 Director, Second International Information Div., First Examination Dept., Osaka Regional Taxation Bureau
Jul. 2016 District Director, Nishi Tax Office, Osaka Regional Taxation Bureau
Jul. 2017 Director, Research Management Div., First Examination Dept., Osaka Regional Taxation Bureau
Jul. 2019 Deputy Assistant Regional Commissioner, Second Examination Dept., Osaka Regional Taxation Bureau
Jul. 2020 District Director, Kita Tax Office, Osaka Regional Taxation Bureau
Jul. 2021 Retired from Kita Tax Office, Osaka Regional Taxation Bureau
Aug. 2021 Registered as Licensed Tax Accountant
Aug. 2021 President, Hiroharu Hara Tax Accountant office (current position)
Jun. 2023 Outside Audit & Supervisory Board Member (current position)
<Significant concurrent positions>
President, Hiroharu Hara Tax Accountant office

Corporate Officers

Koji Honma
Department Manager, Personnel
Department

Yoshizumi Tanaka
Head of Regulatory Affairs
Supervision and Assurance Division

Hayato Wada
Department Manager, Kansai
Business Office

Keiichi Kuwano
Department Manager, Discovery
Research Labs.

Masaya Toda
Head of Licensing & Alliance
Division

Katsumi Noda
Department Manager, Tokyo
Business Office

Kazuyuki Yamate
Head of Digital Transformation
Division

Hiroji Hayashi
Department Manager, Corporate
Planning Department

Masafumi Taira
Head of Global Business Division

Toru Yamaguchi
Department Manager, Odawara
Central Factory

Mitsuharu Koizumi
Head of Sales and Marketing
Planning Division

Kazuyuki Iwata
Department Manager, Nagoya
Business Office

Eleven-Year Financial Data

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

JGAAP

	(FY)	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
For the year											
Net sales		69,941	76,517	79,991	84,209	98,781	101,448	114,716	116,637	121,885	137,547
Pharmaceuticals		58,318	63,345	66,340	70,489	85,315	87,416	100,223	101,643	106,478	120,650
Functional Food		11,622	13,172	13,651	13,720	13,466	14,031	14,492	14,994	15,406	16,897
Cost of sales		34,776	39,033	41,226	44,016	44,835	46,929	50,952	53,155	49,954	50,657
Gross profit		35,165	37,483	38,764	40,192	53,946	54,519	63,764	63,481	71,931	86,890
Total selling, general and administrative expenses		28,263	29,445	30,202	31,643	38,666	37,439	43,119	41,813	45,796	58,591
Selling, general and administrative expenses		19,214	19,914	21,233	21,904	23,762	24,217	26,418	27,819	29,692	32,204
R&D expenses		9,049	9,530	8,968	9,739	14,903	13,221	16,701	13,994	16,104	26,386
Operating income		6,901	8,038	8,562	8,549	15,280	17,079	20,644	21,668	26,134	28,299
Net income attributable to owners of the parent		4,647	5,750	5,882	6,340	11,749	12,953	16,302	16,866	20,702	23,044
Depreciation and amortization		2,759	2,704	2,665	2,452	2,648	2,773	3,418	3,468	3,550	2,933
Capital investment		1,332	1,072	1,239	3,554	3,949	2,811	1,242	2,500	2,583	4,264
Cash flows from operating activities		3,767	6,015	6,113	8,915	18,916	6,719	15,310	12,737	21,388	16,018
Cash flows from investing activities		(2,026)	(3,357)	(3,718)	(3,978)	(5,750)	(11,342)	511	(2,339)	(1,564)	(6,359)
Cash flows from financing activities		(1,413)	(1,606)	(1,773)	(1,907)	(2,193)	(3,787)	(3,708)	(5,660)	(6,199)	(6,801)

End of the year

Total assets	113,730	118,188	129,757	135,370	150,905	155,887	168,763	175,017	197,028	210,052
Interest-bearing debt	35	—	—	—	—	—	—	—	—	—
Net assets	89,529	93,186	101,207	102,762	114,316	125,689	135,190	145,760	162,543	176,767

Financial information per share (yen)

