



Helping people lead healthier,  
happier lives

Annual Report  
2020

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#### Editorial Policy

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

#### Period Covered

Fiscal 2019 (April 1, 2019–March 31, 2020). Some sections of the report also discuss initiatives from April 2020 onwards

#### Companies Covered

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

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#### 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 uncertainties. Actual results may therefore differ from those in the forward-looking statements.

\* Figures presented in this report are taken from Nippon Shinyaku's Financial Report for the year ended March 31, 2020. As figures have been rounded, totals may not exactly equal the sum of their composite statistics.

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

\* Information in this report, including comments, has all been obtained in an appropriate manner.

## To Our Stakeholders

### We aspire to build a meaningful existence in healthcare by playing an indispensable role

Nippon Shinyaku is committed to bringing people better health by providing society with distinctive products of high quality through the pharmaceuticals and functional food segments. We aspire to be a unique organization that has earned society's trust and respect, by building a meaningful existence in the healthcare field.

To that end, we seek to achieve sustainable growth in both pharmaceuticals and functional food by steadily applying our business philosophy of helping people lead healthier, happier lives. Based on our guidelines for action—which are to meet challenges, take speedy action, maintain a spirit of investigation, and keep on smiling—we encourage every one of our employees to work to achieve their targets with promptness and a strong sense of ethics. In this way, we are able to build relationships of trust with patients and our many other stakeholders, and carry out business activities with full integrity.

The 6th Five-Year Medium-term Management Plan that we commenced in April 2019 targets sustainable growth through the pursuit of further originality, based on six actions. In this report, we discuss the initiatives that we are taking to realize this plan and thereby create sustainable growth for the benefit of all Nippon Shinyaku stakeholders.

I ask for your ongoing understanding and support as Nippon Shinyaku continues laying the foundations for sustainable growth.

August 2020

*S. Maekawa*

Shigenobu Maekawa  
President



## Nippon Shinyaku's DNA

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



Nippon Shinyaku is committed to contributing to people's health  
by supplying distinctive products of high quality through the pharmaceuticals  
and functional food segments.

We aspire to be a unique organization that has earned society's trust and respect,  
by building a meaningful existence in the healthcare field.

### 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.

Please refer to our website for a detailed corpo-rate history.  
[https://www.nippon-shinyaku.co.jp/english/company\\_profile/company\\_history.php](https://www.nippon-shinyaku.co.jp/english/company_profile/company_history.php)



FY2019 Net Sales

¥116,637 million

## History of Nippon Shinyaku

# Overcoming Challenges to Create Future Medicines

We are dedicated to discovering new medicines by thinking outside the box, overcoming national and ethnic differences, and pushing beyond limits so that patients and their families around the world can enjoy a brighter future.



Uptravi



WINZONE

2016

- Uptravi, treatment for pulmonary arterial hypertension
- WINZONE ENERGY × ENERGY

2017

- AGE-SHUT Beauty Jelly (glycation care supplement)

2018

- WINZONE ENERGY GEL sports supplement
- Gazyva, treatment for CD20-positive follicular lymphoma

2019

- Erleada, treatment for prostate cancer
- Zytiga, treatment for prostate cancer
- Defitelio, treatment for sinusoidal obstruction syndrome
- Mangostia (Food with Functional Claims)
- Kioku no Kobako (Food with Functional Claims)



Defitelio



Mangostia

Kioku no Kobako

2020

- Viltepsa, treatment for Duchenne muscular dystrophy



Viltepsa

Launch of products contributing to society

- Pharmaceuticals
- Functional Food

Established  
1919

Net Sales

1929

- Extracting Santonin crystal from a new plant. Naming of the new plant as mibuyomogi (*Artemisia maritima*), derived from Mibu, where the new plant was successfully cultivated

1940

- Santonin, vermicide for roundworms



Santonin

1967

- Eviprostat, treatment for benign prostatic hypertrophy



Eviprostat

1979

- Bladderon, treatment for overactive bladder



Bladderon

1984

- Estracyt, treatment for prostate cancer



Estracyt

1989

- Gaslon N, treatment for gastric ulcers and gastritis

1992

- Selectol, treatment for hypertension and angina pectoris



Selectol

1994

- Orcl, antirheumatic agent
- Hypen, analgesic and anti-inflammatory agent



Hypen

1998

- Garcinia extract, health food ingredient

2002

- Odric, ACE inhibitor

2008

- Lunabell, treatment for dysmenorrhea associated with endometriosis
- Launch of protein preparations

2009

- Cialis, treatment for erectile dysfunction
- Adcirca, treatment for pulmonary arterial hypertension
- Erizas, treatment for allergic rhinitis



Erizas



Adcirca

2010

- Tramal, treatment for cancer pain and chronic pain

2011

- Vidaza, treatment for myelodysplastic syndrome

2013

- Regtect, aid for maintaining alcohol abstinence

2014

- Zalutia, treatment for urinary disorders caused by benign prostatic hypertrophy



Zalutia



Onetram

2015

- Onetram, a controlled-release treatment for cancer pain and chronic pain
- Opsumit, treatment for pulmonary arterial hypertension

1990

2000

2010

FY2020

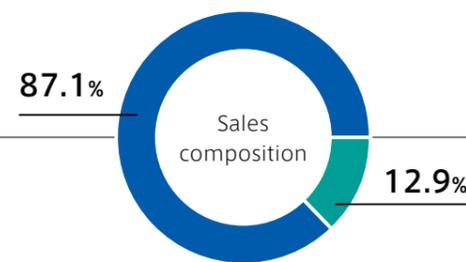
# Nippon Shinyaku: Overview

## Business Segments **Developing two businesses that supply products of high quality and originality**

### Pharmaceuticals

Net Sales  
**¥ 101,643 million**

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



### Functional Food

Net Sales  
**¥ 14,994 million**

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



Four Fields of Focus

Four Fields of Focus

Pharmaceuticals	Business Strengths	Therapeutic field	Products (brand names)
	In the Pharmaceuticals business, we have sought to expand our development pipeline by focusing on four therapeutic areas with unmet treatment needs and where other companies are relatively inactive. We aim to create distinctive products for these fields using the three pipeline pillars of in-house drug discovery, in-licensing, and product life cycle management (PLCM). Adding new drug-discovery modalities and technologies such as nucleic acid drugs and gene therapy to our drug-discovery platform that has produced small molecule drugs, we are widening the scope of our drug discovery to develop our abilities to create highly innovative and differentiated medicines. Having brought to market a stream of new drugs, we have also earned praise for our high-quality detailing to service the varied information needs of medical professionals. On the global stage, we are building our export operations using Upravi, which was discovered in-house. Our aim is to maximize product value by licensing out this and other in-house-developed products or by building our own local sales capabilities, subject to market conditions. By prioritizing resources in disease areas with unsatisfied therapeutic needs, we aim to provide drugs that excel in terms of efficacy, safety and patient quality of life improvement.	Urology	Zalutia, Erleada, Zytiga, Cialis, Estracyt, Bladderon, Eviprostat, etc.
		Hematology	Defitelio, Gazyva, Vidaza, Amnolake, Trisenox, Cylocide N, Cylocide
		Intractable and Rare Diseases	Viltepso, Upravi, Opsumit, Adcirca
		Gynecology	Lunabell Tablets ULD, Lunabell Tablets LD
Other		Erizas, AzunoI Gargle Liquid, Livostin, Cephadol, Isobide, Onetram, Tramal, Regtect	

Functional Food	Business Strengths	Area	Products
	We have earned praise and trust in the Functional Food business for technical capabilities and strict quality control developed by Nippon Shinyaku as a supplier of pharmaceuticals. In health food ingredients, we are constantly introducing new products in line with rising health consciousness and continued aging of society. In preservatives, we are helping to reduce food waste by extending shelf life while preserving the taste of food. In protein preparations, we have developed a wide range of innovative products to satisfy diverse needs in terms of function and nutrition. We are also developing our supplements business into a major growth driver for the segment through increased market penetration, based on the concept of contributing to a longer, healthier and more active life. We will look to continue supplying high-value-added products that cater to market requirements, based on making the best use of internal and external resources to strengthen our R&D capabilities.	Health Food Ingredients	Mangosteen Aqua, Hyaluronic Acid 3000, Garcinia Powder J, Bacopa Extract Powder
		Preservatives	Mirai Ace Nu, Binesh Deli, Mikaku Fine S, Mikaku Fine BK, Mikaku Fine Z
		Protein Preparations	Lactocrystal plus, PROGEL800, Enlacto HG, Fitness S
		Supplements	Sports supplements (WINZONE series), aging care supplements (Mangostia, Kioku no Kobako, etc.)

## Financial and Non-Financial Highlights

### Summary of Consolidated Financial Indicators

(FY)

	2015	2016	2017	2018	2019	2019
					Millions of Yen	Thousands of U.S. Dollars
<b>For the year</b>						
Net sales	84,209	98,781	101,448	114,716	116,637	1,070,064
Pharmaceuticals	70,489	85,315	87,416	100,223	101,643	932,504
Functional food	13,720	13,466	14,031	14,492	14,994	137,559
Operating income	8,549	15,280	17,079	20,644	21,668	198,788
Net income attributable to owners of the parent	6,340	11,749	12,953	16,302	16,866	154,733
Depreciation and amortization	2,452	2,648	2,773	3,418	3,468	31,816
Capital investment	3,554	3,949	2,811	1,242	2,500	22,935
R&D expenses	9,739	14,903	13,221	16,701	13,994	128,391

### End of the year

	2015	2016	2017	2018	2019	2019
					Millions of Yen	Thousands of U.S. Dollars
Total assets	135,370	150,905	155,887	168,763	175,017	1,605,660
Net assets	102,762	114,316	125,689	135,190	145,760	1,337,247

### Financial information per share

	2015	2016	2017	2018	2019	2019
					Yen	U.S. Dollars
Earnings per share	94.10	174.42	192.31	242.04	250.42	2.30
Dividend per share	28	48	52	70	86	0.78

### Principal financial indicators

	2015	2016	2017	2018	2019	2019
					%	%
Equity ratio	75.8	75.6	80.5	80.0	83.1	—
Return on equity	6.2	10.8	10.8	12.5	12.0	—
Payout ratio	29.8	27.5	27.0	28.9	34.3	—

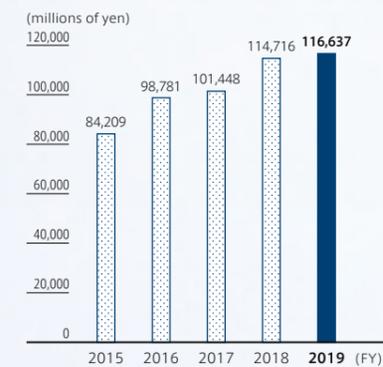
### Summary of ESG Indices

	2015	2016	2017	2018	2019	2019
Total energy consumption (Main business locations*) (thousands of GJ)	193	199	209	212	211	—
CO <sub>2</sub> emissions (Main business locations*)	10,059	10,165	10,609	10,129	9,435	—
CO <sub>2</sub> per unit of revenue (t/million yen)	0.119	0.103	0.104	0.089	0.081	—
Number of employees (people)	1,914	1,934	1,962	1,998	2,026	—

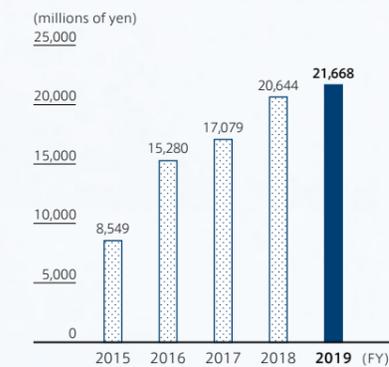
\* Main business locations: Head Office area, Odawara Central Factory, Discovery Research Laboratories in Tsukuba

### Financial Highlights

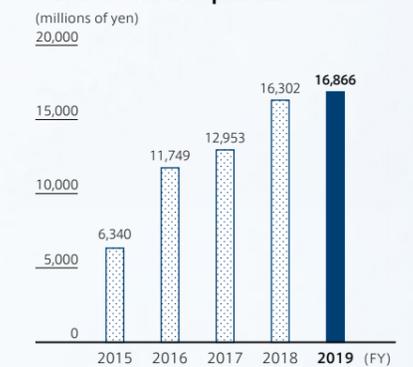
#### Net sales



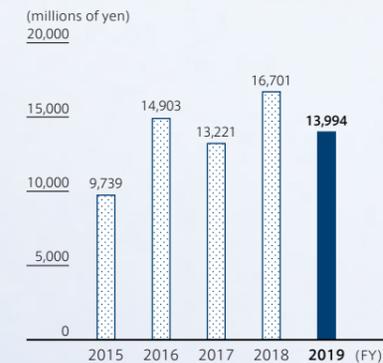
#### Operating income



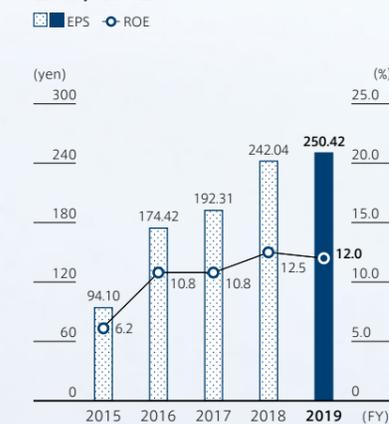
#### Net income attributable to owners of the parent



#### R&D expenses



#### EPS / ROE

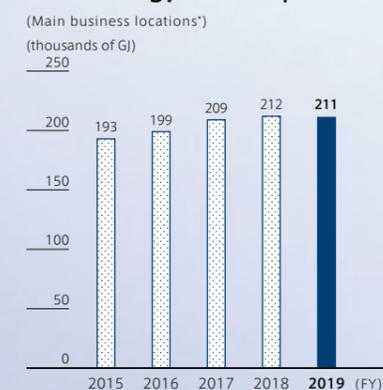


#### Dividend per share / Payout ratio



### Non-Financial Highlights

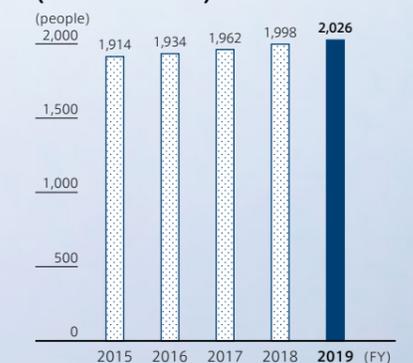
#### Total energy consumption



#### CO<sub>2</sub> emissions



#### Number of employees (consolidated)



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

# Our Value Creation Model

Nippon Shinyaku aims to grow sustainably and be globally acclaimed as a "company with a meaningful existence in healthcare."

### Operating Environment

- Declining birthrate, aging population
- Decrease in working population
- Arrival of the era of centenarians
- Diversification in workstyles
- Measures to promote greater use of generics
- Drug price reductions to curb medical expenses
- Diversification in drug discovery modalities
- Advances in personalized medicine
- Penetration of health/prevention-oriented mindset

New management plan reflects our view that change in the operating environment is a business opportunity



Strengthening Nippon Shinyaku's Management Resources (strengths)

Corporate vision: To become a company with a meaningful existence in healthcare

## Message from the President



**Shigenobu Maekawa**  
President

**By supplying distinctive products of high quality,  
Nippon Shinyaku contributes to people leading healthier  
and happier lives**

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

(Consolidated)	FY2018 results	FY2019 results	FY 2023 target	CAGR <sup>*1</sup>
Net sales	¥114,716 million	¥116,637 million	¥150,000 million	5.5%
Pharmaceuticals	¥100,223 million	¥101,643 million	¥133,000 million	5.8%
Functional Food	¥14,492 million	¥14,994 million	¥17,000 million	3.4%
Operating income	¥20,644 million	¥21,668 million	¥40,000 million	14.2%
Net income attributable to owners of the parent	¥16,302 million	¥16,866 million	¥30,000 million	13.0%
EPS <sup>*2</sup>	¥242	¥250	¥445	13.0%
ROE <sup>*3</sup>	12.5%	12.0%	10% or more during term of 6th Plan	

\*1 CAGR: Compound Annual Growth Rate \*2 EPS: Earnings Per Share \*3 ROE: Return On Equity

## 6th Five-Year Medium-term Management Plan: Progress Status

**In fiscal 2019, the management plan's first year, we made steady progress towards achieving our fiscal 2023 performance goals.**

The Japanese economy slowed considerably due to the impact of the consumption tax hike and the COVID-19 outbreak, amid a persistently uncertain outlook. Conditions for Nippon Shinyaku and the broader pharmaceutical industry were harsh due to various initiatives to restrict healthcare spending in Japan, including stronger measures to promote greater use of generics. The coronavirus outbreak also had the effect of restricting numbers of patient visits to doctors. In the food industry, conditions remained challenging due to the low growth in spending by thrifty households, rising logistics and labor costs, and more intense competition.

Amid these business conditions, we recorded net sales of ¥116,637 million in fiscal 2019, a rise of 1.7% year on year despite the negative impact of the NHI price revision and lower revenues from the licensing of industrial property rights compared to fiscal 2018, when milestone payments were received for the pulmonary arterial hypertension (PAH) treatment Upravi. Co-promotion sales

revenues increased in fiscal 2019, and new products reporting higher sales included Gazyva (CD20-positive follicular lymphoma), Vidaza (myelodysplastic syndromes), Upravi (PAH), and Zalutia (urinary disorders caused by benign prostatic hypertrophy). There was also a fresh contribution from Defitelio, which we introduced in September 2019 for the indication of sinusoidal obstruction syndrome. Net sales of pharmaceuticals rose 1.4% to ¥101,643 million. In the Functional Food business, higher sales of protein preparations, preservatives and other products contributed to a 3.5% year-on-year increase in net sales to ¥14,994 million.

In terms of profits, operating income increased 5.0% to ¥21,668 million due to the growth in sales offsetting the increase in the cost-of-sales ratio caused by factors such as the NHI price revision. Ordinary income rose 4.2% to ¥22,442 million, and net income attributable to owners of the parent increased 3.5% to ¥16,866 million.

Fiscal 2019 was the first year of our medium-term management plan. Overall, as in fiscal 2018, we recorded growth in sales and profits, representing steady progress towards achieving the fiscal 2023 performance goals.