Earnings per share (EPS)	68.87	85.25	87.26	94.10	174.42	192.31	242.04	250.42	307.37	342.14
Net assets per share	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	2,620.02
Dividend per share	21	23	25	28	48	52	70	86	99	110

Major financial indicators regarding profitability and valuation

Operating income to net sales (%)	9.9	10.5	10.7	10.2	15.5	16.8	18.0	18.6	21.4	20.6
R&D expenses to net sales (%)	12.9	12.5	11.2	11.6	15.1	13.0	14.6	12.0	13.2	19.2
Equity ratio (%)	78.5	78.7	77.8	75.8	75.6	80.5	80.0	83.1	82.4	84.0
Return on assets (ROA) (%)	6.3	6.9	7.0	6.5	10.8	11.2	12.7	12.6	14.0	13.9
Return on equity (ROE) (%)	5.4	6.3	6.1	6.2	10.8	10.8	12.5	12.0	13.5	13.6
Price book value ratio (PBR) (times)	1.0	1.4	2.9	2.9	3.3	3.8	4.0	3.9	3.4	3.2
Price earnings ratio (PER) (times)	19.4	23.0	50.1	46.8	32.5	37.0	33.3	33.9	26.8	24.4
Payout ratio (%)	30.5	27.0	28.7	29.8	27.5	27.0	28.9	34.3	32.2	32.2
Number of outstanding shares (shares)	70,251,484	70,251,484	70,251,484	70,251,484	70,251,484	70,251,484	70,251,484	70,251,484	70,251,484	70,251,484
Market capitalization (millions of yen)	93,856	137,482	307,350	309,107	398,326	500,191	566,227	595,733	578,170	585,195

* IFRS adopted from the fiscal year ended March 31, 2022.

IFRS

(Millions of yen)

	(FY)	2021	2022
For the year			
Revenue		137,484	144,175
Pharmaceuticals		120,650	121,988
Functional Food		16,834	22,187
Cost of sales		50,191	55,980
Gross profit		87,293	88,195
Selling, general and administrative expenses		32,173	34,812
R&D expenses		22,863	24,135
Operating profit		32,948	30,049
Profit attributable to owners of parent		24,986	22,812
Depreciation and amortization		4,588	5,041
Capital expenditures (Including investment in intangible assets)		10,744	13,034
Cash flows from operating activities		21,316	26,170
Cash flows from investing activities		(10,037)	(17,631)
Cash flows from financing activities		(8,407)	(9,605)

End of the year

Total assets	219,943	237,451
Interest-bearing debt (Including lease liabilities)	2,713	2,665
Total equity	180,886	195,933

Financial information per share (yen)

Basic earnings per share (EPS)	370.97	338.70
Equity attributable to owners of parent per share	2,681.18	2,904.49
Dividends	110	114

Major financial indicators regarding profitability and valuation

Operating profit to revenue (%)	24.0	20.8
R&D expenses to revenue (%)	16.6	16.7
Ratio of equity attributable to owners of parent to total assets (%)	82.1	82.4
Profit before tax to total assets (ROA) (%)	15.7	13.3
Return on equity attributable to owners of parent (ROE) (%)	14.5	12.1
Price book value ratio (PBR) (times)	3.1	2.0
Price earnings ratio (PER) (times)	22.5	17.2
Payout ratio (%)	29.7	33.7
Number of outstanding shares (shares)	70,251,484	70,251,484
Market capitalization (millions of yen)	585,195	409,566

Non-Financial Data

Environment

Material Flow Data

INPUT	Classification	FY2020		FY2021		FY2022
	Materials	Raw materials (t)	225	244		288
		Packaging materials (t)	232	302		245
	Energy	Electricity (1,000 kWh)	15,251	15,350		15,881
		Heavy oil (kL)	0	0		0
		Kerosene (kL)	4	1		0
		City gas (1,000 m³)	1,549	1,523		1,562
		LPG (m³)	1	9		6
		Gasoline (kL)	389	428		398
		Diesel (kL)	2	3		3
	Water consumption	Tap water (1,000 m³)	59	58		54
		Well water (1,000 m³)	101	107		101
OUTPUT	Products	Shipped products (t)	461	483		479
		Transported products (10,000 t-km)	13	10		13
	Gas & Water emissions	CO ₂ emissions*1 (Scope1,2)(t-CO ₂)	10,496	9,686		9,182
		Wastewater (1,000 m³)	161	165		155
	Waste substances	Amount generated (t)	428	363		388
		Final amount of landfilled waste (t)	3.9	4.7*2		2.3
	Container and package recycling*3	Waste containers and packages (Amount contracted out as post-consumer recovered waste) (t)	195	170		172
	Class I Designated Chemical Substances handled*4	Acetonitrile (kg)	5,557	6,633		5,558
		Dichloromethane (kg)	2,075	2,483		1,349
		N-hexane (kg)	2,697	2,729		2,575
		Toluene (kg)	—	1,346		203