### Products to be launched during the 6th Five-Year Medium-term Management Plan

Already launched (as of August 20, 2020)

<b>In-house</b>	Viltepso (generic name: viltolarsen) Duchenne muscular dystrophy (DMD)	Japan/ overseas	<b>In-licensed</b>	Defitelio (generic name: defibrotide sodium) Sinusoidal obstruction syndrome (treatment)	Japan
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Regulatory approval targeted by FY2023

<b>In-house</b>	Exon 44 skipping drug DMD	Japan/ overseas	<b>NS-018 (ilginatinib)</b> Myelofibrosis	Overseas
<b>In-licensed</b>	NS-32 (ferric derisomaltose) Iron deficiency anemia	Japan	<b>ZX008</b> Intractable epilepsy	Japan
<b>PLCM</b>	NS-304 (selexipag) Chronic thromboembolic pulmonary hypertension	Japan	<b>NS-304 (selexipag)</b> Arteriosclerosis obliterans	Japan
	Macitentan Chronic thromboembolic pulmonary hypertension	Japan	<b>NS-17 (azacitidine)</b> Acute myeloid leukemia	Japan

Early regulatory approval targeted from FY2024

<b>NS-580</b> Endometriosis	<b>NS-304</b> Lumbar spinal stenosis	<b>NS-87</b> Secondary acute myeloid leukemia	<b>NS-917</b> Relapsed/refractory acute myeloid leukemia
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DMD treatments other than Viltepso and exon 44 skipping drug

## Progress with “Six Actions” from 6th Five-Year Medium-term Management Plan

We are taking “six actions” to realize our vision, with the aim of strengthening our platform for sustainable growth.

### 1. Creation of new value through R&D

In the Pharmaceuticals business, we are working to enhance our development pipeline by focusing on four therapeutic areas (urology, hematology, intractable and rare diseases, and gynecology) and utilizing external and internal resources to pursue in-house drug discovery, in-licensing, and product life cycle management (PLCM), while seeking

to add new drug-discovery modalities such as nucleic acid drugs and gene therapy. In the urology field, we began co-promotional activities with Janssen Japan for the launch in Japan of two new prostate cancer treatments, Erleada in May 2019 and Zytiga in February 2020. In the hematology field, besides launching Defitelio for the treatment of sinusoidal obstruction syndrome in September 2019, we also began Phase I/II clinical trials with NS-87, a treatment for secondary acute myeloid leukemia in-licensed from Jazz Pharmaceuticals plc. In addition, we received manufacturing and marketing approval in Japan for the Duchenne muscular dystrophy (DMD) treatment Viltepso in March 2020, and we began selling it in May 2020. We also began development of an oligonucleotide therapy for treating novel coronavirus infections within a broader review of the positioning of our existing sales and clinical development portfolio.

In the Functional Food business, we use external and internal resources to supply ingredients for functional foods with the excellent quality and originality expected of a pharmaceutical maker. In fiscal 2019, we launched a series of new products, in line with our policy of introducing high-value-added products that satisfy market needs.

### 2. Development of global business

In collaboration with our global licensee Actelion Pharmaceuticals Ltd, a Janssen Pharmaceuticals company of Johnson & Johnson, we are steadily expanding sales of our in-house product Upravi in Japan and overseas markets. Efforts to broaden its indications are also underway.

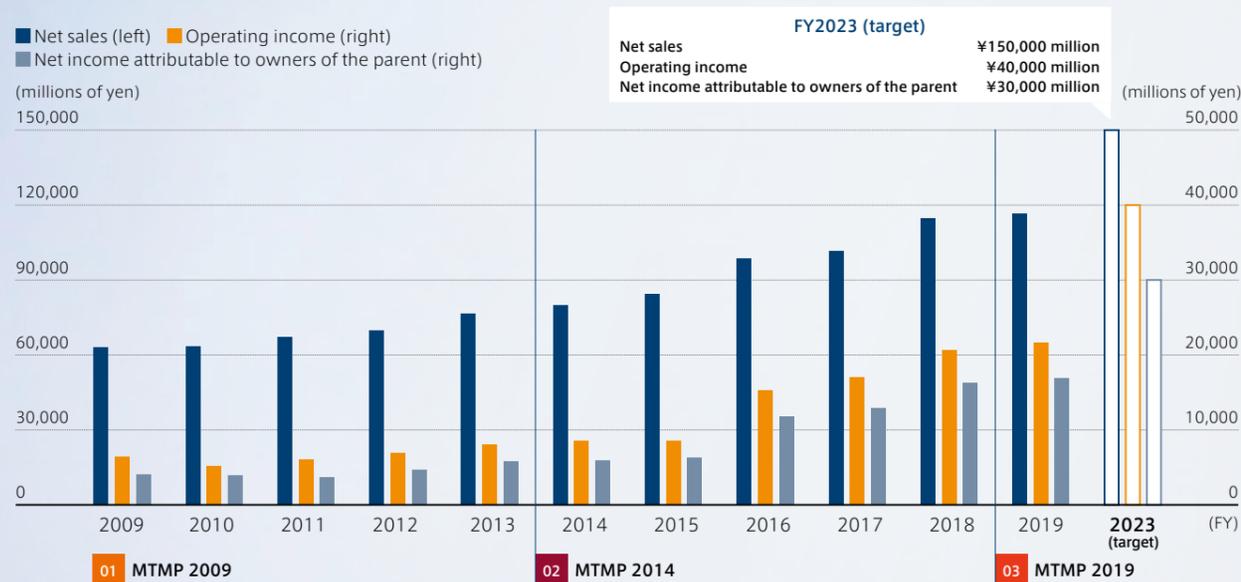
We commenced a rolling submission of an NDA to the US FDA for Viltepso in February 2019 based on the outcome of the Phase II clinical trials in the US. This

process ended in September 2019, and we received official notification of acceptance in February 2020. Joint international Phase III clinical trials are currently underway. Our local US subsidiary NS Pharma is hiring sales personnel and building a local sales network. We expect to create a base for sustained growth in the US from the launch of Viltepso and successor oligonucleotide drugs and the myelofibrosis treatment NS-018, among other products. In Europe and China, we are targeting early NDA submissions for Viltepso, and we are also considering developing local sales networks utilizing in-house resources or our alliances with strategic partners.

Please refer to the Feature section (pp. 18–23) for more detailed information about “1. Creation of new value through R&D” and “2. Development of global business.”

## Evolution using Medium-term Management Plans

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



### 01 2009: 4th Five-Year Medium-term Management Plan Innovation and Growth

Overview	Plans	Results
1. Pipeline enhancement	In-house drug discovery, in-licensing, product life cycle management (PLCM)	In-house drugs: NS-018, NS-065/NCNP-01 In-licensed: ACT-064992, NS-24, GA101, tadalafil, Lunabell ULD
2. Scientific product management	Well-balanced growth between existing products and new products	Investment in detailing based on clear allocation of resources in response to promotion of generics; steady progress with new products
3. Functional Food	Expand business and generate stable profits	Business expanding, but transformation to stable profit structure still underway
4. Low cost management	Improved profitability	Target of about ¥2 billion in cost reductions achieved
5. Supporting employee growth	HR development support Revise HR systems	Creation of CASA (CAreer Support Academy) for development support/training; initiatives include Terakoya Academy, training for executives, next-generation leader training, level-specific training, support for MBA/PhD qualifications
6. CSR activities	Earning public trust	New CSR initiatives: Children’s Literary Awards, Nippon Shinyaku Kira-Kira Mirai Kodomo Bokin children’s fund, Smiles Art Project, Public Service Award for Kyoto Kiwanis

### 02 2014: 5th Five-Year Medium-term Management Plan Aiming for New Growth –Pursuit of Originality–

Overview	Plans	Results
1. R&D strategy	Develop pipeline to support regular product launches in areas of focus Reduce costs and speed up R&D by building manufacturing facility for clinical trial APIs	Launched seven products, including Zalutia and Upravi Enhanced pipeline via in-licensing agreements for six compounds, including NS-73 and NS-32 Completed clinical trial API manufacturing facility in March 2016; R&D sped up due to faster production of oligonucleotides and other APIs
2. Marketing strategy	Develop product groups in three areas (PAH, urology, hematology) into growth drivers	New growth drivers created in Vidaza and Zalutia, each with sales of more than ¥10 billion Increased awareness of our presence in field of PAH due to detailing activities linked to launches of Upravi and Opsumit
3. Supply chain strategy	Invest in production facility for high-bioactivity drugs to enable manufacture of in-house products	Manufacturing plant for highly active solid formulations completed in July 2017 Manufacturing of Upravi shifted in-house
4. Overseas business strategy	Expand operations using approaches tailored to conditions in each national market	Upravi: substantial contribution to growth from launch in many overseas markets NS-065/NCNP-01: preparations made to file US NDA and establish local sales organization
5. Functional Food business	Transform Functional Food business into highly profitable entity	Operating margin significantly improved Supplement business started, creating foundation for transformation
6. Human resource strategy	Upgrade recruitment and training, recognizing that human capital is the source of originality	Flextime system introduced for MRs (industry first in Japan) Outside specialist personnel recruited Recognized as “White 500” firm in Certified Health and Productivity Management Organization Program

### 03 2019: 6th Five-Year Medium-term Management Plan Aiming for Sustainable Growth –Pursuit of Further Originality–

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



### 3. Increase in corporate value by strengthening ESG management

We are working to raise corporate value through a strengthened focus on management based on ESG (Environmental, Social and Governance) aspects. This includes business activities such as creating treatments for intractable diseases to help patients, and providing high-value-added supplements for consumers. In January 2020, we signed the United Nations Global Compact (UNGC). By adhering to "The Ten Principles" of the UNGC, our aim is to build and maintain the trust of all stakeholders in Japan and abroad. Moreover, the announcement illustrates our commitment to working proactively as a corporate citizen to address societal issues.

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

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

Going forward, we will continue to respect the diversity of employees and seek to provide every individual with opportunities to grow by facing challenges proactively. In this way, we will ensure the organizational climate allows everyone to play a significant role and to flourish.

### 5. Active use of AI and adoption of IT

In fiscal 2019, we introduced Robotic Process Automation (RPA) across 13 divisions to improve productivity by boosting process efficiency and reducing costs. During this initial phase, the RPA project successfully generated annual savings of around 10,000 hours through automation of fixed processes and other improvements.

Looking ahead, we plan to extend this initiative on a larger scale across the company, while utilizing the time saved through greater process efficiency for creative purposes so that we can translate the gains into sustained growth. Moreover, through more active use of AI and adoption of IT, our policy is to boost productivity based on faster new product creation and streamlined operations.

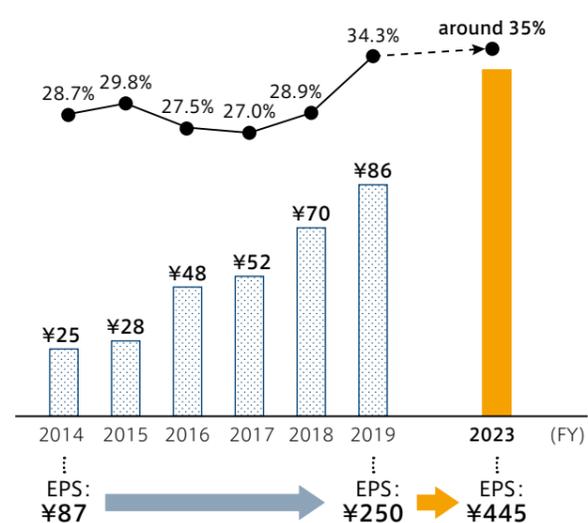
### 6. Further strengthening of management base

As mentioned earlier, we made steady progress in fiscal 2019 by increasing sales and profits as we work to achieve the performance targets in the 6th Five-Year Medium-term Management Plan.

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

Over the period of the 6th Five-Year Medium-term Management Plan, we aim to utilize performance-linked dividends to boost the consolidated payout ratio to around 35%, with increases in EPS helping to grow total dividends per share.

### Dividend per share / Payout ratio



## Aspiring to be a "company with a meaningful existence in the healthcare field"

### Outlook for FY2020, second year of 6th Five-Year Medium-term Management Plan

#### Our aim in fiscal 2020 is to set fresh records by growing sales and profits further.

In fiscal 2020, we are expecting an 8.9% increase in net sales to ¥110.7 billion. In pharmaceuticals, while we expect a negative impact from the NHI price revision, the advent of generic competition for Zalutia and the erectile dysfunction treatment Cialis, and other COVID-related impacts, we think these will be offset by several factors. In addition to higher sales of new products such as Upravi, Gazyva and Defitelio, we are expecting growth in royalty income associated with overseas sales of Upravi, higher co-promotional sales revenue, and a sales contribution from the launch of Viltepso. In functional food, we are expecting an increase in sales of 2.0% to ¥15.3 billion due to a sharp focus on the development and launch of new products, coupled with reinforced initiatives relating to core products. Overall, we expect consolidated net sales for the Nippon Shinyaku Group to increase 8.0% to ¥126.0 billion.

In terms of profit, we project year-on-year gains at every level, setting new records alongside net sales. We expect operating income of ¥25.0 billion (up 15.4%), ordinary income of ¥25.5 billion (up 13.6%), and net income attributable to owners of the parent of ¥19.0 billion (up 12.6%).

In R&D, we will focus on enhancing our pipeline, mainly targeting our core therapeutic areas, based on the three pillars of in-house drug discovery, in-licensing and PLCM. At the same time, we will continue working to launch drugs in our existing pipeline. Elsewhere, we have started R&D into potential nucleic acid treatments for COVID-19. We will also review the positioning of our current drug portfolio and development pipeline.

In fiscal 2020 to date, we have made a steady start as we work toward achieving the targets in the 6th Five-Year Medium-term Management Plan. We will continue to focus on realizing this plan.

### Looking to prosper for another century

#### We are working to maintain the trust of every stakeholder and to be held in esteem as a vital enterprise.

We celebrated our 100th anniversary as a company in 2019. We cannot realize the sustained growth needed to prosper for another 100 years within a rapidly changing pharmaceutical industry unless we continue to produce distinctive products that take originality to new heights. Since we focus on the development of treatments for intractable and rare diseases with small patient populations, this is an area where we can deliver particularly original value. In addition, our aim is to maintain the trust of every stakeholder and to be held in esteem as a vital enterprise, not only by fulfilling our mission to patients and medical professionals, but also by contributing to the achievement of the Sustainable Development Goals (SDGs) through our enriched ESG initiatives.

Moving forward, we will aspire to be a "company with a meaningful existence in healthcare" based on realizing sustained growth through the efforts of all employees boldly taking up the challenge of achieving our goal to pursue originality and create distinctive products.

*S. Maekawa*

Shigenobu Maekawa  
President

Feature Progress with the 6th Five-Year Medium-term Management Plan

1 Creation of New Value Through R&D

First Antisense Oligonucleotide Discovered in Japan

# Viltepso

Generic name: viltolarsen

One of the R&D challenges faced by Nippon Shinyaku is to develop therapies for intractable and rare diseases with no established treatment. We have been researching nucleic acid drugs at the Discovery Research Laboratories in Tsukuba for more than 20 years.

## Societal issues in developing treatments for intractable and rare diseases

Total intractable/rare disease patients (Japan)

**7.5 – 10** million

Over 6,000–7,000 types of intractable and rare diseases have been identified worldwide, with total patient numbers estimated at 7.5–10 million in Japan. Inherited disorders account for roughly 70% of the total, or 4,000–5,000 diseases. No effective treatments exist for many inherited disorders. Muscular dystrophy is an inherited intractable disease, with **Duchenne muscular dystrophy (DMD)** accounting for the bulk of cases. Since DMD is a serious and progressive neuromuscular condition for which no therapies other than symptomatic treatment have been established, the development of new treatments has been eagerly awaited.

The genetic cause of many intractable and rare diseases makes them especially difficult to treat with conventional drugs such as small molecules or antibodies. Small patient cohorts also make it difficult to gather sufficient epidemiological data or establish a clinical evaluation methodology. It is often unclear whether drug development will be economic for such conditions due to the high costs involved, and many pharmaceutical firms hesitate before committing to development.

Number of patients in Japan

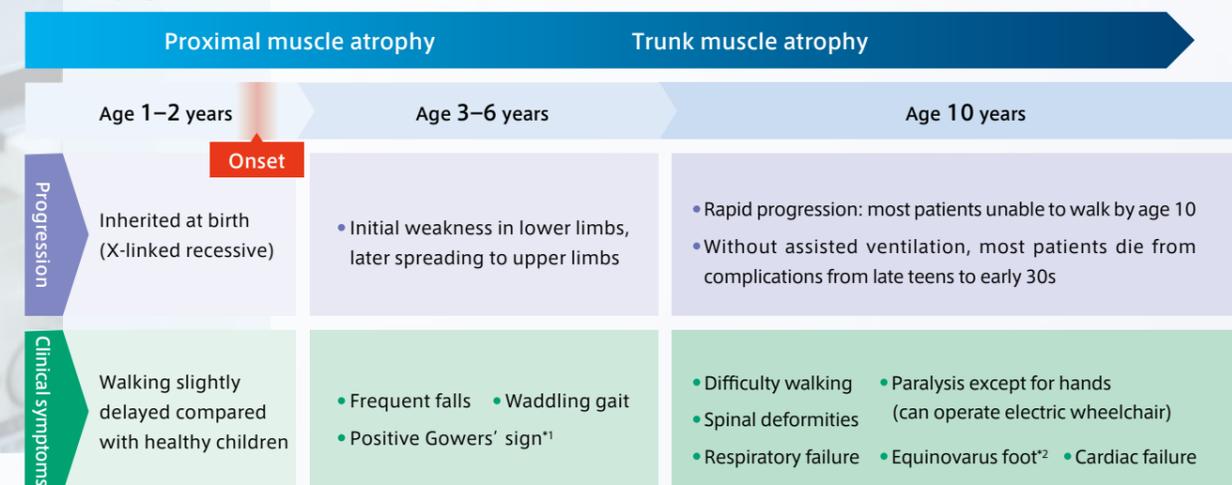
Approx. **5,000**

### What is Duchenne muscular dystrophy (DMD)?

DMD inheritance follows an X-linked recessive pattern. It predominantly affects boys, with an incidence of about one case per 3,500 births. The estimated DMD patient population in Japan is about 5,000. In muscular dystrophies, the muscle fibers undergo degeneration and necrosis, which leads to progressive muscle weakness and a range of pathological changes. DMD is the most prevalent of the muscular dystrophies, generally causing weakness in or near the central trunk of the body. Muscular dystrophies were designated as intractable diseases in Japan in July 2015.

DMD is caused by a mutation in the gene coding for dystrophin, a protein that plays an essential role in maintaining the structural integrity of the cells as muscle tissue regenerates. Patients lose the ability to produce dystrophin. The deficiency weakens the membranes surrounding the cells in muscle tissue, causing progressive weakening of muscles as normal regeneration is blocked. This leads inexorably to loss of various capabilities, notably motor function.

### Clinical symptoms of DMD



Source: Byouki ga Mieru ("Atlas of Disease") Vol. 7 (Brain and Nerves) p. 374 (Medic Media, 2017)

<sup>1)</sup> Gowers' sign: due to weakness in the pelvic muscles, the patient can only get off the floor by first rising to all fours and then "walking" hands up the knees  
<sup>2)</sup> Also known as clubfoot, a deformity where the instep extends and the heel does not touch the floor when standing or walking

Feature Progress with the 6th Five-Year Medium-term Management Plan

1 Creation of New Value Through R&D

Nippon Shinyaku's Approach

# Viltepso (generic name: viltolarsen)

(NS-065/NCNP-01)



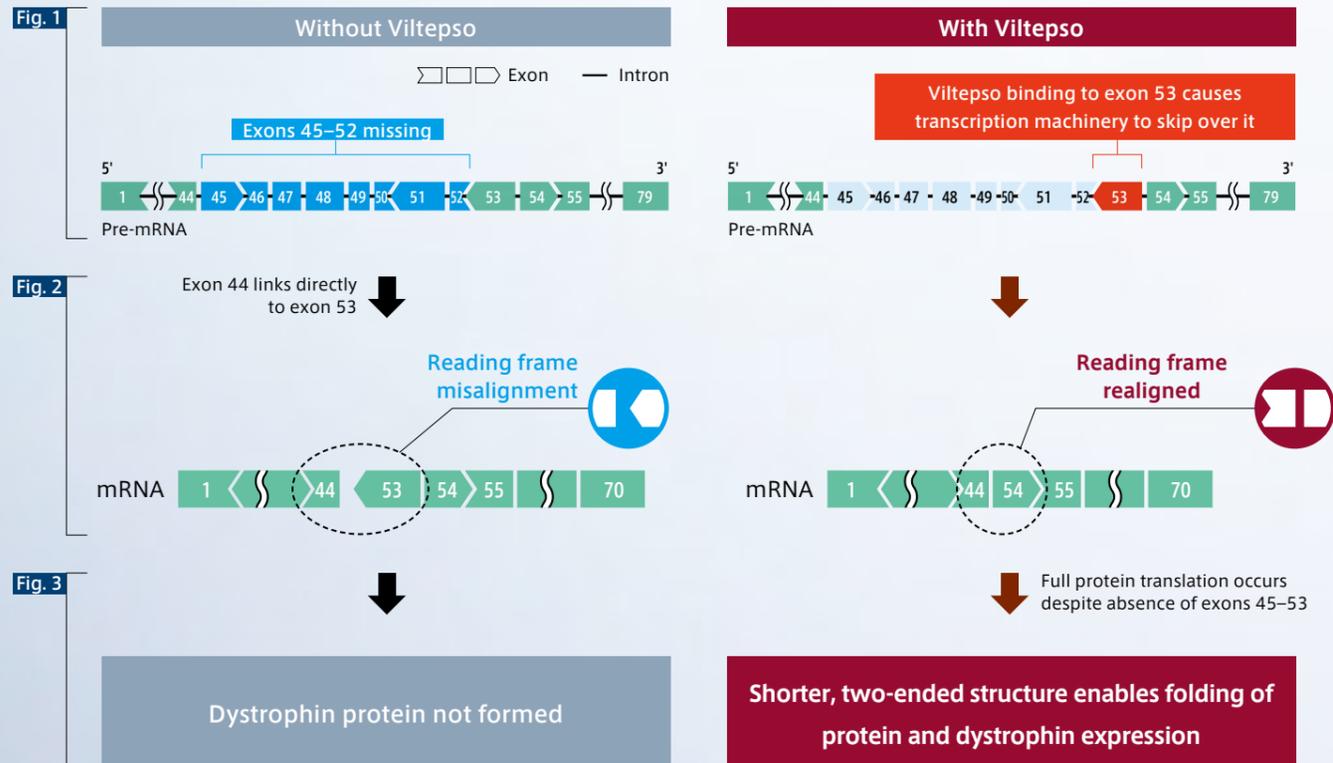
Makeup of oligonucleotide drug Viltepso

DNA includes regions with genetic information for making proteins (exons) and regions that are non-coding (introns). The genetic information in the DNA is first **transcribed into a precursor of messenger RNA (pre-mRNA)** that contains exons and introns **Fig. 1**. The **final mRNA strand is then created** by linking together just the protein-encoding exons **Fig. 2**. Next, **the protein is synthesized** from the instructions contained in the mRNA template **Fig. 3**. It is hoped oligonucleotide drugs can be developed to treat previously intractable heritable diseases, since they can act directly on the genes causing the conditions with a high degree of specificity.

Without Viltepso, the absence of exons upstream of exon 53 leads to a misalignment of the mRNA reading frame, and the dystrophin protein cannot be synthesized. As an antisense oligonucleotide, Viltepso binds to exon 53, enabling the cellular transcription machinery to skip over exon 53. The reading frame is realigned and dystrophin protein is made. Genetic testing can establish whether patients have a form of DMD amenable to treatment based on exon 53 skipping.

Although the dystrophin protein produced with exon 53 skipping is shorter than normal, it is expected to have sufficient functionality to help alleviate or restrict the muscle weakness in DMD patients.

Viltepso mechanism of action



Source: Yoshitsugu Aoki et al., Journal of Clinical and Experimental Medicine, Recent Developments in Muscular Dystrophy, Ishiyaku Pub, Inc. (p. 6, 2017)

History of Viltepso development to regulatory approval

March 2020

## Manufacturing and marketing approval (Japan)

\* Marketing approval gained in US in August 2020

Until now, there has not been an approved DMD therapy in Japan to treat the underlying disease and reverse progressive muscle weakness or loss of motor function. We initiated a joint research project with the National Center of Neurology and Psychiatry (NCNP) in 2009 and discovered the exon 53 skipping drug NS-065/NCNP-01. It was first administered to human subjects in June 2013 in a physician-led study conducted by the NCNP. The trial met its primary endpoints of safety and expression of dystrophin. Using these results, we conducted Phase I/II studies in Japan and Phase II studies overseas. The clinical trials demonstrated dystrophin expression via exon 53

skipping. No serious adverse events were noted in any of the clinical trials.

Based on these results, we filed an NDA for regulatory approval in Japan in September 2019. In March 2020, MHLW granted manufacturing and marketing approval for viltolarsen for the indication of Duchenne muscular dystrophy in patients amenable to exon 53 skipping therapy, having earlier designated the drug as applicable for conditional early approval.

The US FDA also granted regulatory approval in August 2020.

Timeline of Viltolarsen development to simultaneous NDA filings in US/Japan

Development milestones	US/Japan development history		Regulatory milestones
Viltolarsen synthesized	2009	Nippon Shinyaku initiates joint research with NCNP (Japan)	Regular discussions with the PMDA-appointed concierge enable efficient project management and resolution of pre-filing issues, accelerating development
System used to discuss clinical trial strategy, non-clinical studies package and investigational drug quality issues	2011	Pharmaceutical Affairs Consultation on R&D Strategy system introduced by PMDA (Japan)	
	Good tolerability and dystrophin expression demonstrated	2013	Early-stage exploratory (physician-led) clinical studies initiated by NCNP (Japan)
Oct. 2015		"Sakigake" designation received from MHLW (Japan)	
	2016	Phase I/II studies initiated (Japan)* Phase II studies initiated (US)*	Multiple rounds of discussion held with US FDA on clinical/non-clinical work and quality issues prior to rolling submission of NDA based on Phase II trial data from US and Japan
	Oct. 2016	Fast-track designation by FDA (US)	
	Jan. 2017	Orphan drug designation (US) Rare Pediatric Disease designation (US)	Near-simultaneous filing in US and Japan Regulatory review process in Japan shortened to 6 months due to "Sakigake" designation
	Feb. 2019	Rolling submission of NDA initiated (US)	
	Aug. 2019	Orphan drug designation (Japan)	
	Sep. 2019	Regulatory applications filed (Japan/US)	

★ Results of P I/II studies (Japan)

**Target** DMD patients (Japan): 16  
**Method** 24-week administration schedule at 40 or 80 mg/kg  
**Results** Significant dystrophin expression in 14 out of 16 enrolled patients; no serious adverse events

★ Results of P II studies (US)

**Target** DMD patients (US/Canada): 16  
**Method** 20- or 24-week administration schedule at 40 or 80 mg/kg  
**Results** Dystrophin expression in all 16 enrolled patients; no serious adverse events

Market for nucleic acid medicines expected to grow

Projected global market size in 2030

Approx. **¥2,100 billion**

Nucleic acid drugs are expected to be the next major therapeutic modality after antibody drugs. The global market for nucleic acid medicines is projected to reach ¥2,100 billion by 2030. As of December 2019, only 11 such products were on the market around the world. Of these, five have been launched since 2018. The pace of R&D into oligonucleotide drugs is accelerating, led by efforts to find therapies for intractable and rare diseases.

Besides the exon 53 skipping drug Viltepso, we are developing multiple exon skipping drugs to target DMD using a similar mechanism of action to Viltepso. This would allow us to offer therapy to more DMD patients. We are also looking at nucleic acid medicines as potential therapies for conditions that are intractable to conventional drugs such as small molecules and antibodies. As well as neuromuscular and other rare genetic conditions, we aim to develop distinctive new treatments across a range of therapeutic areas, including cancer and coronavirus infections.

# 1 Creation of New Value Through R&D

## On the R&D Frontline

### Technology and experience gained from nucleic acid medicine development

There was no predetermined R&D path since it was the first nucleic acid drug discovered in Japan, and the process involved repeated trial and error. Our Discovery Research Laboratories in Tsukuba had been researching oligonucleotides for a long time, and so we had the basic technology platform for nucleic acid synthesis and evaluation at the time of development. However, Viltepso was a type of modified nucleic acid known as a morpholino that was quite different chemically from natural oligonucleotides. This made it hard for us from the start of R&D to synthesize even tiny sample quantities, and evaluation was just as difficult. We managed to find candidate sequences finally through painstaking sequence optimization after identifying the regions of high bioactivity.

We utilized a general solid-phase synthesis for supplying the quantities of drugs required in the non-clinical and clinical trials during early-stage development, but the yields were unacceptably poor when we tried to scale-up the production process. We teamed up with an external partner to develop a production method for large-scale synthesis. The method we developed was not only scalable and reliable, but was also better in that the yield was sufficiently high to translate into a reduced need for nucleic acid monomer.

### Kazuchika Takagaki

Corporate Officer  
Department Manager,  
Discovery Research Laboratories



Guaranteeing the quality of any investigational compound based on analysis is an indispensable part of the safety assurance process. Since there were hardly any examples of oligonucleotide drug development in either Japan or overseas for our reference, we had limited information. Lacking an established safety evaluation method for nucleic acid drugs, we held extremely detailed discussions with regulators under the "Sakigake" designation. To solve the technical issues required cooperation between our internal departments responsible for analysis/QC, production, pharmacokinetics and product safety.

DMD is a rare disease. The number of patients who can be treated is further restricted if we can only select those whose condition is amenable to exon 53 skipping. Our clinical development team recruited patients for the trial from around Japan after the National Center of Neurology and Psychiatry granted us access to their patient database. In contrast, in the US, our Group subsidiary NS Pharma had been working since 2014 with Head Office and local trial design consultants, as well as prominent researchers in the field, to ensure we had an integrated trial strategy from the outset. Since we also needed to confirm higher intracellular dystrophin concentrations after administration of the investigational drug to gauge its efficacy, our clinical development teams worked to solve this issue in collaboration with NS Pharma and the Discovery Research Laboratories in Tsukuba.

### Future development

While we all hope that Viltepso will alleviate the suffering of DMD patients and their families, only about 8% of DMD patients stand to benefit from the drug. We want to develop other nucleic acid medicines to treat more patients with DMD by targeting other exons. In addition, we plan to continue R&D into nucleic acid drugs to help develop effective treatments for other diseases where conventional pharmaceutical therapies have not demonstrated sufficient efficacy.

Looking ahead, we will continue listening to patients and research physicians as we pursue R&D into medicines with improved efficacy that can help to treat more patients.

# 2 Development of Global Business

## An Increasing Pace of Global Development

**From R&D to production, logistics and sales, we are building an organization completely geared to the development of global business as we seek to supply our distinctive products worldwide. The pace of development in global operations built under the 5th medium-term management plan and other previous plans is now accelerating.**

The concept espoused by Hisomu Ichinose when he founded Nippon Shinyaku was that Japanese would prefer the medicines they take to be made in Japan. Santonin, an anthelmintic that was the company's first domestically produced success, was later exported overseas. Ever since, Nippon Shinyaku has been an R&D-oriented pharmaceutical company making medicines not only for Japan, but overseas markets as well.

The development of global business is one of the "six actions" we defined as part of the 6th Five-Year Medium-term Management Plan that began in fiscal 2019 to achieve our corporate vision by realizing sustained development. It was a theme on which we focused in the 5th Five-Year Medium-term Management Plan as well. Our global growth in recent years has been spearheaded by Upravi, a treatment for pulmonary arterial hypertension that we discovered in-house. Upravi is on the way to becoming a blockbuster product due to the sales efforts of our global partner Actelion Pharmaceuticals Ltd, a Janssen Pharmaceuticals company of Johnson & Johnson across 55 countries worldwide.

Boosted in confidence by Upravi's success, we are expecting to develop another global product in Viltepso, a treatment for Duchenne muscular dystrophy (DMD). Viltepso is gaining attention as an oligonucleotide, a class of drugs that forms a new treatment modality. Its discovery was the product of nucleic acid synthesis and sequencing technologies that we have developed over many years. In Japan, we received manufacturing and marketing approval from MHLW for Viltepso in March 2020, and we started sales and detailing activities in May. In the US, local subsidiary NS Pharma has led the clinical development of Viltepso. Our NDA application was received by the US FDA in February 2020, and we gained marketing approval for the drug in August. NS Pharma has now begun sales and detailing activities in the US. Besides the US, we hope to make Viltepso available to patients in more countries worldwide, starting with Europe and China. We are also developing other treatments for DMD to succeed Viltepso, which treats forms of DMD amenable to exon 53 skipping, with the focus on developing other oligonucleotide drugs that could enable skipping at different exons to help treat more DMD patients.

The Global Business Division that I lead exports not only Upravi, but a range of other products we have developed in-house. These include the synthetic antibiotic prulifloxacin; the gastritis and gastric ulcer treatment Gaslon N; Trisenox, a treatment for relapsed and refractory acute promyelocytic leukemia; and Erizas, a treatment for allergic rhinitis. Our successful development of our export business has led to sales in Europe, the Middle East and Asia. In-licensing activities around the world are another major focus for the Global Business Division as we work to expand our development pipeline.

Global development is the basic assumption of our in-house drug discovery going forward – as seen with NS-018, our myelofibrosis treatment that is currently in US clinical trials. We will continue to work to provide patients worldwide with products in our main specialist areas, most notably intractable and rare diseases.

### Toru Nakai

Director,  
Head of Global Business



# Business Activities

## Pharmaceuticals R&D

Focused mainly on the four key areas of urology, hematology, intractable and rare diseases, and gynecology, we are targeting areas of disease with unsatisfied therapeutic needs and supplying distinctive products of high quality to patients.

Honing the R&D capabilities we have developed to date, we are continuing to create new value by widening the scope of drug discovery through the addition of new modalities and technologies to the drug-discovery platform that produced the small molecule drug Uptravi and nucleic acid drug Viltespo. We are focused on in-licensing and product life cycle management (PLCM) to enhance the R&D pipeline so that we can launch a stream of new products in Japan and target overseas markets.

**Akira Matsuura** Managing Director, Head of R&D



### Growth Strategy

Develop pipeline by strengthening in-house drug discovery, in-licensing and product life cycle management (PLCM), and via higher productivity

### FY2019 Review

#### Two drugs launched for diseases with unsatisfied therapeutic needs

We launched Defitelio (development code NS-73; generic name defibrotide sodium) in Japan in September 2019 after the drug received regulatory approval in June 2019 for treatment of sinusoidal obstruction syndrome. It was granted orphan drug designation in May 2019. As the first product approved for this indication, it is expected to make a major contribution to treatment of this disease in Japan.

We launched Viltespo (development code NS-065/NCNP-01; generic name viltolarsen) in Japan in May 2020 after it gained regulatory approval in March 2020 for treatment of Duchenne muscular dystrophy (DMD). MHLW previously granted the drug "Sakigake"



designation in October 2015 and orphan drug designation in August 2019. This product is expected to make a significant contribution to treatment of DMD patients. An NDA was filed in the US in February 2020, and we are currently preparing for launch once US regulatory approval is received. Joint international Phase III clinical trials for this drug are also underway.

Originally launched in 2016, pulmonary arterial hypertension treatment Uptravi (development code NS-304; generic name selexipag) is in Phase III clinical trials that are being conducted jointly with Janssen Pharmaceutical K.K. for the additional indication of chronic thromboembolic pulmonary hypertension (CTEPH). The drug has received orphan drug designation from MHLW for the CTEPH indication. We are also conducting two separate clinical trials for selexipag for the indications of arteriosclerosis obliterans (late-stage PII) and lumbar spinal stenosis (early-stage PII).

### Medium-to-long-term Outlook

#### Build pipeline by creating products offering new value through a broad-based R&D program

Building on our successes in small molecule and nucleic acid drugs, we are working to broaden our drug-discovery capabilities by integrating new technologies such as AI and induced pluripotent stem cells as well as new modalities such as gene therapy. Our aim is to maximize internal and external resources by promoting open innovation.

Creating new value via such R&D activities, we aim to generate a constant stream of distinctive products to treat diseases with unmet therapeutic needs. Moreover, by building an organization with global R&D capabilities, we plan to provide these distinctive drugs to patients worldwide.

## Pipeline

As of August 20, 2020

### Japan

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase			NDA filing	Launch
						I	II	III		
NS-065/NCNP-01 (Viltolarsen)	Launched PIII	Intractable disease/orphan disease	Duchenne muscular dystrophy	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku	█	█	█	█	█
NS-304 (Selexipag)	PIII		Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Co-development: Janssen Pharmaceutical K.K.	█	█	█	█	█
NS-32 (Ferric derisomaltose)	PIII	Gynecology	Iron deficiency anemia	Licensed-in from: Pharmacosmos A/S	Nippon Shinyaku	█	█	█	█	█
ZX008	PIII	Intractable disease/orphan disease	Dravet syndrome/Lennox-Gastaut syndrome	Licensed-in from: Zogenix, Inc.	Zogenix, Inc.	█	█	█	█	█
NS-304 (Selexipag)	PII	Cardiovascular	Arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
		Orthopedics	Lumbar spinal stenosis	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
NS-580	PII	Gynecology	Endometriosis	Nippon Shinyaku	Nippon Shinyaku	█	█	█	█	█
NS-17 (Azacitidine)	PII	Hematologic malignancies	Acute myeloid leukemia	Licensed-in from: Celgene Corporation	Nippon Shinyaku	█	█	█	█	█
NS-87	PI/II		Secondary acute myeloid leukemia	Licensed-in from: Jazz Pharmaceuticals PLC	Nippon Shinyaku	█	█	█	█	█
NS-917	Preparation for development		Relapsed/refractory acute myeloid leukemia	Licensed-in from: Delta-Fly Pharma, Inc.	Nippon Shinyaku	█	█	█	█	█

### Overseas

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

### Our Will

#### The challenge of R&D for intractable diseases

As a project manager for development themes, I craft strategic proposals for our success in R&D and sales, and I work on time management issues. Recently, I have been focused on the nucleic acid drugs to succeed viltolarsen. This global project aims to create products to help patients worldwide with diseases that currently have no treatment. Nucleic acid drugs also offer potential solutions to treat intractable conditions. Delivering these products is our goal, but we are also conscious of the need for speed because patients suffer while waiting for treatment. In the future, we also hope to develop products that offer value for patients by pursuing development themes based on the introduction of new treatment modalities.