*1 Although electricity consumption increased slightly, CO₂ emissions decreased year on year due to the introduction of renewable energy in part of the Head Office area power grid.
*2 The figure includes approximately 0.9t of unused equipment and other landfilled waste arising from the dismantling of buildings on the site of Odawara Central Factory in addition to normal business activities.
*3 Waste containers and packaging (FY2020 entrusted amount for recycling)
*4 Lists Class I Designated Chemical Substances based on the Pollutant Release and Transfer Register (PRTR) system under the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management thereof with a handling amount of 1,000kg or more.

Putting Environmental Management System Certification into Action

Office name	Acquired certifications	Date of certification acquisition	Last 3rd-party review
Odawara Central Factory	ISO14001	August 2004	February 2023 (Regular review)
Head Office area business office	KES Step2	June 2012	June 2023 (Review for renewal)

Environmental Accounting

Environmental conservation costs*5 (excluding our sales offices)	Costs	FY2021		FY2022	
		Investments	Expenses	Investments	Expenses
	Costs within our business areas (Thousands of yen)	222,012	323,720	197,014	304,493
	• Pollution prevention costs*6 (Thousands of yen)	2,156	18,383	130,743	55,918
	• Global environmental conservation costs*7 (Thousands of yen)	219,856	244,715	66,270	198,527
	• Resource recycling costs*8 (Thousands of yen)	0	60,622	0	50,047
	Upstream & downstream costs*9 (Thousands of yen)	0	6,653	0	5,499
	Management activity costs*10 (Thousands of yen)	1,070	72,911	0	73,905
	R&D costs (Thousands of yen)	0	0	0	0
	Social activity costs*11 (Thousands of yen)	0	809	0	34,384
	Environmental remediation costs (Thousands of yen)	0	0	0	0
	Total (Thousands of yen)	223,082	404,093	197,014	418,281

Environmental conservation benefits	Benefit verification	FY2021	FY2022	Year on year change	Year on year rate
	CO ₂ emissions (t-CO ₂)	9,685	9,182	-503	-5.2%
	• Electricity usage (1,000 kWh)	15,350	15,881	531	3.5%
	• Heavy oil & kerosene usage (kL)	1	0	-1	-100.0%
	• City gas & LPG usage (1,000 m³)	1,532	1,562	30	2.0%
	• Gasoline & diesel usage (kL)	431	401	-30	-7.0%
	Water consumption (main business locations) (1,000 m³)	165	155	-10	-6.1%
	Waste substances generated (main business locations) (t)	363	389	26	7.2%
	Final amount of landfilled waste (main business locations) (t)	5.0	2.3	-2.7	-54.0%

*5 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.
*6 Costs related to environmental damage prevention due to pollution such as water pollution, soil pollution, air pollution, etc.
*7 Costs related to global warming prevention, energy-saving activities, etc.
*8 Costs related to proper disposal of waste, recycling etc.
*9 Consignment fee for recycling of containers and packaging (costs for collection and recycling of packaging containers for pharmaceuticals, etc. in Nippon Shinyaku), etc.
*10 Costs related to maintenance and operation of EMS (Environmental Management System) and environmental education of employees.
*11 Costs related to offering classes to elementary schools in Kyoto city, greening in the workplace, regional cleanup activities, etc.