**Jin Hiruta**  
Project Management Section,  
R&D Administration Department

Business Activities

# Pharmaceuticals Sales

The mission of the Sales and Marketing Division is to provide medical professionals with high-quality information about appropriate therapies so patients can access them as early as possible.

Acting as a treatment partner for patients based on the trust of the medical profession, our basic policy is to ensure integrity in everything we do as we seek to provide information promptly to health professionals based on proper evaluation of related needs.

**Shouzou Sano** Managing Director, Head of Sales and Marketing



**Growth Strategy**

With healthcare evolving at the community level in Japan, develop systems to provide information to cater to the increasingly diverse needs of each area; realize faster and more advanced provision of information, supplementing the detailing by MRs by deploying regional and central technical specialists in each therapeutic field

**FY2019 Review**

**Results driven by rapid market penetration of new products in core areas of focus**

We strove to provide high-quality information in the three areas we have identified as core areas of focus: urology, hematology, and specialty domains.

In the urology field, we launched two new prostate cancer treatments in Japan, Erleada in May 2019, and Zytiga in March 2020 in co-promotion with Janssen Japan. We are contributing to urological patient care through these products and Zalutia, a treatment for



urinary disorders caused by benign prostatic hypertrophy.

In the field of hematology, in August 2019 we launched Defitelio as Japan's only treatment indicated for sinusoidal obstruction syndrome. This supplements Vidaza for myelodysplastic syndromes and Gazyva, a treatment for CD20-positive follicular lymphoma. In serious cases, sinusoidal obstruction syndrome in the liver can be fatal at a high rate due to multiple organ failure. There has been rapid take-up of this drug since previously there was no approved treatment in Japan.

Nippon Shinyaku is the only company in the world that offers three oral treatments for pulmonary arterial hypertension – Adcirca, Opsumit and Upravi – that each have a distinct mechanism of action. Elsewhere, in May 2020, we began selling Viltepso, Japan's first nucleic acid drug for treatment of Duchenne muscular dystrophy (DMD). MHLW had earlier granted Sakigake designation (for accelerated approval) and conditional



early approval. Since it represents the first-ever treatment for DMD, we are focused on detailing this drug so patients can gain early access to it.

**TOPICS**

**Creation of system to cater to regional healthcare needs**

**Sales set-up and detailing activities**  
The recent shift in Japan to systems that promote comprehensive healthcare solutions tailored to local needs means we must ensure drug detailing activities meet these diverse requirements.

In response, we have reorganized our sales force into 113 sales teams, spread across 13 business offices and 43 business branches, so that we can provide information quickly. Each MR draws up a detailing plan for their sales territory, and these are used as the basis for planning the provision of information at the team, office and branch level. Besides MR detailing, we strive to provide

information on appropriate use of products by holding briefings, lectures, seminars, and other events.

**Development of technical support system at regional level**

Nippon Shinyaku MRs receive ongoing training to improve their knowledge since many of our products treat rare or life-threatening conditions. We have an internal system of examinations to grade MRs on their level of medical knowledge. By providing training to help MRs ascertain the varied needs of medical professionals accurately, as well as role-playing and other training, we are raising the quality of our detailing activities.

From fiscal 2019, we began deploying technical specialists in each therapeutic field across the regions to provide highly specialized detailing to supplement information provided by MRs. Each technical specialist coordinates with local MRs to ensure rapid responses to the needs of medical professionals. Independent market research done in 2019 awarded Nippon Shinyaku high marks for the quality of medical detailing.

Launched in Japan in May 2020, the nucleic acid drug DMD treatment Viltepso demands a high level of specialized knowledge for detailing.

We have deployed specially trained MRs to each region to focus on detailing this product.

We continue to develop our training systems and sales set-up to ensure our medical professional detailing activities meet high quality standards.

**Medium-to-long-term Outlook**

**Shift to "omni-channel" detailing approach that combines MRs with digital channels**

Traditionally, MRs have collected information and provided detailing to medical professionals in person. However, the use of digital detailing channels has increased in recent years. With the COVID-19 pandemic severely restricting the opportunities for face-to-face detailing by MRs, the shift to digital channels can only accelerate. More medical professionals are also accessing information via digital channels, in line with the trends at pharmaceutical companies. In future, we expect a shift towards an "omni-channel" approach to medical

detailing combining MRs with the use of digital platforms.

We are already using various digital channels to provide information to medical professionals, including e-detailing, webinars, web-hosted interviews, and remote detailing methods. At the same time, MRs fulfill a critical role in helping to gauge the true needs of medical professionals and respond appropriately. We are shifting to an "omni-channel" approach that emphasizes the respective roles of MRs and digital platforms so we can fulfill our core mission in Sales to help patients gain access to the proper therapies as quickly as possible by focusing on providing information on appropriate use of products.



**Our Will**

**Finding the way with colleagues sharing their wisdom and passion**

Conditions in the pharmaceutical market are changing rapidly, and it is sometimes hard for MRs to perceive the correct option. Yet we must continue to overcome the challenges posed by changing conditions so that as many patients as possible can gain early access to these valuable medicines.

While the correct option may be difficult to see, I have many Nippon Shinyaku colleagues across Japan who stimulate me to face these challenges by imparting wisdom and sharing their passion. Working across interdepartmental boundaries and untied by traditional thinking, together we can find a way to meet every new challenge and contribute to better patient treatment.



**Kazuki Umada**  
Kyoto Business Branch,  
Keiji/Hokuriku Business Office

Business Activities

# Pharmaceuticals Production

We set four goals\*1 as part of achieving the 6th Five-Year Medium-term Management Plan, and formulated 20 specific policies to achieve them. We achieved most of the intermediate fiscal 2019 targets on our policy roadmap. In particular, we made steady progress in preparing the global supply chain needed to support future in-house sales of Viltepso in the US market, reflecting the huge collective efforts of the Departments in Resource Procurement, Production & Assurance.

We remain focused on accomplishing the goals and broader objectives of this plan, based on our mission of providing patients with a stable supply of pharmaceutical products.

**Hitoshi Saito** Director, Head of Resource Procurement, Production & Assurance

\*1 1. Enhance supply stability; 2. Strengthen reliability assurance system; 3. Create profits via continued cost management; 4. Develop global systems for procurement, production, logistics, reliability assurance and supply stability



**Growth Strategy**

**Establish global supply and reliability assurance systems**

**FY2019 Review**

**Construction of global supply and reliability assurance systems for Viltepso; promotion of increased productivity**

In fiscal 2019, we continued establishing global supply and reliability assurance systems ahead of the planned launch of Viltepso in the US market in fiscal 2020. Specifically, we prepared for FDA inspections of related manufacturing sites; built up our local sales network in the US, along with regulatory and medical operations; and compiled a safety database and operating procedures. We also analyzed any gaps in our Odawara Central Factory operations relative to global standards, assuming in-house production, and assembled a coordination team to handle any adjustments.

Building on the success of the previous medium-term management plan, we enhanced supply chain productivity by reinforcing our stable supply framework while improving operational efficiency and cost management practices. Specifically,

we focused on ensuring the quality, efficacy and safety of APIs and finished products through the development of quality management systems. We also targeted cost reductions for API procurement and logistics with our mainstay products as part of our low-cost management approach. In terms of risk mitigation, we maintained inventory target levels and managed our supply chain to ensure uninterrupted products supplies; we also revised emergency manuals as part of the promotion of the Business Continuity Plan (BCP).

**Medium-to-long-term Outlook**

**Focus on establishing global supply system while evaluating nucleic acid drug-related capex**

The overseas markets of the US, Europe, China and other developing economies are increasingly important for us as conditions become ever more challenging within the Japanese pharmaceuticals market. To develop these markets aggressively, we are building a global supply system as well as developing logistics infrastructure compliant with Good Distribution Practice (GDP) and reliability assurance systems to handle



overseas inspections and regulations.

In addition, we are adapting the Odawara Central Factory to the market shift into specialty domains and to more diverse pharmaceutical modalities. Specific measures include production of highly bioactive solid formulations as part of the PLCM development of selexipag and the evaluation of potential capital investments relating to nucleic acid drugs.

Alongside this, we continue to focus on boosting profits by cutting procurement and logistics costs as part of our cost management approach.

**Quality Assurance and Supply Stability**

**Ensuring reliability from R&D to production and post-marketing**

Efforts at Nippon Shinyaku to ensure the required quality, efficacy and safety of pharmaceuticals are led by the Regulatory Affairs, Safety Management and Quality Assurance Division.

Non-clinical and clinical studies are conducted at the R&D stage, after which we

prepare application documents to obtain manufacturing and marketing approval. These documents are audited by the Regulatory Affairs, Safety Management and Quality Assurance Division at the appropriate stage to ensure the reliability of data from all R&D studies.

After manufacturing and marketing approval is gained, work continues to ensure full compliance with the terms of approval via close cooperation between the general marketing supervisor, QA manager and safety manager. This ensures compliance with approved matters and proper maintenance and management of the license for marketing and license for manufacturing as part of ensuring the quality and safety of the products, thus fulfilling our responsibilities to the market.

**Pharmaceutical products reliability assurance**

R&D stage	
Non-clinical tests	Clinical trials
Test data reliability assurance based on GLP and reliability criteria	Clinical trial reliability assurance based on GCP



Post-manufacturing and marketing		
Quality control	Safety management	Maintenance and management of approval and licenses
Quality control based on GMP and GQP	Safety management based on GVP	Maintenance and management of manufacturing and marketing approval and license for marketing, etc.

**Pharmaceutical risk management initiatives**

Risk management for Nippon Shinyaku products is based on the use of a Risk Management Plan (RMP)\*2. The aim is to ensure pharmaceutical safety at the post-marketing stage by using the RMP to evaluate the benefits and risks across all stages from R&D to post-marketing and to put in place any required safety measures in line with the results of the analysis. RMPs are published on the websites of the Pharmaceuticals and Medical Devices Agency (PMDA) and Nippon Shinyaku.

The Safety Management Department prepares manuals to support persons responsible for RMP execution. It is also developing a system to allow borderless Group cooperation for RMP processes.

Efforts are also underway to ensure the integrated global management of safety information relating to the development of Viltepso in the US.

\*2 Risk Management Plan: An RMP defines the critical risks for an individual drug at the post-marketing stage and collates the measures taken by the company to mitigate such risks

**Building QA systems for pharmaceuticals**

The Quality Assurance Department develops our pharmaceutical QA systems in full compliance with Good Quality Practice (GQP) and Good Manufacturing Practice (GMP). We constantly work to improve quality systems, product quality

and resource allocation via management reviews. As we develop our US business, with the aim of creating world-class pharmaceutical QA systems, we are building local QA infrastructure in the US; investing in English communication skills; and recruiting and training people with QA-related knowledge and experience in overseas markets.

**Securing stability of supply**

In fiscal 2014, we introduced an in-house accreditation system for qualifications at the Odawara Central Factory to support multi-skills development by employees. In addition, as part of our vision to make the facility competitive in terms of cost and quality, we have introduced BSC\*3 management to help us formulate and realize strategy based on a multifaceted perspective that covers financials, customers, business processes, human capital and workplace reforms. We are also using KPIs\*4 to evaluate progress. On the logistics side, we have developed systems to manage temperature during storage and transport and to distribute inventory across multiple sites to mitigate disaster-related risks while preserving quality.

\*3 Balanced Score Card (BSC): An approach for comprehensive measurement of how corporate strategy is being implemented

\*4 Key Performance Indicators (KPIs): Critical indicators from the business process monitoring targets set to achieve corporate goals under the BSC approach

**Our Will**

**Sustained growth through a global supply chain**

I am leading our project to build a global supply chain for Viltepso, from the procurement of raw materials to the supply of products to Japan and overseas markets. Building a supply chain in the US in particular is a first for Nippon Shinyaku, and it has been a case of trial and error. However, we have been conscious of the need to get innovative drugs to patients as quickly as possible through the efforts of the whole company. The process involves not only NS Pharma, the Group's US subsidiary, but also many other divisions. My role is to ensure it flows smoothly based on good interdepartmental cooperation and communication. Establishing a US supply chain that is compliant with local laws and regulations has been a challenge, but we have solved the issues one at a time by working out how best to succeed together. My hope is that future business development based on this global supply chain will translate into sustained growth.



**Akiko Yasuura**  
Manufacturing Planning Section,  
Manufacturing Planning Department

# Functional Food

The Functional Food business takes a different approach from the Pharmaceuticals business in helping people to lead healthier and happier lives. Besides supporting people's daily dietary habits, we aim to promote better health using health food ingredients and supplements and address societal challenges such as food waste. We aspire to be a significant contributor to people's improved health and longevity by bringing to market a continuous stream of highly innovative products, based on our efforts to upgrade R&D capabilities.

**Kenro Kobayashi** Director, Head of Functional Food



## Growth Strategy

Expand earnings from supplement business while contributing to improvements in healthy longevity and active lifestyles through safe foods

## FY2019 Review

**Higher sales and profits achieved via introduction of innovative high-value-added products in every core area of focus**

In an era when more people are reaching 100 years of age, the goal is not merely to live a long time, but also to lead a rich and meaningful life. The low birth rate and aging population in Japan has caused huge growth in social healthcare spending, prompting governments to try to lower healthcare costs by promoting early diagnosis and treatment of diseases, greater use of OTC medication, and taking more responsibility for one's own care. These trends have cultivated increased health consciousness among Japanese, and this is magnifying the role of evidence-based health supplements and health foods.

In supplements, which are a growth driver for the Functional Food business, we are focusing on the two sectors of sports supplements and aging care products. Our aim is to develop supplement ranges that are brand leaders among athletes, while also leveraging our status as a pharmaceutical maker to be a pioneer in supplying supplements that help to prevent disease or provide aging care benefits.

In the bulk materials business, which is the major part of the earnings base, we are investing in R&D in three core focus areas: health food ingredients, preservatives, and protein preparations. Distinctive products in each of these areas were released in a systematic fashion in fiscal 2019.

Based on these initiatives, we posted higher sales and profits in each of the three core focus areas of health food ingredients, preservatives, and protein preparations.

### TOPICS

**Mangostia: Japan-first FFC (Food with Functional Claims)**

Known as the "queen of fruits" for the delicate flavor of its white flesh

combining sweetness with acidity, the mangosteen is a tropical evergreen of the family Hypericaceae. We were the first in the world to discover in mangosteen peel a functional ingredient called rhodanthone B that possesses strong anti-glycation properties.

As discussed recently in the media, glycation is an internal process in which proteins react with any excess sugars. It is now known that glycation can cause proteins to lose their original function, with various negative effects on the body. Our studies have demonstrated improved water retention in the skin among a group taking a mangosteen extract compared with the placebo control group, pointing to the benefits of glycative stress reduction in terms of enhanced moisture retention by the skin. We have since developed and launched Mangostia as Japan's first approved Food with Functional Claims (FFC) where the underlying mechanism of action is based on glycative stress reduction.

This product has made a big impact within the industry. Its designation as an FFC prompted many inquiries from consumers.



## Kioku no Kobako "Little Box of Memory": a supplement designed to support cognitive function

Kioku no Kobako is the first FFC to use bacopa saponins\* as the functionally active ingredient. It has been reported that taking three capsules per day can help to enhance memory (the cognitive function enabling the memorization and recall of information used in daily life, which deteriorates with age).

According to the WHO, the number of dementia sufferers worldwide increases by one every three seconds. This is a serious problem in Japan, where the population of dementia patients is forecast to exceed 7 million by 2025 due



to the rapid aging of society. With no effective treatment for dementia yet established, and with lesions developing in the brain for 10–20 years before symptoms appear, the early use of evidence-based supplements offers one potential approach to disease prevention.

Going forward, we will seek to develop various aging care products.

\*Bacopa saponins are contained in the Bacopa monnieri plant, an herb used in traditional Indian Ayurvedic medicine to support cognitive function. It has been reported that these substances work by boosting neural transmission, aiding the process of laying down and recalling memories.

## Medium-to-long-term (see pg. 28) Outlook

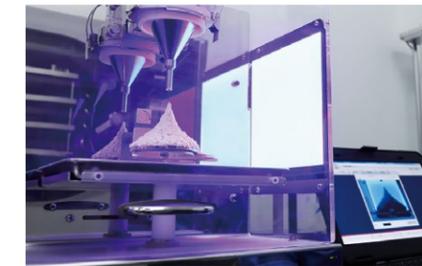
**Expand revenues from supplements business while helping to address societal issues**

We see our mission as contributing through food to the prevention of disease and the extension of healthy longevity. In the bulk materials business, which constitutes most of the earnings base of the Functional Food business, we face a

contraction of the processed foods market due to Japan's falling population, with fierce price-based competition as ingredients become commoditized. Leveraging our R&D expertise as a pharmaceutical maker, we have sought to create new markets and transition to a higher-margin business by bringing to market high-value-added products that satisfy market needs. Moreover, based on these R&D capabilities, we are positioning the development and supply of final products that can translate in-house concepts directly into consumer benefits as a major growth driver, with the aim of improving profit margins further.

Our efforts to develop preservatives contribute to the realization of SDGs by helping to reduce food loss via wastage. We expect this contribution to continue as we try to develop original technology to extend shelf life while preserving taste, thereby reducing how much food is destroyed.

In this way, our policy is to increase profits from the Functional Food business while contributing to efforts to address societal issues.



## Our Will

### Developing original health food ingredients

I am searching for original health food ingredients to use in innovative Nippon Shinyaku aging care products. In particular, my work focuses on the field of anti-glycation materials, a critical area for the Functional Food business. We are doing joint research with universities in this area, based on our in-house library of plant extracts.

The material search processes are conducted by a team, and part of my job is to motivate the team. For example, by increasing the opportunities for team members to communicate, it helps everyone understand the purpose of the process and makes us more aware of what we can do. The enhanced awareness helps work to proceed more efficiently. In addition, in collaboration with universities and other groups, we are trying to gather information from as wide a range of contacts as possible so our materials development work produces truly unique results.



**Kenjiro Hayashi**  
Food Development Labs,  
Functional Food Division



## CSR Management



**We promote sustainability  
by actively incorporating  
the essence of ESG.**

**Takashi Takaya**

Director,  
Head of Administration

### Initiatives for the 6th Five-Year Medium-term Management Plan

Nippon Shinyaku's goal is to become a "company with a meaningful existence in healthcare." In aspiring to that goal, the Group's corporate social responsibility (CSR) is summarized in the slogan of "Helping people lead healthier, happier lives." In terms of management policy, it means seeking to prosper with society by supplying unique and high-quality products; to earn the trust of society; and to develop each employee. Our fundamental CSR policy is to conduct our business activities in line with this thinking on a continuous basis, thereby making a broad-based contribution to society.

One of the goals of the 6th Five-Year Medium-term Management Plan is to increase our corporate value by strengthening ESG management. In an increasingly uncertain business environment, we aim to achieve sustained growth by reinforcing ESG-based management initiatives as part of our business activities in ways that maximize internal resources and strengthen our management platform.