	FY2018	FY2019	FY2020	FY2021	FY2022
CO₂ emissions (t-CO₂)					
Main business locations*12	10,129	9,435	9,181	8,271	7,845
Sales offices, etc.	2,509	1,783	1,315	1,414	1,337
Supply chain emissions by scope (t-CO₂)					
Scope 1: Direct greenhouse gas (GHG) emissions from owned or controlled sources	—	5,063	4,396	4,449	4,471
Scope 2: Indirect emissions that occur through the use of purchased electricity, steam, and heat	—	6,155	6,101	5,236	4,711
Scope 3: Purchased goods and services	—	—	163,905	171,906	188,834
Scope 3: Capital goods	—	—	13,385	14,639	20,043
Scope 3: Fuel- and energy-related activities not included in Scope 1 or Scope 2	—	—	1,924	1,938	1,942
Scope 3: Transportation and delivery (upstream)	—	—	678	721	658
Scope 3: Waste generated in operations	—	—	223	225	208
Scope 3: Business travel	—	—	233	235	233
Scope 3: Employee commuting	—	—	231	270	287
Scope 3: Transportation and delivery (downstream)	—	—	1,813	1,977	—*13
Scope 3: End-of-life treatment of sold products	—	—	99	139	140
Scope 3: Leased assets (downstream)	—	—	628	628	628
Total energy consumption (Thousands of GJ)					
Main business locations*12	212	211	210	209	216
Sales offices, etc.	40	30	23	24	23
Electricity (1,000 kWh)					
Main business locations*12	14,180	14,109	14,305	14,400	14,916
Sales offices, etc.	878	878	946	950	965
City gas (1,000 m³)					
Main business locations*12	1,639	1,627	1,546	1,521	1,560
Sales offices, etc.	2	2	2	2	2
Water (1,000 m³)					
Main business locations*12	204	182	161	165	155
Waste substances generated (t)					
Head Office area	185	177	198	185	155
Odawara Central Factory	315	282	213	150	209
Discovery Research Laboratories in Tsukuba	22	23	18	28	24

*12 Main business locations: Head Office area, Odawara Central Factory, Discovery Research Laboratories in Tsukuba.
*13 The calculation of emissions in FY2022 is incomplete as a portion of the data of the relevant pharmaceutical wholesalers is undisclosed at calculation time.

Social

	FY2018	FY2019	FY2020	FY2021	FY2022
Employee Numbers and the Promotion of Women in the Workplace (persons)					
Number of employees (parent company)	1,761	1,793	1,806	1,827	1,857
Number of female employees	494	516	529	552	565
Ratio of female employees (%)	28.1	28.8	29.3	30.2	30.4
Number of executives	555	554	555	571	596
Number of female executives	72	78	84	92	100
Ratio of female executives (%)	13.0	14.1	15.1	16.1	16.8
Number of managers	321	329	331	343	301
Number of female managers	25	32	34	38	40
Ratio of female managers (%)	7.8	9.7	10.3	11.1	13.3
Number of recruits	72	79	76	57	62
Number of female recruits	25	28	33	28	20
Ratio of female recruits (%)	34.7	35.4	43.4	49.1	32.3
Average number of years of service	17.5	17.8	17.3	17.4	17.5
Average number of years of service of female employees (years)	17.3	18.1	16.7	16.5	16.6
Average number of years of service of male employees (years)	17.5	17.7	17.6	17.8	17.8
Number of employees taking parental leave for childcare (Male)	0	7	14	30	61
Rate of uptake of parental leave for childcare (Male %)	0.0	9.7	20.3	50.0	69.3
Number of employees taking parental leave for childcare (Female)	18	22	19	19	25
Rate of uptake of parental leave for childcare (Female %)	100	100	100	100	100
Paid annual leave acquisition rate (%)	70.6	71.3	63.5	63.5	69.6
Total annual working hours (hours)	1804.22	1791.6	1821.96	1819.89	1841.69
Employee turnover (%)	1.49	1.68	1.97	1.66	1.92
Human Resources Development (hours)					
Training hours by level per employee				7.23	10.01
Hours of self-development training per employee				10.73	10.32
Education and research expenses per employee (Thousands of yen)				79	83

Governance

	FY2018	FY2019	FY2020	FY2021	FY2022
Number of directors (persons)					
Number of outside directors	12	12	12	12	12
Number of female directors	4	4	4	4	4
Ratio of female directors (%)	1	1	1	3	25
Number of audit & supervisory board members (persons)					
Number of outside audit & supervisory board members	4	4	4	4	4
Ratio of outside audit & supervisory board members (%)	2	2	2	2	2
	50	50	50	50	50

Glossary of Terms

Healthcare and Medicines	Acute Myeloid Leukemia (AML)	A disorder marked by an abnormal proliferation of immature myeloid cells. Normal hematopoietic function is impaired by unlimitedly proliferation of leukemia cells in the bone marrow, causing a variety of symptoms that include infectious disease and bleeding.
	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)	A disorder whereby organized thrombi cause a occlusion in the artery leading from the heart to the lungs (pulmonary artery), leading to abnormally high blood pressure in the pulmonary artery. Clinical symptoms include shortness of breath during exertion.
	Dravet Syndrome	A rare, devastating and life-long form of epilepsy that generally begins in infancy or early childhood and is marked by frequent, treatment-resistant seizures, frequent resulting hospitalizations and medical emergencies, significant developmental and motor and behavioral impairments. Dravet Syndrome has been designated as an intractable disease by the Ministry of Health, Labour and Welfare, and there are estimated to be about 3,000 patients living with this disease in Japan.
	Duchenne Muscular Dystrophy (DMD)	A hereditary muscular disorder whereby dystrophin gene abnormalities cause a loss of dystrophin proteins, which protect muscle cell membranes. It is the most frequently occurring type of muscular dystrophy, occurring in one of every 3,500 newborn boys. It is identified by symptoms such as a tendency to fall and inability to walk quickly in children aged 2 to 5, with muscular atrophy and muscle strength deterioration following. Patients become unable to walk on their own before their early teens, require the use of a wheelchair, and generally die in their 20s or 30s from respiratory failure or heart failure.
	Exon Skipping	Restoring the open reading frame of amino acids via medications that use antisense oligonucleotides to remove (skip) certain parts of the mRNA region (exon) that are translated into proteins. This has the effect of generating functional proteins.
	Iron Deficiency Anemia	Anemia caused by iron deficiency and reduction of hemoglobin synthesis associated with excessive menstruation, post-partum hemorrhage in women, gastrointestinal bleeding, and poor absorption of iron through the intestinal tract and other relevant diseases. In addition to symptoms such as palpitations, shortness of breath, and easy fatigue due to anemia and spoon nails due to iron deficiency are also observed.
	Modality	A drug discovery method for therapies such as low-molecular weight compounds, peptide (medium molecule weight) drugs, and nuclear acid drugs.
	Myelodysplastic Syndromes (MDS)	Intractable diseases that carry a poor prognosis and very often lead to leukemia. The main symptoms are general fatigue caused by anemia, an increased susceptibility to infections due to a decrease in white blood cells, and bleeding tendency as a result of a decrease in platelet count.
	Nucleic Acid Drugs	Drugs that consist of nucleic acids, which make up genes, and target genes that cause of disease. These nucleic drugs work by either stopping or regulating the production of proteins from those genes. Referred to by many as next-generation drugs, they show promise for treating diseases that are difficult to treat with traditional low-molecular drugs.
Other	Pulmonary Arterial Hypertension (PAH)	A life-threatening disorder characterized by abnormally high blood pressure in the artery leading from the heart to the lungs. PAH has a variety of symptoms that begin with minor shortness of breath and fatigue during everyday activity, then restricted physical activities, eventually leading to death due to right ventricular failure.
	Drug Price	The price of a pharmaceutical paid to an insurance pharmacy or medical institution providing services covered by health insurance. What category a pharmaceutical can be used for as part of medical care, as well as prices, are determined by the Health, Labor and Welfare Minister.
	Patient Centricity	This is a concept which involves always putting the patient at the center, providing responses that are focused on the patient, and ultimately respecting the individual judgement of the patient to the maximum extent.
	PLCM	An abbreviation of Product Life Cycle Management. With new pharmaceutical development having become increasingly challenging, this is a means of improving the value of existing products by adding additional indications and dosage forms.
	Priority Review Voucher	A voucher issued by the FDA in the U.S. to incentivize new drug development for rare conditions affecting children (including tropical diseases), priority review vouchers grant the right to have a new drug designated for priority review at the time of application approval. These rights can also be traded.
	PRTR System	An abbreviation of Pollutant Release and Transfer Register. A PRTR is a system for tracking, aggregating, and publishing data about the extent to which various toxic chemical substances are released into the environment and are transferred off-site as part of waste, as well as the origin of these substances.