Our environmental initiatives are guided by the Nippon Shinyaku Basic Environmental Policy. We are working to reduce environmental impact, based on environmental targets set within the following five areas: conservation and global warming countermeasures; saving resources, reducing waste and promoting the 3Rs; proper management of chemical substances; environmental management system promotion; and communication with local communities. Global warming is a contributing factor in recent extreme

weather events, which has in turn made natural disasters more damaging. It can also be an underlying factor in pandemics. Realizing this, we are actively working to cut greenhouse gas emissions. Proper management of chemicals is a key environmental issue for us as a pharmaceutical manufacturer. In addition, we are contributing to greater biodiversity through the operations of the Yamashina Botanical Research Institute.

Within our social initiatives, we use a "motivation management" approach to our investment in human capital to foster an organizational culture in which individual employees are positively challenged to grow. It is also vital to promote greater diversity and inclusion as part of building a base for sustainable business growth. Gender neutrality is a fundamental principle of our recruitment, and we also apply this in various aspects of HR management such as skills development and promotion. Moreover, we have developed a range of skills development support programs designed to suit the varying lifestyles and life stages of our employees.

The flextime system that we first introduced in the Pharmaceutical Sales and Marketing Division has been extended to be available to all employees as a "super-flextime" system without set core working hours. In addition, having upgraded telework systems to help limit the spread of coronavirus, we expect to make telework a permanent feature of post-COVID management due to its significant benefits in terms of enhanced workstyle diversity and support for greater work-life balance for employees.

Our approach to health management sees employee health as a goal rather than a means to an end. In 2018, our president made a declaration on health. In 2019, Nippon

Shinyaku was selected as a "White 500" Certified Health and Productivity Management Organization. We remain actively focused on varied measures to cut smoking rates inside the company to zero by 2022. Our social contribution program includes the Nippon Shinyaku Children's Literary Awards, initially established to commemorate our 90th anniversary and now in their 11th year, and the Public Research Grant Scheme, which was created to commemorate our centenary. Elsewhere, we give support to non-profits; sponsor sporting and cultural events; and seek to enrich community life through access to company facilities, notably the Yamashina Botanical Research Institute. We also undertake a range of disease-related educational activities so the knowledge we possess can play a role in creating a healthier society. In April 2020, we introduced a system to grant employees leave to make their own social contribution through volunteering.

In terms of governance initiatives, in line with our basic policy on CSR, we are focused on ensuring full compliance with laws, regulations and internal rules across all aspects of management, along with proper transparency. Constantly aware of our social responsibility to every stakeholder, we try to ensure our corporate actions are sincere and highly ethical.

### Building employee awareness of the importance of ESG-based management

Using ESG-based management to boost enterprise value will not work if only management or a part of the organization follows that approach. Our view is that contributing to the realization of the Sustainable Development Goal (SDG) targets by promoting sustainability requires all employees to incorporate the essence of ESG into their daily lives, as well as their activities at work.

Using articles in internal media, training and other means, we seek to educate our entire workforce, from managers to new recruits, on what we can do at the individual and corporate level to help address social issues. Examples from our training program include SDG training for directors and a materiality analysis project involving younger employees. In another sign of our commitment, Nippon Shinyaku became a signatory to the UN Global Compact in January 2020.

### Implementing ESG-based management

The COVID-19 pandemic has radically altered the business environment. Rather than viewing this as a threat, we regard it as an opportunity to accelerate a range of management reforms.

The choice between health – in this case, preventing the spread of infection – and the economy is often portrayed as a trade-off. Yet, from an ESG-based management perspective, we should be working to realize both aims in a sound and healthy manner.

Our core aim as a pharmaceutical manufacturer is to contribute through R&D for developing drugs. Our focus is on developing therapies using nucleic acid technology. Cultivating a workplace culture that fosters innovation is important in accelerating drug development. We will ensure that our management approach fosters an open culture permitting frank debate, irrespective of gender, job status, ethnicity or nationality, while at the same time prioritizing the health and happiness of employees.

The COVID-19 pandemic has transformed people's values, too. Companies displaying no environmental consideration are increasingly seen as self-absorbed entities that harm others, make the situation worse, or pose a danger to the planet. At Nippon Shinyaku, we take seriously our responsibility to help create a more sustainable society by, for example, shifting to renewable energy to counter global warming, or by ensuring the responsible management of chemicals.

Effectively functioning governance is indispensable to fulfilling our duties to stakeholders, ranging from patients, business partners and users to shareholders, investors and employees. Cognizant of the risk of compliance breaches, we are focused on developing a compliance-oriented management set-up and on ensuring the effectiveness of governance structures such as the Board of Directors and the Board of Auditors. We are also ensuring transparency and objectivity by reinforcing the supervisory functions of external directors. Lastly, we aim to create a good workplace environment with a culture that inhibits and prevents any malfeasance.

Initiatives for the Environment

# Environmental Management

## Nippon Shinyaku Basic Environmental Policy

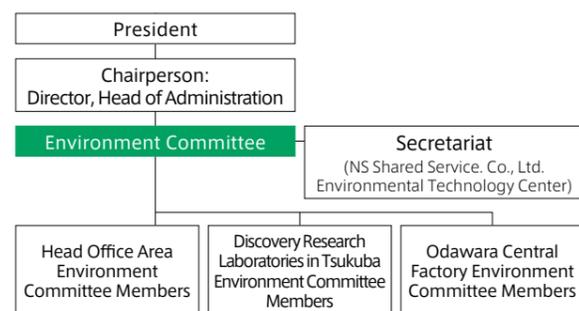
At Nippon Shinyaku, our mission is to help people lead healthier, happier lives. When we seek growth, it should be growth in harmony with the natural environment. That is why we strive to protect, sustain, and improve the environment through eco-considerate business activities.

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

## Environmental Management System

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

### Environmental Management Structure



## Putting Environmental Management System Certification into Action

Our production site at the Odawara Central Factory targets continuous improvement in environmental performance as part of environmental management activities, based on a framework created using its ISO 14001-certified environmental management system. The environmental management activities for the R&D facility at our Head Office site are based on KES Environmental Management System Standard Step 2 ("KES" Step 2) certification.

In fiscal 2019, the Odawara Central Factory underwent its periodic review and the Head Office also had its annual document review and on-site inspection. No serious problems that would lead to environmental pollution were found, and each certification was continued.

\* Abbreviation for Kyoto Environmental management system Standard, originating in Kyoto

## Environmental Accounting

The following is an accounting of the environmental costs and benefits in fiscal 2019.

### Environmental conservation costs

Costs	Investments	Expenses
Costs within our business areas	182,129	231,657
Pollution prevention costs	30,700	25,384
Global environmental conservation costs	151,429	141,062
Resource recycling costs	0	65,211
Upstream & downstream costs	0	4,768
Management activity costs	19,049	78,362
R&D costs	0	0
Social activity costs	0	1,995
Environmental remediation costs	0	84
<b>Total</b>	<b>201,178</b>	<b>316,866</b>

(thousands of yen) (excluding our sales offices)

### Environmental conservation benefits

Benefit verification	Units	FY2019 results	Year-on-year change
CO <sub>2</sub> emissions	Tons	11,218	-1,420
Electricity usage	1,000 kWh	14,987	-71
Heavy oil & kerosene usage	kl	3	0
City gas & LPG usage	1,000 m <sup>3</sup>	1,630	-11
Gasoline & diesel usage	kl	602	-298
Water consumption (main business locations)	1,000 m <sup>3</sup>	182	-22
Waste substances generated (main business locations)	Tons	482	-40
Final amount of landfilled waste (main business locations)	Tons	3.0	1.5

## The 5th Nippon Shinyaku Environmental Targets Plan (FY2017–2019)

The Nippon Shinyaku Environmental Targets Plan sets specific voluntary targets for the company to carry out in order to comply with its Basic Environmental Policy. The 5th Nippon Shinyaku Environmental Targets Plan, a three-year plan that began in April 2017, adds to previous targets a

new set of numerical targets—basic units for CO<sub>2</sub> emissions and volume of waste generated, and for the waste recycling rate. In fiscal 2019 we continued working toward the targets set in the 5th Nippon Shinyaku Environmental Targets Plan.

To promote further environmental conservation efforts, we will formulate the 6th Nippon Shinyaku Environmental Targets Plan (FY2020–2022) in fiscal 2020.

The 5th Nippon Shinyaku Environmental Targets Plan <sup>1</sup>	Numerical Targets	Results in FY2019	Progress Toward Numerical Targets	
Promotion of Energy Conservation and Global Warming Countermeasures	Reduce total energy consumption (Gj) in FY2019 to below FY1990 levels.	230,432 Gj or less	Total energy consumption: 211,137 Gj ▶ 8% reduction from FY1990 level	Reached
	Reduce the CO <sub>2</sub> emissions <sup>2</sup> basic unit <sup>3</sup> by about 40% from the FY1990 level by FY2019.	0.13 or less	Basic unit of CO <sub>2</sub> emissions: 0.081 ▶ 63% improvement from FY1990 level	Reached
Saving Resources, Reducing Waste and Promoting the 3Rs	Reduce the final amount of landfilled waste by about 70% from the FY2005 level by FY2019.	4.38 tons or less	Final amount of landfilled waste: 3.01 tons ▶ 80% reduction from FY2005 level	Reached
	Reduce the basic unit of waste generated <sup>4</sup> by about 50% from the FY2005 level by FY2019.	0.53 or less	Basic unit of waste generated: 0.41 ▶ 60% reduction from FY2005 level	Reached
	Keep the waste recycling rate at 55% or more by FY2019.	55% or more	Waste recycling rate: 81.5%	Reached
	Promote green purchasing and procurement practices.	—	We added a function to the in-house purchasing system that allows us to ascertain whether or not we are buying "green products" when placing orders, making it easier to implement green purchasing.	—

The 5th Nippon Shinyaku Environmental Targets Plan <sup>1</sup>	Results in FY2019
Promote Proper Management of Chemical Substances	Promote the proper management of chemical substances, including those stipulated under the Pollutant Release and Transfer Register (PRTR) system, and continuously reduce their emission into the natural environment.
Promote an Environmental Management System (EMS)	Consumption of PRTR substances compared with FY2018: reductions of 49% (acetonitrile) and 20% (n-hexane); increase of 33% (dichloromethane)
	Effectively improve the results of our environmental performance by maintaining certifications for environmental management systems (ISO 14001 and KES).
	Certifications renewed for following environmental management systems: • Odawara Central Factory: ISO 14001 • Head Office: KES Step 2
Communication with Society and Local Neighbors	Appropriately disclose information to society and to the local areas of our business offices.
	Information is disclosed on the Nippon Shinyaku website and in Nippon Shinyaku reports.
	Actively participate in activities to give back to the areas where we do business.
	Cleanup activities, school workshops, research laboratory tours, charitable donations, etc.
	Promote activities related to biodiversity that benefit society.
	Ongoing cultivation, dedication and provision of endangered plants.

<sup>1</sup> Progress toward numerical targets is evaluated on the basis of the sum total from the Head Office, Odawara Central Factory and Discovery Research Laboratories in Tsukuba  
<sup>2</sup> Calculated using the actual CO<sub>2</sub> emissions factor from the Ministry of Economy, Trade and Industry  
<sup>3</sup> Value of CO<sub>2</sub> emissions (tons) divided by unit sales (100 million yen)  
<sup>4</sup> Value of waste generated (tons) divided by unit sales (100 million yen)



Initiatives for the Environment

# Environmental Performance

## Promotion of Energy Conservation and Global Warming Countermeasures

We have formulated guidelines to support collective efforts by all employees to save energy. Topics covered include using appropriate settings for air-conditioners and thermostats in coordination with flextime arrangements; turning off any lights not in use; and recommending that people take the stairs.

We continually seek to make facilities more energy-efficient through the repair, upgrade or installation of air-conditioning, heating and refrigeration equipment. We are also steadily replacing lighting with LEDs.

As a result of these efforts, we achieved our targets for total energy consumption and basic units for CO<sub>2</sub> emissions in fiscal 2019.

## Saving Resources, Reducing Waste, and Promoting the 3Rs

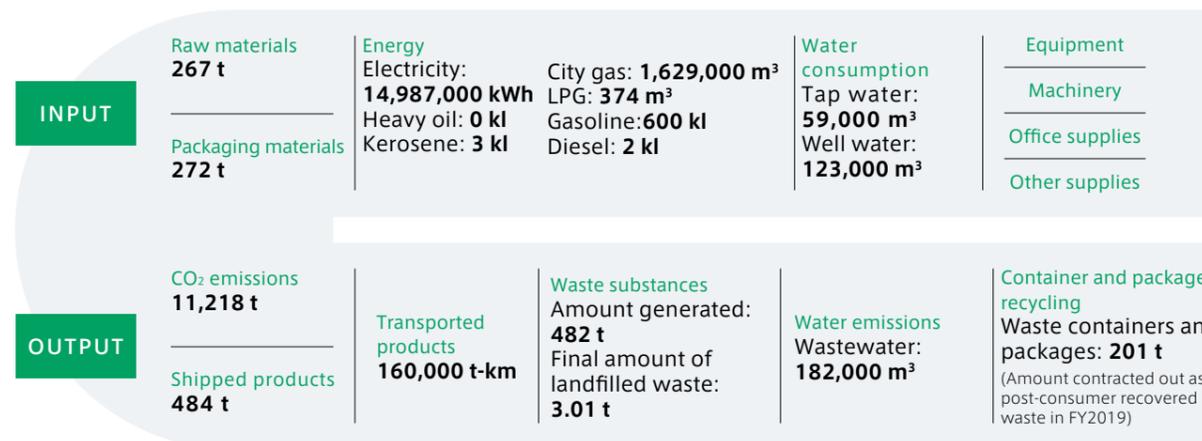
In fiscal 2019, we achieved our targets in terms of reducing the final amount of landfilled waste and basic unit of waste generated, and keeping the waste recycling rate.

We actively promote the 3Rs (Reduce, Reuse, Recycle) to make our resource usage as efficient as possible. We only engage certified subcontractors when we outsource the transportation, collection and disposal of wastes. This system is supported by electronic manifests for proper waste management and regular in-house audits of waste subcontractors.

## Proper Management of Chemical Substances

Under the Japanese law governing the Pollutant Release and Transfer Register (PRTR) system, we are required to submit reports to the authorities for business sites that handle at least one ton of Class 1 Designated Chemical Substances per year. The applicable PRTR substances for Nippon Shinyaku are acetonitrile, n-hexane, and dichloromethane at the Head Office, and dichloromethane at the Discovery Research Laboratories in Tsukuba. We maintain full compliance with mandatory reporting.

## Material Balance of Our Business Activities



While our usage of dichloromethane increased by 33% compared with fiscal 2018, our consumption of acetonitrile and n-hexane fell by 49% and 20%, respectively.

Dichloromethane usage increased due to operation of an in-house API production facility. Atmospheric release of substances generated in API production is minimized by installing solvent adsorption traps.

## Communication on the Environment

We participate in or cooperate with many types of community environmental activities, and also give environment-related donations and offer school workshops.

### The Yamashina Botanical Research Institute

The Yamashina Botanical Research Institute was established in 1934 as the Yamashina Pilot Farm. Since then, we have preserved and cultivated over 3,000 varieties of medicinal and useful (and in some cases, rare) plants from around the world, including mibuyomogi (*Artemisia maritima*). We used this plant to produce the anthelmintic Santonin, an intestinal worm treatment that played a large part in our corporate development.

The institute's collection includes more than 160 plant sources for crude drugs listed in the Japanese Pharmacopoeia, as well as many plants on the Japanese Ministry of the Environment's endangered plants list, and rare plants such as tree tumbo (*Welwitschia mirabilis*), that are recognized the world over as endangered. The institute also is heavily involved in plant cultivation as a means of preserving biodiversity.

During fiscal 2019, more than 1,600 people visited the institute across various events. Besides opening the facility on seven public holidays, we provided tours for the public, pharmacist training courses, seminars for medicinal plant specialists, and summer indigo-dyeing workshops aimed at local



Touring Yamashina Botanical Research Institute

elementary school students. The city of Kyoto recognized the institute for its contribution to the region with two awards for corporate excellence.

In addition, the institute participates in activities to help protect and propagate rare local plants such as

### Helping Local Clean-up Initiatives

- Head Office: Nishioji Station vicinity clean-up groups
- Odawara Central Factory: "Clean Sakawa" (a concerted effort by local residents to clean up the Sakawa River) and factory vicinity clean-up activities
- Discovery Research Laboratories in Tsukuba: Clean-up activities run by Tsukuba City

### Environment-related Donations

- Proceeds from the sale of metal scrap and recyclable paper are donated to the Nippon Shinyaku Kira-Kira Mirai Kodomo Bokin children's fund
- Recyclable waste with resale value provided to designated consultation support office for disabled children
- Books and DVDs collected for Kanagawa Kintaro Book Donation program
- Donations funded by cashbacks received as SHiDAX corporate member
- Gift of rescue stretchers funded by collection of aluminum cans
- Plastic bottle caps supplied for vaccine exchange program
- Funds collected using drink vending machines for the Red Feather Fund and Green Fund

Japanese wild ginger (*Asarum caulescens*), Kikutani-giku (*Chrysanthemum seticuspe*), and fragrant eupatorium (*Eupatorium japonicum*). As such, it has been recognized by the city as a part of the Kyoto Biological & Cultural Regeneration Project.

### Workshops/Lab Tours

- "Connected by Plants" lab tour on environment and medicine for Takao Elementary 6th graders

### Research Laboratory Tours

- Head Office's Discovery Research Labs: 18 lab tours for Saikyo Junior High School and other schools (junior high to college students, adults)
- Discovery Research Laboratories in Tsukuba: One lab tour for Tsuchiura First High School

### Contributions to Biodiversity

- Conservation of tree tumbo (*Welwitschia mirabilis*) and other endangered plants
- Raising Japanese wild ginger (*Asarum caulescens*) for the Aoi Festival (Kamigamo Shrine, Kyoto Prefecture)
- Raising *Chrysanthemum seticuspe* for the Green Water Corridor (Kyoto Station) and Kikutani Forest of Flowering Chrysanthemums (Kyoto City, Kyoto Prefecture)
- Participation in Rice Paddy Appreciation Association and Sakawa River System Medaka Supporters Association (Odawara City, Kanagawa Prefecture) activities, loan of parking lot

## TOPICS

### Let's get rid of plastic: "Plastics Smart" initiative



Since December 2019, Nippon Shinyaku has been making efforts in line with the Ministry of the Environment-sponsored "Plastics Smart" campaign\* to reduce marine plastic litter. Under a registered initiative called the "Blue Smile Project," we distributed reusable bottles commemorating our centenary to employees for use in the office, during work-related travel and outside work to help lower plastics consumption. In addition, in line with this thinking, we have been removing drinks in PET bottles from sale in vending machines at our Head Office site since November 2019.

The aim is to stimulate interest in environmental issues among employees and generate opportunities for behavioral change.

\* The Ministry of the Environment campaign aims to speed up efforts to solve the problem of marine plastic litter, vast quantities of which are still being generated every day. The campaign encourages initiatives by individuals, companies, organizations and government bodies to address an environmental pollution issue of global scale and concern.