IR FAQ

Q1 Please explain President Nakai's three commitments in detail.

We aim to achieve further growth for the Company through three commitments: 1. Continue to launch at least one unique product each year on average, 2. Generate at least 50% of consolidated sales from overseas, and 3. Target at least 100% gains in sales and operating profit compared to FY2020.

Q2 How does the Company plan to generate at least 50% of consolidated sales from overseas?

Viltepso, a therapy for Duchenne muscular dystrophy (DMD), was launched in Japan and the U.S. in FY2020. To bring the drug to more places around the world, we are now taking steps aimed at gaining early approval in China, Europe, and other regions. Going forward, we will develop a pipeline for exon-skipping drugs that follow Viltepso and other globally developed drugs, and plan to increase the percentage of sales from overseas operations to at least 50% by 2030.

Q3 What are the factors that caused your forecast for FY2023 to fall short of the numerical targets of the 6th Five-Year Medium-term Management Plan?

The main reasons why the forecast for FY2023 fell short of the numerical targets of the 6th Five-Year Medium-term Management Plan are that the launch of Viltepso in the U.S. was delayed due to COVID-19 and that product sales in Japan decreased due to the introduction of off-year price revisions by MHLW.

On the other hand, we believe that long-term growth is possible through the development of new modalities, such as gene therapy, and pipeline items outside the DMD field, in addition to the nucleic acid drug group and cell therapy drug currently under development.

Q4 Please tell us about how you will overcome Upravi's patent cliff.

The patent for Upravi is expected to expire in October 2026 in the U.S. and April 2027 in the rest of the world. The patent expiration is expected to reduce both sales of Upravi in Japan and overseas royalty income, but sales and profit growth are considered possible due to Viltepso's growth, nucleic acid drugs for DMD in development, CAP-1002, a DMD cell therapy, and the global launch of in-house developed products such as NS-580 and NS-018.

Q5 How do you plan to roll out nucleic acid drugs?

To provide drugs to as many DMD patients as possible, we are working to develop nuclear acid drugs beyond Viltepso. In addition, we are proceeding with research on peptide-conjugated nucleic acids, stereocontrolled nucleic acids, and novel sequence nucleic acids as next-generation antisense nucleic acids. In addition to DMD, we are also working on the development of NS-035 for patients with Fukuyama congenital muscular dystrophy.

Q6 What pipeline items are you focusing on going forward?

In the area of DMD, we are working on the development of nucleic acid drugs NS-089, NS-050, NS-051, exon 45 and exon 55 skipping drugs as follow-ons to Viltepso, and we believe that together these nucleic acid drugs will be able to treat about 40% of all DMD patients. In addition, the cell therapy drug CAP-1002, for which we entered into a distribution agreement with Capricor Therapeutics in the U.S. in January 2022, and in Japan in February 2023, is expected to enable us to treat DMD patients who have difficulty walking, which represents approximately half of them.

In addition, we are developing NS-018, a treatment for myelofibrosis, NS-580, a treatment for endometriosis, and NS-025, a treatment for urological diseases and other in-house products. We plan to carry out development of in-house products on a global basis.

Q7 What are your plans regarding corporate mergers and acquisitions (M&A)?

We will be constantly gathering and analyzing information about companies and venture firms in Japan and overseas, and will be thinking about possibilities for strategic partnerships (business and capital alliances) and M&A.

Q8 What steps are you taking with regard to sustainability?

To further promote sustainability within the Nippon Shinyaku Group, the "basic CSR policy" was revised to and became the "Nippon Shinyaku sustainability policy." Based on our business philosophy, we clearly state that we view addressing social issues as an important business issue and aim to realize a sustainable society. In addition, the Sustainability Committee, which is chaired by the President, reviews progress made toward establishing sustainability plans and achieving materiality targets, as well as progress made in carrying out initiatives involving issues of materiality, and reports and makes suggestions to the Board of Directors. The Board of Directors deliberates on and makes decisions about important matters.

Declaration of Authenticity



Takanori Edamitsu

Director, Business Management & Sustainability

Nippon Shinyaku has released integrated reports since 2012, with Integrated Report 2023 being the 12th release. The Company recently established “Helping People Lead Healthier, Happier Lives” as the foundation of its business, and along the way to achieving sustainable growth, has developed innovative new drugs and functional foods that provide new value.

In our Integrated Report 2023, we redefined our stakeholders in terms of our business model and the value creation process based on it, looking to make it easier to understand who they are and Nippon Shinyaku's strengths. In addition, by linking issues of materiality to our business, we have tried to clearly show the path to solving these issues.

As the Director in charge of overseeing the production of this report, I attest to the legitimacy of the report production process and the accuracy of the information contained herein.

I hope that this Integrated Report 2023 will help you better understand our company. We will continue to refine this report and strive to make it a valuable resource for communication with our stakeholders.

August 2023

Corporate Data and Investor Information

(As of March 31, 2023)

Corporate Data

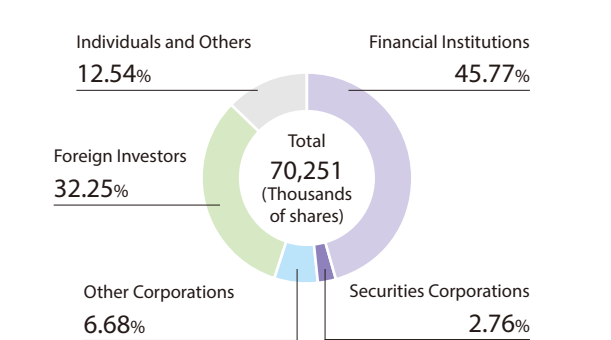
Corporate Name	Nippon Shinyaku Co., Ltd.
Founded	November 20, 1911
Date of Incorporation	October 1, 1919
Head Office	14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan Phone: +81-75-321-1111 Facsimile: +81-75-321-0678 https://www.nippon-shinyaku.co.jp/english/
Paid-in Capital	¥5.2 billion (Tokyo Stock Exchange Prime Market since April 4, 2022)

Representative Directors	Shigenobu Maekawa, Chairman Toru Nakai, President
Independent and Certified Public Accountants	Deloitte Touche Tohmatsu LLC Shijokarasuma FT Square 20, Naginataboko-cho, Karasuma-higashiiru, Shijo-dori Shimogyo-ku, Kyoto 600-8008, Japan
Issued and Outstanding Number of Shares	70,251,484
Number of Shareholders	7,599
Share Registrar	Mitsubishi UFJ Trust and Banking Corporation 6-3, Fushimimachi 3-chome, Chuo-ku, Osaka 541-0044, Japan

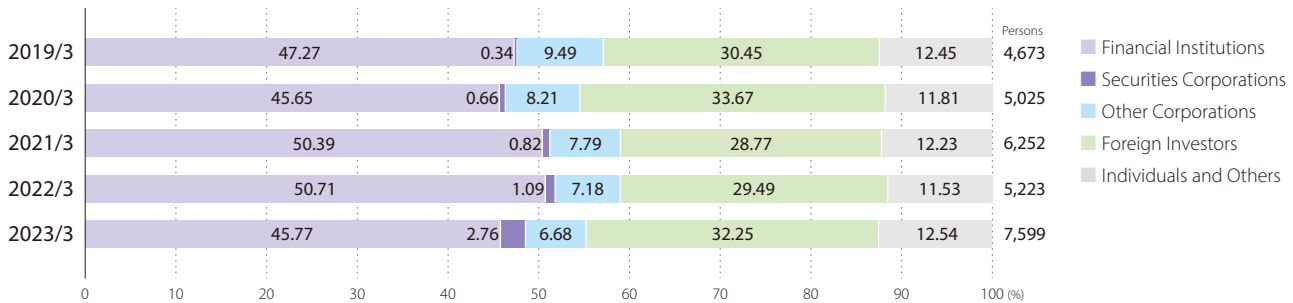
Major Shareholders

The Master Trust Bank of Japan, Ltd. (Trust account)
Meiji Yasuda Life Insurance Company
Custody Bank of Japan (Trust account)
The Bank of Kyoto, Ltd.
MUFG Bank, Ltd.
STATE STREET BANK AND TRUST COMPANY 505001
Nippon Life Insurance Company
STATE STREET BANK WEST CLIENT - TREATY 505234
Tokio Marine & Nichido Fire Insurance Co., Ltd.
GOVERNMENT OF NORWAY