Employees with their commemorative bottles

Please refer to the following web pages for further details (Japanese only).

- Ministry of the Environment Plastics Smart website <https://plastics-smart.env.go.jp/>



- Nippon Shinyaku-related information available at following URL: <https://plastics-smart.env.go.jp/case/?id=1361>





Initiatives for Society

# Supporting Value Creation in HR

## Basic View on Human Resources (HR) Development

At Nippon Shinyaku, we regard human resources as the key to sustaining growth, and to that end the concept of “developing each employee” is enshrined in our management policy, under which we respect the rights and personalities of individuals and aim to ensure that every single employee has the opportunity to grow and develop.

Developing a globally capable workforce has become a top priority as our business becomes more international in scope. To that end, in fiscal 2015 we instituted an Overseas Training Program for employees engaged in research and development.

This program provides our R&D personnel with opportunities to study abroad at a university or research institution. To further facilitate overseas expansion, we have also been running two kinds of English training courses since fiscal 2016, one for elite employees and one for those attending of their own accord. We believe that a globally capable workforce has a broader perspective and a more balanced mindset, and therefore is better equipped to identify and overcome the challenges of modern business, both domestically and overseas.

## HR Development

### Career Support System, CASA (Career Support Academy)

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

### Developing the Next Generation of Leaders

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

In fiscal 2019, we held the 7th Next-Generation Leader Development Program. We sought nominations from within the company, either via self-recommendation or recommendation by others, and selected 13 participants from several departments. Between August 2019 and March 2020 these employees undertook group training as well as attending external education programs at a business school to acquire basic management knowledge in areas such as management strategy, marketing and financial accounting. These programs also aim to cultivate greater business awareness based on two-way communications with senior management.



Next-Generation Leader Development Challenge Program

This initiative has actively supported the growth of next-generation business leaders by providing original ways to learn and gain management experience outside daily work.

### Support for Overseas Study

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

## Developing Workforce Diversity

### Promoting Women in the Workplace

At Nippon Shinyaku, promoting increased activity by women is an important aspect of the company’s mission. We are working to prepare an environment and create opportunities for growth so that women who, due to various circumstances, are hesitant about their next actions can step boldly forward.

In fiscal 2019, External Director Miyuki Sakurai organized a roundtable meeting with female managers to discuss the promotion of women in the workplace. Participants talked about the need to be aware of unconscious bias at the organizational and personal levels. Varied opinions were



Meeting involving External Director Sakurai and female managers



A disabled employee at work

offered, suggesting that unconscious bias can manifest in relation not only to gender, but also to age and different aspects of workplace culture. The conclusions from the meeting were shared via an internal publication to help build greater awareness of these issues among individual employees.

Going forward, as part of creating a diverse, capable workforce, Nippon Shinyaku remains committed to promoting workplace diversity, including greater promotion of women.

### Hiring Employees with Disabilities

Operating on the belief that proactively hiring employees with disabilities is one of the social responsibilities incumbent upon us as a corporation, Nippon Shinyaku is working toward expanding employment and creating new job opportunities based on the principle of inclusion. On the subject of expanding employment, we have been collaborating with a special-needs support school since fiscal 2007, offering a dual system of study while working\*. In fiscal 2019, we gave students from a special-needs support school in Kyoto the chance to support the Nippon Shinyaku amateur baseball team at the 45th National Championship of the Japan Amateur Baseball Association. The passion shown by players, cheerleaders and spectators alike made this a great social event with a special atmosphere.

To expand job opportunities for employees with disabilities, we are trying to simplify and standardize various routine tasks so this work can be included within their roles, in some cases by utilizing work-sharing. We also have consultants stationed in the workplace to help promote an environment where those with disabilities can work productively side by side with colleagues in a good work environment.

Since the enactment in April 2016 of the Act on the Elimination of Discrimination against Persons with Disabilities and Revised Act on Employment Promotion, etc., of Persons with Disabilities, we have taken steps to eliminate obstacles to persons with disabilities in the workplace.

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

As well as proactively hiring people with disabilities, at Nippon Shinyaku we also provide our workplace as a venue for work experience and practical training, in collaboration with employment transfer support offices and administrative organs. By offering workplace tours and sharing successful case studies involving the employment of persons with disabilities, we seek to ensure that our know-how can also be of use to society as a whole.

\* A training system that combines corporate internship with education at a special-needs support school

### Reemployment of Retired Workers

Nippon Shinyaku has adopted a continuing employment system (that is, reemployment system) allowing continued work until age 65. This system takes in workers again after they have left the company, to leverage their experience, techniques, and skills on behalf of the company. The system offers both full-time and part-time employment, in accordance with employees’ wishes. Those re-entering the company under this system go about their day-to-day duties having set their own goals in accordance with the objectives of the workplace as a whole, and progress toward those goals is rewarded appropriately, for example in the next year’s salary.



Initiatives for Society

# Occupational Health and Safety (OH&S) and Health Management

## Basic Stance on Occupational Health and Safety

To ensure workplaces are comfortable and provide conditions that will safeguard employee health and safety, we work to prevent workplace accidents or injuries as part of maintaining OH&S, including upgrading systems and having OH&S committees.

Besides basic OH&S activities, our approach is also to address OH&S issues from a health and productivity management perspective. This means that we ensure the physical and mental health and safety of everybody in the workplace while aiming to create a rewarding working environment.

## Mental Healthcare

Nippon Shinyaku has utilized an externally developed Employee Assistance Program (EAP) to support early detection, prevention and treatment of mental health issues since March 2003. Based on an annual evaluation, this program complies with the mandatory Stress Check Program introduced in Japan in 2015. In fiscal 2019, we also began offering an on-site counselling service to help workers communicate any concerns, while stationing mental health professionals at worksites to provide support. Going forward, we will continue to fine-tune our approach to mental health management.

## Basic Stance on Health Management

The Health Declaration issued by the President of Nippon Shinyaku in October 2018 committed the company to actively maintaining the health of all employees and supporting family members, based on management of the workplace environment and working conditions through a health management approach.

OH&S initiatives to date have included measures to reduce excessive working hours, support early mental healthcare interventions, and revise workstyles. Initiatives were upgraded with the issuance of the Health Declaration. Nippon Shinyaku was featured in the Certified Health and Productivity Management Organization Recognition Program in 2019 and 2020, gaining selection as a White 500 company in the 2019 program.

Our fundamental belief is that employees and their families should enjoy good physical and mental health, leading to a workplace that overflows with smiles and vitality.

At Nippon Shinyaku, we want employees to help support the welfare of the company by pursuing better individual health and happiness, coupled with active engagement (a sense of attachment and belonging, an understanding of the direction of the company, and a shared desire to act).



## Health Management Promotion System

Beyond making it an easy place to work, the true goal of health management at Nippon Shinyaku is to create a motivating workplace where people are naturally smiling and happy to work.

Since April 2019, we have established the Health Promotion Office to plan and execute measures to maintain and promote health in cooperation with the OH&S committees across the Group, OH&S physicians, and the Health Management Working Group (working in partnership with the health insurance association and labor unions).



## Specific Health Management Initiatives

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

Name of initiative	Outline
<b>1 Improving health literacy</b>	
Campaign to undertake "Health Challenge"	To help achieve better health outcomes by altering lifestyle habits in an enjoyable manner, we are enrolling employees in the "Health Challenge" program* offered by Tokio Marine & Nichido Medical Service Co., Ltd. * A self-selected 10-part program with challenges such as quitting smoking, drinking less, or walking
Group walking events (organized by Kencom)	These events encourage people to team up with work colleagues, other club members, friends or other fellow workers to compete for 2 kg bags of rice as prizes awarded to each member of teams achieving average daily step counts of at least 8,000.
RIZAP health seminars	Based on the wellness program offered by RIZAP Co., Ltd., this initiative includes seminars and body composition tracking to help promote health awareness and improve lifestyle habits. 
Introduction of "smart meals"	We introduced "smart meals" at our Head Office canteen to provide more nutritionally well-balanced menu choices for employees interested in adjusting daily dietary habits to their physical condition. 
Seminar on combating effects of aging	A seminar was organized with the Functional Food Division entitled, "Creating a Younger Body Using Anti-Glycation Products." The seminar was combined with separate checks on personal glycation levels and vegetable intake (by Kagome Co., Ltd.). 
Stay-at-home promotion measures	As part of our internal information dissemination efforts to help prevent the spread of COVID-19, we provided a range of information to help employees doing telework stay healthy, including ways to relieve stress, keep exercising, stay connected and eat correctly, among other stay-at-home lifestyle tips. While preventing the spread of infection, this information also helped to promote better health.
Lecture on presenteeism	We invited an outside medical expert to give a lecture on presenteeism* and the connection between sleep and higher productivity at work. * Presenteeism causes lower employee productivity due to health issues.
<b>2 Support for quitting smoking</b>	
Quit smoking support measures	One of our workplace health management goals is to help all employees quit smoking by the end of September 2022. From October 2020, smoking on Nippon Shinyaku premises is completely banned. This has also been reflected in flextime systems.



Initiatives for Society

# Workplace Reforms

## Medium-term Management Plan Policy

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

### Flextime system

We introduced a flextime system for MRs in January 2018. This enables more flexibility in organizing preschool drop-offs or pick-ups, or caring for sick children. The feedback has been positive, with many people reporting it allows easier switching between on/off work modes and more effective use of private time to do housework, attend the gym, or pursue other activities to keep healthy. To help make workstyles more compatible with different lifestyles, we extended the flextime system to all\* of Nippon Shinyaku from October 2019.

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

### Telework system

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

From April 2019, we extended the system to allow flextime workers to work from home or a rented conference facility under circumstances where it is difficult to commute to the designated workplace due to bad weather, suspension of public transport, illness or injury, childcare commitments, or the need to take an elderly relative to hospital. Going forward, we plan to further revise the conditions to facilitate more remote working irrespective of location.

## TOPICS

### Telework even for new graduate hires

The ceremony to welcome 67 new graduates to the Company was held on April 1, 2020, with everyone wearing face masks and hands sanitized. To help prevent COVID-19 spread, all new employees started teleworking from the following day, using work PCs provided to enable teleconferencing as well as access to the Internet and Company intranet. After their induction training, graduate hires are assigned to training or to work duties in their allocated sections.

With the declaration of a state of emergency extending telework arrangements, it was vital to support new graduate hires with constant communication as they adjusted to their new roles in society. Besides traditional email and phone, we used new communication methods such as business chat tools to support closer ties with superiors, work colleagues and HR support personnel, thereby helping to relieve any stress felt by new employees.

# Responsible Procurement

## Basic Rationale

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

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

## Responsible Procurement Guidelines

### Stringent legal compliance

Nippon Shinyaku complies with all relevant legislation (Antimonopoly Act, Subcontract Act, Unfair Competition Prevention Act, etc.) and industry and internal rules, also refraining from making unreasonable demands or taking unfair advantage.

### Confidentiality

We take thoroughgoing measures to prevent leaks of confidential information concerning business partners, also eschewing fraudulent transactions.

### Equitable business practices

In our dealings with all business partners, Nippon Shinyaku offers transparent, fair, and equitable transactions based on free competition principles.

### Rational selection of suppliers

Nippon Shinyaku chooses its suppliers by taking comprehensive account of factors including management stability, the quality and prices that they offer, their development prowess, their social credibility, and their concern for the environment.

### Consideration for the environment

We comply with laws and regulations pertaining to the environment and undertake environmentally friendly procurement in adherence to our Basic Environmental Policy.

## Framework for Supplying Products

We have put in place a framework to secure the rapid and stable supply of high-quality pharmaceuticals through the use of sophisticated supply chain management (SCM), from production and quality control through to logistics management.

Our diverse initiatives in this area include efforts to reduce lead times by enhancing the efficiency of our overall production process including quality control processes, and regularly evaluating our suppliers to encourage improvement.

## Framework for supplying products

### SCM supply Chain Management



## Activities in Fiscal 2019

Since fiscal 2013, as part of the responsible procurement program, Nippon Shinyaku has conducted a Responsible Procurement Survey of major domestic and overseas suppliers on a biannual basis.

Initiated as a supplier evaluation project, this became the Responsible Procurement Survey in fiscal 2017. Besides compliance status and consideration for the environment, the survey covers procurement reliability issues such as supply continuity preparedness, compliance with product quality and delivery standards, and production capacity.

The survey response rate in fiscal 2019 was over 90%. Survey results have been used to work with suppliers to implement a range of responsible procurement initiatives, including measures to safeguard continuity of supply.

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



Initiatives for Society

# Social Contribution Activities

Please refer to our website for further details.  
<https://www.nippon-shinyaku.co.jp/english/csr/#contributions>



## Basic Concepts

Besides its core mission of supplying the world with high-quality medicines as a manufacturer of pharmaceuticals, Nippon Shinyaku is committed to fulfilling its role as a corporate citizen to help local and regional communities. Our activities to enrich community life include providing support for non-profits; sponsoring sporting and cultural events; and opening a botanical research institute and other in-house facilities to the public. In addition, we fund public research grants in a bid to foster scientific developments in the fields of medicine and pharmacology.

### For the Next Generation

We are engaged in various activities designed to support future generations, including the Nippon Shinyaku Children's Literary Awards and the Nippon Shinyaku Sparkling Future Mobile Library.

Designed to commemorate our 90th anniversary, the Nippon Shinyaku Children's Literary Awards were established in 2009 with the support of the Japan Juvenile Writers Association as a way of inspiring the dreams and nurturing the spirits of children through picture books. Awards are made in the two categories of stories and artwork, and the two first-prize winners collaborate to produce a picture book with a print run of 30,000 copies. The books are distributed to children nationwide through medical institutions such as children's hospitals and via public facilities. They can also be viewed on the Nippon Shinyaku website.

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

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



Nippon Shinyaku Sparkling Future Mobile Library

### Public Research Grant Scheme

As part of our centenary celebrations, Nippon Shinyaku initiated a "Public Research Grant Scheme" to contribute to the advancement of science in medical and pharmacological fields in which the company is active. Under the scheme, we aim to support young researchers by offering grants to successful applicants. With the second round of grants for fiscal 2020, we sought applicants to perform fundamental research in two fields: hematopoietic tumors and pulmonary hypertension. After rigorous examination by an external review committee, we awarded grants to six projects in the field of hematopoietic tumors and four in the field of pulmonary hypertension.

### Activities to Preserve and Maintain the Culture of Kyoto

For more than half a century, each year Nippon Shinyaku has produced calendars with pictures made using *Katazome*, a traditional local stencil dyeing technique. The calendars feature Kyoto's seasonal scenery, customs, and historical events. We also publish a quarterly PR magazine entitled "Kyo" to showcase the huge appeal of Kyoto—from the city's many shrines, temples and other cultural assets to its cuisine and local produce.



Calendar and quarterly magazine "Kyo"

### Supporting Education through Sports

Working with governments at the municipal and local level and baseball associations, the Nippon Shinyaku amateur baseball team offers baseball clinics for elementary, junior and senior high school students in places including Kyoto (head office), Odawara (factory) and Kushimoto, Wakayama Prefecture (training facility). These events improve the baseball skills and strength of children while fostering interaction with local communities.



Children's baseball clinic

# Stakeholder Engagement

## Basic Concepts

Nippon Shinyaku conducts business with the support of various stakeholders. At Nippon Shinyaku, we consider it important to listen closely to and engage in dialog with all our stakeholders, from patients to business partners, users, shareholders and investors, employees, community groups and environment. By incorporating in our business activities the information we thus glean on stakeholders' opinions and needs, we seek to grow the company while also creating and providing new value to society.

<p><b>Patients</b></p>	<p><b>Policy</b> In the Pharmaceuticals business, our emphasis is first and foremost on patients suffering from illnesses. To ensure that medical professionals deliver the appropriate medication to patients, we train employees working as medical representatives to arm them with knowledge concerning our products, and means for conveying that information. We also provide patients with information concerning various diseases via our website and smartphone apps, as well as through public lectures.</p> <p><b>Engagement</b></p> <ul style="list-style-type: none"> <li>• <b>Disease awareness-raising via website</b> Pulmonary arterial hypertension (PAH), alcohol dependence, Duchenne muscular dystrophy (DMD), period pain, erectile dysfunction and its treatments, hay fever and allergic rhinitis</li> <li>• <b>Patient education via smartphone apps</b> PAH Care Notebook for PAH patients</li> <li>• <b>Inquiries regarding medicines</b> Healthcare consumers, <b>1,950</b>; healthcare professionals, <b>13,791</b>; other, <b>116</b></li> </ul>
<p><b>Business partners</b></p>	<p><b>Policy</b> Through relationships based on mutual trust, we aim to maintain healthy and proper dealings with business partners, so that we can grow together. We established Responsible Procurement Guidelines under which we engage in CSR procurement together with business partners in order to fulfill our social responsibilities.</p>
<p><b>Users</b></p>	<p><b>Policy</b> In the Functional Food business, we draw on our technical prowess as a pharmaceutical company to provide high-value-added products addressing market needs.</p> <p><b>Engagement</b></p> <ul style="list-style-type: none"> <li>• <b>Glycative Stress Research Laboratory website on glycation in the body and Advanced Glycation End-products (AGEs): Updated as necessary</b></li> <li>• <b>Nippon Shinyaku Official Healthcare Shop for online sales of supplements: Updated as necessary</b></li> <li>• <b>Booths at domestic marathon competitions and sports events: 17 times in fiscal 2019</b></li> </ul>
<p><b>Shareholders and Investors</b></p>	<p><b>Policy</b> We strive to return profits to shareholders by securing reasonable returns via capital-conscious management, while also promoting timely and fair disclosure of company information alongside proactive dialog.</p> <p><b>Engagement</b></p> <ul style="list-style-type: none"> <li>• <b>Individual meetings with institutional investors and analysts (roughly 150 in fiscal 2019)</b></li> <li>• <b>Results briefings (in May and November)</b></li> <li>• <b>Earnings calls (in August and February)</b></li> <li>• <b>General Meeting of Shareholders (in June)</b></li> <li>• <b>Delivery of information via IR site and response to inquiries (as needed)</b></li> </ul>
<p><b>Employees</b></p>	<p><b>Policy</b> In line with our management policy of developing each employee, we offer education and training programs aimed at cultivating employees capable of always thinking critically and taking necessary action on their own. We think that employees who think and act on their own and actively take on challenges will experience personal growth that flows through to growth for the company.</p> <p><b>Engagement</b></p> <ul style="list-style-type: none"> <li>• <b>Participant numbers for various training programs in fiscal 2019</b>  <ul style="list-style-type: none"> <li>• Training for newly hired employees: 66</li> <li>• Training for newly promoted employees: 174</li> <li>• Training for executives: 32</li> <li>• Training for newly appointed managers: 38</li> <li>• "Brother" training: 66</li> <li>• Next-Generation Leader Development Program: 13</li> <li>• English-language training for elite employees: 8</li> </ul> </li> <li>• <b>Ratio of employees with disabilities: 2.37%</b> * Ratio based on number of employees with disabilities as of June 1, 2020.</li> </ul>
<p><b>Community Groups and Environment</b></p>	<p><b>Policy</b> As a corporate citizen, we closely communicate with and engage deeply with society, and actively pursue socially beneficial initiatives. In addition, we seek to secure growth in harmony with the environment, by engaging in business activities that are friendly to the global environment and pursuing initiatives that conserve, maintain, and improve the environment.</p> <p><b>Engagement</b></p> <ul style="list-style-type: none"> <li>• <b>Social contribution activities</b> (Nippon Shinyaku Children's Literary Awards, Nippon Shinyaku Sparkling Future Mobile Library, Smiles Art Project, Yamashina Botanical Research Institute tours/seminars, children's baseball clinics hosted by Nippon Shinyaku amateur baseball team, environmental instruction for elementary school students, Yancha Fiesta, etc.)</li> <li>• <b>Contributions in medical field</b> (accepting applications for public research grants)</li> </ul>

GOVERNANCE

Corporate Governance

Basic Concepts

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

The Corporate Governance Basic Policy was instituted on December 15, 2015, and sets forth our basic concepts of corporate governance. The Policy was revised on December 17, 2018.

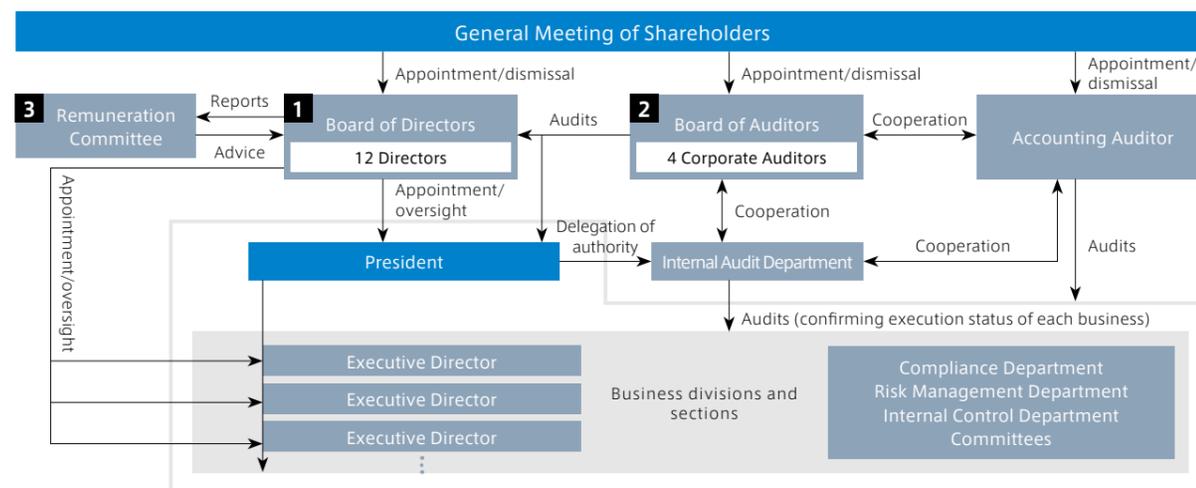
Corporate Governance Basic Policy  
[http://www.nippon-shinyaku.co.jp/english/img/company\\_profile/CorporateGovernanceBasicPolicy\\_December17\\_2018.pdf](http://www.nippon-shinyaku.co.jp/english/img/company_profile/CorporateGovernanceBasicPolicy_December17_2018.pdf)

Steps taken to strengthen corporate governance

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

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

Organization for Corporate Governance

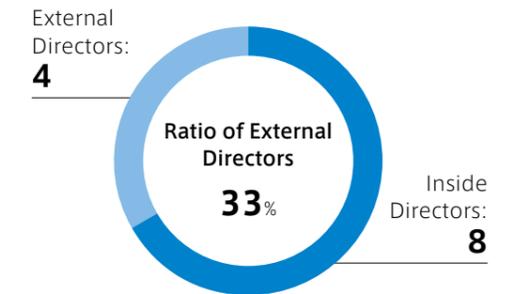


The following items are posted on our website. [https://www.nippon-shinyaku.co.jp/english/company\\_profile/governance.php](https://www.nippon-shinyaku.co.jp/english/company_profile/governance.php)  
 • Corporate Governance Report • Corporate Governance Basic Policy



1 Board of Directors

Role	<ul style="list-style-type: none"> <li>Ensures business fairness and transparency through general management oversight.</li> <li>Makes decisions in the best interests of the Company by (1) setting policies governing the appointment/dismissal of directors and auditors using procedures that are objective, timely and transparent, based on findings of the Nominating Committee; (2) evaluating the serious risks facing the Company and formulating related countermeasures; and (3) making important business decisions.</li> </ul>
Meeting frequency	Monthly; extraordinary sessions if required 12 meetings held in fiscal 2019
Attendees	All directors and auditors



External Directors: Appointment Rationale and Main Activities

Name	Reasons for Appointment	Attendance at Board of Directors meetings (Fiscal 2019: meetings attended / meetings held)
Yukio Sugiura	Appointed because he offers advice to management from a practical perspective, based on his expertise and insight from an independent standpoint as a pharmacologist.	(12/12)
Hitoshi Sakata	Appointed because he offers advice to management from a practical perspective, based on his expertise and insight from an independent standpoint as a lawyer.	(12/12)
Miyuki Sakurai	Appointed because she offers advice to management from a practical perspective, based on her expertise and insight from an independent standpoint as a lawyer.	(12/12)
Yoshinao Wada	Appointed because he offers advice to management from a practical perspective, based on his expertise and insight from an independent standpoint as a physician.	(10/10)

Analysis/evaluation of effectiveness of the Board of Directors

Frequency	Annual
Methodology	Self-evaluation survey completed by all directors
Content	The Board's effectiveness in discussing and deciding issues was determined by asking each director if they actively voice their opinion; if discussions are conducted based on multi-faceted, wide-ranging perspectives; if debate is free and constructive; and if the discussions support appropriate decisions by management.

Results of fiscal 2019 evaluation: As previously, the survey confirmed that all Board members believe that meetings provide the opportunity to actively voice opinions; to engage in free, constructive debate based on multi-faceted, wide-ranging perspectives; and that the discussions support appropriate management decisions. This result indicates the Board of Directors is broadly effective.

2 Board of Auditors

Role	<ul style="list-style-type: none"> <li>Provides corporate oversight in coordination with the Board of Directors, supporting the corporate governance system by supervising the actions of the Board as an independent entity accountable to shareholders.</li> <li>Based on its specialized knowledge and vast experience, the Board of Auditors actively expresses opinions to the Board of Directors and management.</li> </ul>
Meeting frequency	Monthly; extraordinary sessions if required 16 meetings held in fiscal 2019
Attendees	All auditors



## GOVERNANCE

### Cooperation with Accounting Auditor

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

### Cooperation with Internal Audit Department

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

### External Auditors: Appointment Rationale and Main Activities

Name	Reasons for Appointment	Attendance at Board of Directors meetings (Fiscal 2019: meetings attended / meetings held)
Tsuyoshi Kondo	Appointed because he offers advice that will enhance management soundness and transparency while also improving compliance, based on his expertise and insight from an independent standpoint as a lawyer.	(12/12)
Sumitaka Maruyama	Appointed because he offers advice that will enhance management soundness and transparency while also improving compliance, based on his expertise and insight from an independent standpoint as a licensed tax accountant.	(10/10)

### 3 Nominating Committee and Remuneration Committee

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

### Committee Composition

	Committee Name	All Committee Members	Full-time Members	Inside Directors	External Directors	Outside Experts	Other	Chairperson
Committee Corresponding to Nomination Committee	Nominating Committee	4	0	2	2	0	0	External Director
Committee Corresponding to Remuneration Committee	Remuneration Committee	4	0	2	2	0	0	External Director

### Training for Directors and Auditors

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

### Officers' Remuneration

#### Policy on Determining Remuneration Amounts and Calculation Methods

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

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

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

As of March 31, 2020

Officer category	Total remuneration (millions of yen)	Subtotals for each type of remuneration (millions of yen)		Number of recipients
		Fixed basic remuneration	Performance-linked remuneration	
Directors (excl. External Directors)	405	197	207	8
Auditors (excl. External Auditors)	34	34	—	3*
External Directors/Auditors	57	57	—	7

\* Includes directors who were in office between July 2018 and June 2019

### Internal Control System

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

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

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

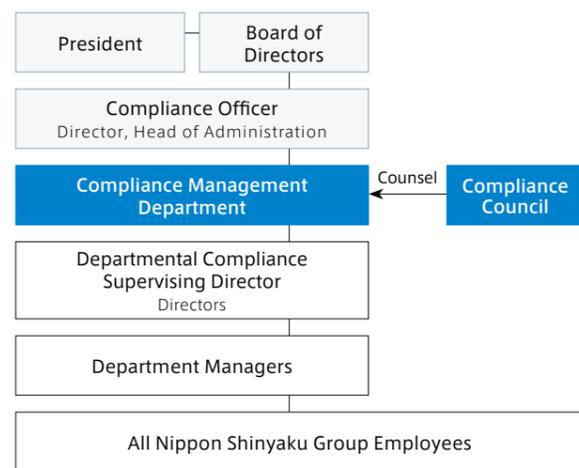
GOVERNANCE

# Compliance

## Framework for Compliance

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

### Compliance Framework Chart



## Compliance Initiatives

Groupwide compliance initiatives are planned, formulated and implemented by the Compliance Management Department, with input from the Compliance Council.

### Compliance Training in Fiscal 2019

Type of Training	Description
Departmental compliance training (monthly)	Departmental training incorporating company-wide content and department-specific content.
Training for new employees (April)	Training that focuses on teaching new employees about compliance concepts and approaches, and stressing the importance of compliance.
Training for mid-career recruits (as and when required)	Training covers compliance concepts and approaches for mid-career recruits.
Training for newly promoted managers (March, October)	Training that focuses on teaching compliance to newly promoted managers.
Enhanced Training (October–November)	Departmental compliance training (October) reinforced by e-learning (November), with main theme for fiscal 2019 as "prevention of workplace harassment."
Training on the Charter of Business Conduct for new employees (as and when required)	Enhancing understanding of and compliance with the Charter of Business Conduct.

The Information Service Supervisory Department was created in fiscal 2019. Messages from the President in April 2019 and October 2019 stressed the importance of raising compliance standards even higher. Related training and education activities (as outlined in the preceding table) were conducted throughout the year.

## Employee Hotline for Compliance Reporting

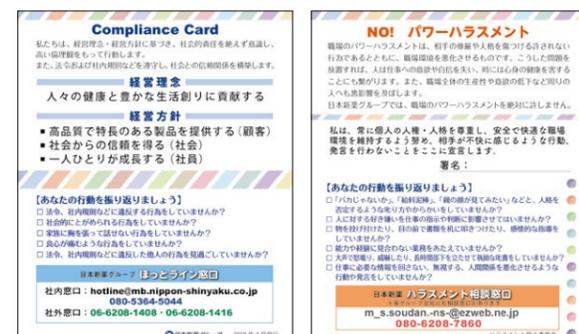
We operate an employee hotline for compliance reporting, so that any employee of Nippon Shinyaku or group companies can report on or discuss regulatory violations or other compliance issues, as a means of self-policing. We have set up hotline call centers both within and outside the company and these can be reached through a dedicated phone number or e-mail address, with guidelines in place to protect the privacy of reporting employees and to secure confidentiality.

Protections for whistleblowers are explicitly stated in the guidelines and all efforts are made to protect employees from subsequent transfers that are not in their best interests, or from any other prejudicial actions, so that the reporting system operates properly.

Furthermore, we regularly inform employees about the hotline for compliance reporting, in order to further spread awareness throughout our group companies.

## Education Initiatives

- Conducted e-learning concerning compliance for employees in their second year at the company.
- Winners of a Group-wide competition to create compliance slogans were recognized, with compliance education posters based on the slogans made for display in departments.
- Created compliance cards combined with safety contact cards and distributed these to new employees among others.



Compliance Card

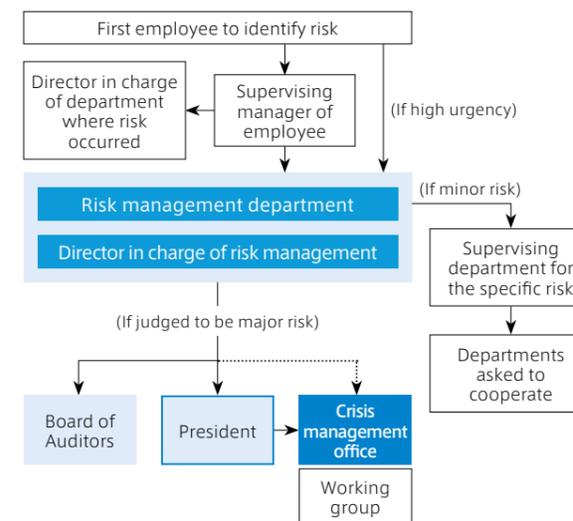
# Risk Management

## Framework for Risk Management

The Nippon Shinyaku Group has in place Basic Risk Management Rules for identifying underlying risks and aiding the departments responsible for each risk in formulating preventive policies as well as measures for responding when such situations arise. Additionally, each year we identify highly critical risks. In fiscal 2019, these included "cyberattacks," "information leakage," "disasters," "harassment," and "breaches of labor laws," which led us to strengthen controls and raise awareness. Furthermore, every year we conduct a self-check survey of all group employees for the purpose of verifying each individual's risk awareness.

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

### Path of Risk Notification (as of April 1, 2020)



## Initiatives for Information Security

Nippon Shinyaku has in place a basic policy and rules to guide our initiatives for information security. Our Information Security Management System (ISMS) Committee implements specific rules for information security, guided by the basic policy and rules.

We are also advancing technological measures tailored to advancements in IT and changes in society in order to

protect the Nippon Shinyaku Group's information assets from a variety of risks. At the same time, we have revised various company rules and continue to educate our employees so they thoroughly recognize the importance of information security, and also give training to guard against targeted e-mail attacks.

In fiscal 2019, we established the Security Operation Center (SOC) to undertake 24/7 surveillance of our networks and computer systems. Set up in fiscal 2018 in anticipation of cyberattacks, our NS-Computer Security Incident Response Team (NS-CSIRT) is also working to reinforce operating systems through training. Constant efforts are being made to strengthen our information security.

(N/A)



Training session by NS-CSIRT

## Prevention of workplace harassment

We treat harassment as a serious issue that disrespects individuals and infringes upon their human rights. Besides establishing the Harassment Prevention Committee to help prevent workplace harassment of any kind and maintain a good working environment, we have formulated the Group Harassment Prevention Rules. Various activities during the year support compliance with these rules, including compliance and manager training programs and the distribution to all employees of anti-harassment policy pamphlets and portable awareness cards.

## Disaster Countermeasures (Formulating a BCP)

To ensure uninterrupted supply of medicines to patients in emergency situations such as earthquakes, storms, floods or other natural disasters, we have formulated a Business Continuity Plan (BCP) to keep our factory at Odawara running even after an earthquake measuring six or higher on Japan's seismic scale. We revise the BCP every three years, most recently in fiscal 2018. We are also committed to promoting disaster readiness through BCP-related activities such as the reinforcement of support ties with inventory storage facilities and partner companies.

In response to the COVID-19 pandemic, we have created a crisis management office in line with our Basic Risk Management Rules. Our response includes varied measures such as the promotion of telework arrangements.

GOVERNANCE

## Messages from External Directors

The four Nippon Shinyaku external directors share their thoughts on the challenge of developing sustained growth in a rapidly moving business environment, as well as related issues and expectations.



**Yukio Sugiura**  
External Director

### Ensuring stable management and strong profitability

The coronavirus crisis has led efficiency-minded firms to reconsider the value of flexibility. As an external director, I see it as my job to watch where the company should be going while also striving to improve corporate governance to contribute to the growth of Nippon Shinyaku's enterprise value.

With a history of more than a century, I trust Nippon Shinyaku has a clear future direction that is based on its strengths and position. It is a wonderful achievement to have launched the first treatment in Japan for Duchenne muscular dystrophy. One advantage of nucleic acid drugs is that it is possible to develop them quickly once the development framework is complete, even if the drug discovery target changes. Another is that the unique mechanism of action enables more unmet medical needs to be satisfied by widening the scope of the drug discovery program. I see Nippon Shinyaku creating new value as a global player in the nucleic acid medicine field.

A constantly regenerating development pipeline of innovative in-house drugs will be essential to ensure stable management and strong profitability going forward. To this end, I want us to build the systems and framework needed to promote further open innovation, make best use of human capital, and react to changing conditions.



**Hitoshi Sakata**  
External Director

### Contributing to balanced management that focuses on the value inherent in the protection of human health and lives

Creating innovative drugs has always been Nippon Shinyaku's core mission. In fiscal 2019, we made huge strides in the U.S. towards overcoming intractable and rare diseases. This was arguably the first step towards our goal of helping people lead healthier and happier lives across the world. All employees must work hard if we are to realize this ideal in the future.

The COVID-19 global pandemic has led to major disruption in 2020, and there are many enterprises left threatened. Have companies done enough to protect the lives, health and property of employees and other stakeholders in this crisis? Maximizing the value of shares was held in high regard by society, but has proved powerless in the middle of a pandemic.

In such a challenging situation, my role as an external director is to ensure proper, transparent business execution and to help enhance management efficiency. In addition, I aim to contribute to balanced management that focuses on the value inherent in the protection of human health and lives.



**Miyuki Sakurai**  
External Director

### Huge growth potential from harnessing the Group's capabilities

Whether we like it or not, the coronavirus pandemic has overturned all our previous assumptions, creating an unprecedented challenge. Part of Nippon Shinyaku's response has been to revise the BCP from various angles while introducing reforms such as remote working support to allow more diverse work styles. I think we need to see this situation as a critical opportunity for positive change. My duty as an external director is to continue communicating proactively, based on my experience.

"Creation of an organizational climate in which every employee can flourish" is one of the six Medium-term Management Plan actions for Nippon Shinyaku, with an emphasis on HR development policies. As part of the growth strategy, it is vital that we develop good leadership within the ranks of middle management to ensure all employees are happy and motivated to work hard. Only then can we harness the efforts of everyone within the Group.

At the same time, it is important that we create a continuous stream of innovative drugs of high quality and differentiability while also expanding the global business. Under the strong leadership of President Maekawa, I expect the Group to achieve significant growth based on superior drug R&D and production capabilities, backed up by sales and marketing, supply chain and integrated management expertise.



**Yoshinao Wada**  
External Director

### Building the next-generation Nippon Shinyaku

My impression from my first year as an external director of Nippon Shinyaku is that the Board of Directors does function effectively. A great example of this was one agenda item where the on-the-ground research was adequate, but we ended up rejecting the proposal by discussing it from a standpoint of the future challenges that Nippon Shinyaku faced.