Distribution of Shares Issued



Shareholder composition over the past five years



Network

(As of July 1, 2023)

Main Offices

Tokyo Office **Business Offices** Sapporo, Tohoku, Kanetsu, Tokyo, Chiba/Saitama, Yokohama, Nagoya, Kansai, Keiji/Hokuriku, Chushikoku, Kyushu
Discovery Research Laboratories, Discovery Research Laboratories in Tsukuba, Food Science Laboratories, Yamashina Botanical Research Institute, Odawara Central Factory, East Logistic Center, West Logistic Center

Domestic Subsidiaries

Sioe Pharmaceutical Co., Ltd., Tajima Shokuhin Kogyo Co., Ltd., Nippon Shinyaku Advance Co., Ltd.

Overseas Offices and Subsidiary

London office, NS Pharma, Inc., Beijing Nippon Shinyaku Co., Ltd., Tianjin Nippon Shinyaku Co., Ltd.

Nippon Shinyaku Today

A New Way of Life

In Pursuit of Originality

ESG as the Foundation for Growth

Corporate Data

Recognition by External Parties

Inclusion in ESG indices



FTSE Blossom Japan Index

FTSE Blossom Japan Index

The FTSE Blossom Japan Index is one of the ESG indices of Japanese stocks adopted by the Government Pension Investment Fund (GPIF), and is constructed by FTSE Russell, a subsidiary of the London Stock Exchange Group. It consists of Japanese equities that have excellent ESG practices.



FTSE Blossom Japan Sector Relative Index

FTSE Blossom Japan Sector Relative Index

The FTSE Blossom Japan Sector Relative Index relatively reflects the performance of Japanese companies demonstrating strong environmental, social, and governance (ESG) practices in each sector. To facilitate the transition to a low-carbon economy, companies with particularly high greenhouse gas emissions are included in the index if their improvement efforts are acknowledged by the TPI Management Quality Score.



S&P/JPX Carbon Efficient Index

The S&P/JPX Carbon Efficient Index is an ESG index jointly developed by S&P Dow Jones Indices LLC and Japan Exchange Group, Inc. which measures the performance of constituent companies of the Tokyo Stock Price Index (TOPIX) based on their level of carbon efficiency (carbon emissions per unit of revenue) and environmental information disclosure.

2023 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

MSCI Japan Empowering Women Index (WIN)

The MSCI Japan Empowering Women Index (WIN) is an ESG index developed by the U.S.-based MSCI, which selects outstanding companies in terms of employment and promotion of women and information disclosure on gender diversity, such as diversity initiatives.

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CDP

CDP is one of the world's most important indicators of corporate value, demanded by institutional investors globally, that requires companies to disclose their environmental strategies and greenhouse gas measures. Companies are scored on 13 general categories, including governance, risks and opportunities, business strategy, and targets and performance. Nippon Shinyaku has received a "B" rating.



"White 500" Health & Productivity Management Outstanding Organization

The Ministry of Economy, Trade and Industry (METI) and the Nippon Kenko Kaigi have designated Nippon Shinyaku as one of the "White 500" Health & Productivity Management Outstanding Organizations 2023 (large enterprise category), a system that recognizes corporations that practice particularly excellent health management.



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 Tokyo Stock Exchange.



Nikkei Smart Work Management Survey

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



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-star rating evaluation based on four factors: "economic value," "social value," "environmental value," and "governance." Nippon Shinyaku received three stars in the latest survey.



Digital Transformation Certification

Nippon Shinyaku was recognized as a company ready to promote digital transformation based on the Act on Partial Revision of the Act on Facilitation of Information Processing.