With the COVID-19 outbreak spreading rapidly in society and magnifying the risk of mental health deterioration, colleagues and superiors can have less opportunity to check on fellow workers. I will do what I can as an external director to see that we maintain both the quality and quantity of communications so that we can make our work more efficient while ensuring that employees stay smiling and focused on the opportunities of reform and growth.

The core therapeutic area of intractable and rare diseases is a potential source of new enterprise value creation for Nippon Shinyaku. For example, gene therapies will demand novel marketing strategies, since the conditions defy categorization along the traditional lines of neurology, metabolic disorders, endocrinology or immunology. Our goal is to make people associate Nippon Shinyaku automatically with gene therapy so we can gain first mover's advantage in the field. I expect this to be a major element in building the next-generation Nippon Shinyaku.

GOVERNANCE

Board of Directors, Corporate Officers and Corporate Auditors



**Shigenobu Maekawa**  
President

1976 Joined Nippon Shinyaku Co., Ltd.  
1992 Temporarily transferred to Japan Federation of Employers' Associations (now Keidanren (Japan Business Federation))  
2002 Department Manager, Corporate Planning Dept., Corporate Strategy Office  
2004 Corporate Officer  
2005 Director  
2005 Head of Corporate Planning, Finance & Accounting, and Information System; Department Manager, Corporate Planning Dept.  
2006 Managing Director  
2007 Head of Corporate Planning, Finance & Accounting, and Information System  
2007 President (current position)

Attendance at board meetings (FY2019): 12/12



**Akira Matsuura**  
Managing Director  
Head of R&D

1988 Joined Nippon Shinyaku Co., Ltd.  
2004 Department Manager, Chemical Research Dept., Discovery Research Labs., R&D  
2007 Department Manager, Discovery Research Labs., Medicine Development Center, R&D  
2008 Corporate Officer; Department Manager, Discovery Research Labs., R&D  
2010 Director  
2010 Head of R&D (current position)  
2016 Managing Director (current position)

Attendance at board meetings (FY2019): 12/12



**Shouzou Sano**  
Managing Director  
Head of Sales and Marketing

1984 Joined Nippon Shinyaku Co., Ltd.  
2008 Department Manager, Saitama Business Office, Sales and Marketing  
2010 Corporate Officer; Department Manager, Osaka Business Office, Sales Promotion Div., Sales and Marketing  
2013 Corporate Officer; Head of Tokyo Area Div., Sales and Marketing  
2015 Corporate Officer; Head of Sales and Marketing  
2015 Director  
2015 Head of Sales and Marketing (current position)  
2019 Managing Director (current position)

Attendance at board meetings (FY2019): 12/12



**Hitoshi Sakata**  
External Director

1985 Registered with Kyoto Bar Association  
1989 Joined Inoue Sakata Law Office  
1995 Partner, Oike Law Office (current position)  
1998 Vice President, Kyoto Bar Association  
2010 Guest researcher, Faculty of Law, University of Cambridge  
2011 Professor, Doshisha Law School, Graduate School of Doshisha University  
2013 Director (current position)  
2016 Outside Auditor, Kyocera Corporation (current position)

Attendance at board meetings (FY2019): 12/12



**Miyuki Sakurai**  
External Director

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

Attendance at board meetings (FY2019): 12/12



**Yoshinao Wada**  
External Director

1975 Joined Osaka University Hospital  
1981 Department of Obstetric Medicine, Osaka Medical Center for Maternal and Child Health  
1989 Obtained the degree of Doctor of Medicine (Osaka University)  
1991 Head, Department of Molecular Medicine, Research Institute, Osaka Medical Center for Maternal and Child Health  
1998 Director, Research Institute, Osaka Medical Center for Maternal and Child Health  
2011 Director, Department of Obstetric Medicine; Director, Research Institute  
2014 Chief Director, Department of Obstetric Medicine; Director, Research Institute, Osaka Medical Center for Maternal and Child Health  
2016 Part-time physician, Department of Obstetric Medicine, Osaka Medical Center for Maternal and Child Health  
2017 Part-time physician, Department of Obstetric Medicine, Osaka Women's and Children's Hospital (current position)  
2018 Visiting Professor, Yokohama City University  
2019 Director (current position)

Attendance at board meetings (FY2019): 10/10



**Hitoshi Saito**  
Director  
Head of Resource Procurement, Production & Assurance

1978 Joined Nippon Shinyaku Co., Ltd.  
2005 Department Manager, Sourcing & Purchasing Dept., Manufacturing Management & Material Procurement Center  
2008 Department Manager, R&D Administration Dept., R&D Administration Div., R&D  
2010 Corporate Officer; Head of R&D Administration Div., R&D  
2014 Director (current position)  
2014 Head of Resource Procurement, Production & Assurance (current position)

Attendance at board meetings (FY2019): 12/12



**Kenro Kobayashi**  
Director  
Head of Functional Food

1982 Joined Nippon Shinyaku Co., Ltd.  
2007 Department Manager, Kyoto Business Office, Sales and Marketing  
2010 Corporate Officer; Department Manager, Nagoya Business Office, Sales Promotion Div., Sales and Marketing  
2013 Corporate Officer; Head of Kinki Tokai Div., Sales and Marketing  
2015 Corporate Officer; Deputy Head of Functional Food  
2015 Director (current position)  
2015 Head of Functional Food (current position)

Attendance at board meetings (FY2019): 12/12



**Takashi Takaya**  
Director  
Head of Administration

1984 Joined Nippon Shinyaku Co., Ltd.  
2005 Department Manager, Marketing Dept., Sales and Marketing  
2009 Department Manager, Marketing Dept., Sales and Marketing Planning Div., Sales and Marketing  
2010 Department Manager, Marketing and Planning Dept., Sales and Marketing Planning Div., Sales and Marketing  
2011 Head of Sales and Marketing Planning Div., Sales and Marketing  
2012 Corporate Officer; Head of Sales and Marketing Planning Div., Sales and Marketing  
2018 Director (current position)  
2018 Head of Administration (current position)

Attendance at board meetings (FY2019): 12/12



**Morio Matsuura**  
Standing Corporate Auditor

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

Attendance at board meetings (FY2019): 10/10



**Kenji Kuwabara**  
Standing Corporate Auditor

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

Attendance at board meetings (FY2019): 10/10

Corporate Officers

**Taro Sakurai**  
Department Manager, Finance & Accounting Dept.

**Hirokata Harada**  
Head of Medical Affairs Div.

**Koji Honma**  
Department Manager, Personnel Dept.

**Hideki Sasaki**  
Department Manager, Odawara Central Factory

**Hiromu Nakajima**  
Chief Medical Officer

**Kazuya Mori**  
Head of R&D Administration Div.

**Kazuchika Takagaki**  
Department Manager, Discovery Research Labs.

**Hitoshi Ishizawa**  
Department Manager, Osaka Business Office

**Hayato Wada**  
Department Manager, Tokyo Business Office

**Noboru Nishikawa**  
Head of Sales and Marketing Planning Div.

**Masaya Toda**  
Head of Licensing & Alliance Div.

**Kazuyuki Yamate**  
Department Manager, Corporate Planning Dept.

**Masafumi Taira**  
Head of Clinical Development Div.

**Mitsuharu Koizumi**  
Department Manager, Nagoya Business Office



**Takanori Edamitsu**  
Director  
Head of Business Management

1989 Joined Nippon Shinyaku Co., Ltd.  
2011 Department Manager, Corporate Planning Dept.  
2013 Corporate Officer; Department Manager, Corporate Planning Dept.  
2018 Director (current position)  
2018 Head of Business Management (current position)

Attendance at board meetings (FY2019): 12/12



**Toru Nakai**  
Director  
Head of Global Business

1995 Joined Nippon Shinyaku Co., Ltd.  
2016 Department Manager, Business Planning Dept.  
2018 Transferred to U.S. subsidiary NS Pharma, Inc.  
2019 Head of Global Business Div. (NS Pharma, Inc.)  
2019 Director (current position)  
2019 Head of Global Business (current position)

Attendance at board meetings (FY2019): 10/10



**Yukio Sugiura**  
External Director

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

Attendance at board meetings (FY2019): 12/12



**Tsuyoshi Kondo**  
External Auditor

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

Attendance at board meetings (FY2019): 12/12



**Sumitaka Maruyama**  
External Auditor

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

Attendance at board meetings (FY2019): 10/10

# Ten-Year Summary

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

(FY)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2019
<b>For the year</b>										Millions of Yen	Thousands of U.S. Dollars
Net sales	63,525	67,304	69,941	76,517	79,991	84,209	98,781	101,448	114,716	116,637	1,070,064
Pharmaceuticals	52,554	55,746	58,318	63,345	66,340	70,489	85,315	87,416	100,223	101,643	932,504
Functional food	10,970	11,558	11,622	13,172	13,651	13,720	13,466	14,031	14,492	14,994	137,559
Cost of sales	30,218	32,702	34,776	39,033	41,226	44,016	44,835	46,929	50,952	53,155	487,660
Gross profit	33,332	34,601	35,165	37,483	38,764	40,192	53,946	54,519	63,764	63,481	582,394
Total selling, general and administrative expenses	28,151	28,588	28,263	29,445	30,202	31,643	38,666	37,439	43,119	41,813	383,605
Selling, general and administrative expenses	19,184	19,174	19,214	19,914	21,233	21,904	23,762	24,217	26,418	27,819	255,220
R&D expenses	8,967	9,414	9,049	9,530	8,968	9,739	14,903	13,221	16,701	13,994	128,391
Operating income	5,181	6,012	6,901	8,038	8,562	8,549	15,280	17,079	20,644	21,668	198,788
Net income attributable to owners of the parent	3,958	3,715	4,647	5,750	5,882	6,340	11,749	12,953	16,302	16,866	154,733
Depreciation and amortization	3,116	2,948	2,759	2,704	2,665	2,452	2,648	2,773	3,418	3,468	31,816
Capital investment	1,185	967	1,332	1,072	1,239	3,554	3,949	2,811	1,242	2,500	22,935
Cash flows from operating activities	3,233	3,658	3,767	6,015	6,113	8,915	18,916	6,719	15,310	12,737	116,853
Cash flows from investing activities	(2,844)	(759)	(2,026)	(3,357)	(3,718)	(3,978)	(5,750)	(11,342)	511	(2,339)	(21,458)
Cash flows from financing activities	(1,393)	(1,341)	(1,413)	(1,606)	(1,773)	(1,907)	(2,193)	(3,787)	(3,708)	(5,660)	(51,926)
<b>End of the year</b>										Millions of Yen	Thousands of U.S. Dollars
Total assets	102,737	106,304	113,730	118,188	129,757	135,370	150,905	155,887	168,763	175,017	1,605,660
Interest-bearing debt	113	75	35	—	—	—	—	—	—	—	—
Net assets	81,692	84,566	89,529	93,186	101,207	102,762	114,316	125,689	135,190	145,760	1,337,247
<b>Financial information per share</b>										Yen	U.S. Dollars
Earnings per share	58.62	55.04	68.87	85.25	87.26	94.10	174.42	192.31	242.04	250.42	2.30
Net assets per share	1,207.43	1,250.11	1,323.87	1,378.93	1,498.88	1,522.33	1,693.81	1,862.54	2,003.39	2,160.11	19.82
Dividend per share	19	19	21	23	25	28	48	52	70	86	0.78
<b>Principal financial indicators</b>										%	%
Operating income to net sales	8.2	8.9	9.9	10.5	10.7	10.2	15.5	16.8	18.0	18.6	—
Equity ratio	79.3	79.4	78.5	78.7	77.8	75.8	75.6	80.5	80.0	83.1	—
Return on assets	5.0	5.8	6.3	6.9	7.0	6.5	10.8	11.2	12.7	12.6	—
Return on equity	4.9	4.5	5.4	6.3	6.1	6.2	10.8	10.8	12.5	12.0	—
Payout ratio	32.4	34.5	30.5	27.0	28.7	29.8	27.5	27.0	28.9	34.3	—

## Non-Financial Data

For further details, see  
[https://www.nippon-shinyaku.co.jp/english/csr/esg\\_data.php](https://www.nippon-shinyaku.co.jp/english/csr/esg_data.php)



### Environment

(FY)

	2015	2016	2017	2018	2019
<b>CO<sub>2</sub> emissions</b> (t-CO <sub>2</sub> )					
Main business locations*	10,059	10,165	10,609	10,129	9,435
Sales offices, etc.	2,697	2,772	2,705	2,509	1,783
<b>Supply chain emissions by scope</b> (t-CO <sub>2</sub> )					
Scope 1: Direct greenhouse gas (GHG) emissions from owned or controlled sources	—	—	—	—	5,063
Scope 2: Indirect emissions that occur through the use of purchased electricity, steam, and heat	—	—	—	—	6,155
Scope 3: Fuel- and energy-related activities not included in Scope 1 or Scope 2	—	—	—	—	1,019
Scope 3: End-of-life treatment of sold products	—	—	—	—	160
<b>Total energy consumption</b> (Thousands of GJ)					
Main business locations*	193	199	209	212	211
Sales offices, etc.	42	43	43	40	30
<b>Electricity</b> (1,000 kWh)					
Main business locations*	12,691	13,039	13,980	14,180	14,109
Sales offices, etc.	918	974	969	878	878
<b>City gas</b> (1,000 m <sup>3</sup> )					
Main business locations*	1,538	1,586	1,619	1,639	1,627
Sales offices, etc.	1	3	3	2	2
<b>Water</b> (1,000 m <sup>3</sup> )					
Main business locations*	246	266	275	204	182
<b>Waste substances generated</b> (t)					
Head Office area	204.1	258	229	184.9	177
Odawara Central Factory	189.7	135.2	246	315.3	282
Discovery Research Laboratories in Tsukuba	20.9	31.3	31.9	21.5	23
<b>Handling amount of PRTR-regulated Class I Designated Chemical Substances</b> (kg)					
Acetonitrile	3,383	5,611	5,124	6,930	3,558
Chloroform	250	196	218	305	344
Dichloromethane	1,682	1,705	2,420	2,256	3,004
N-hexane	2,278	2,801	2,722	2,492	1,983

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

### Social

(FY)

	2015	2016	2017	2018	2019
<b>Number of employees</b> (persons)					
Number of employees (parent company)	1,739	1,727	1,753	1,761	1,793
Number of female employees	480	478	488	494	516
Ratio of female employees (%)	27.6	27.7	27.8	28.1	28.8
Number of executives	577	555	566	555	554
Number of female executives	66	65	69	72	78
Ratio of female executives (%)	11.4	11.7	12.2	13.0	14.1
Number of managers	311	285	319	321	329
Number of female managers	18	14	17	25	32
Ratio of female managers (%)	5.8	4.9	5.3	7.8	9.7
Number of recruits	79	68	74	72	79
Number of female recruits	23	24	22	25	28
Ratio of female recruits (%)	29.1	35.3	29.7	34.7	35.4
Average number of years of service of female employees (years)	18.0	17.3	17.4	17.3	18.1
Average number of years of service of male employees (years)	17.8	17.4	17.6	17.5	17.7
Difference in average length of service for female and male employees (years)	0.2	-0.1	-0.2	-0.2	0.4
<b>Compliance training</b> (times)					
Departmental compliance training	12	12	12	12	12
Training for new employees	1	1	1	1	1
Training for newly promoted managers	2	2	2	2	2

### Governance

(FY)

	2015	2016	2017	2018	2019
<b>Number of directors</b> (persons)					
Number of external directors	9	9	10	12	12
Number of female directors	2	2	3	4	4
Ratio of female directors (%)	0	0	1	1	1
Ratio of female directors (%)	0	0	10	8	8
<b>Number of auditors</b> (persons)					
Number of external auditors	4	4	4	4	4
Ratio of external auditors (%)	2	2	2	2	2
Ratio of external auditors (%)	50	50	50	50	50

## Management's Discussion and Analysis

Please refer to the published securities report for the fiscal year ended March 31, 2020 for an overview of business risks. (Japanese only)  
[https://www.nippon-shinyaku.co.jp/file/download.php?file\\_id=3157](https://www.nippon-shinyaku.co.jp/file/download.php?file_id=3157)



### 1. Overview of Performance

The Japanese economy continued to recover gradually with improvements in jobs and income. However, a slowdown intensified due to the impact of the hike in the consumption tax and the COVID-19 outbreak, amid a persistently uncertain outlook.

Conditions for the Nippon Shinyaku Group and broader pharmaceutical industry stayed harsh due to the various measures to restrict healthcare spending in Japan, including the promotion of greater use of generics. In the functional food business, despite the strong demand for functional food due to increased health consciousness, conditions remained challenging due to low growth in spending by thrifty households; rising logistics and labor costs; and more intense competition.

Under such conditions, the Nippon Shinyaku Group focused on building public trust by honing its reputation as an essential supplier in the healthcare field with a meaningful role to play in society. Net sales grew 1.7% to ¥116,637 million, despite a decline in the revenues from the licensing of industrial property rights compared to fiscal 2018, when milestone payments were received for the pulmonary arterial hypertension (PAH) treatment Uptravi. The result reflected higher sales of new prescription pharmaceuticals in Japan, together with a rise in co-promotion sales revenues. In terms of profits, operating income increased 5.0% to ¥21,668 million due to the growth in sales offsetting the increase in the cost-of-sales ratio caused by factors such as the NHI price revision. Ordinary income increased 4.2% to ¥22,442 million, and net income attributable to owners of the parent increased 3.5% to ¥16,866 million.

### 2. Overview by Segment

#### 1 Pharmaceuticals

Offsetting the impact of reduced revenues from licensing of industrial property rights due to lower milestone payments, as well as the NHI price revisions, products posting higher sales in fiscal 2019 included Gazyva (CD20-positive follicular lymphoma treatment), Vidaza (for myelodysplastic syndromes), Uptravi, and Zalutia (treatment for urinary disorders caused by benign prostatic hypertrophy). Defitelio, a treatment for sinusoidal obstruction syndrome (hepatic veno-occlusive disease) that was launched in September 2019, made a sales contribution as well. Net sales increased 1.4% year on year to ¥101,643 million.

#### 2 Functional Food

Net sales increased 3.5% year on year to ¥14,994 million, due to increased sales of protein preparations, preservatives and other products.

### 3. Financial Condition

Current assets totaled ¥121,925 million at the fiscal year-end, due to an increase in inventories and in cash and cash equivalents compared to the previous fiscal year-end, more than offsetting a reduction in notes and

accounts receivable. Fixed assets declined to ¥53,091 million, mainly due to a decrease in investment securities and deferred tax assets. As a result, total assets increased by ¥6,254 million compared to the previous fiscal year-end, to ¥175,017 million.

Current liabilities totaled ¥24,965 million due to a decrease in other payables and income taxes payable, despite an increase in notes and accounts payable compared to the previous fiscal year-end. Long-term liabilities totaled ¥4,290 million, due to a decrease in liability for retirement benefits. As a result, total liabilities decreased by ¥4,316 million compared to the previous fiscal year-end, to ¥29,256 million.

Equity increased by ¥11,205 million compared to the previous fiscal year-end, to ¥140,032 million. Accumulated other comprehensive income decreased by ¥650 million to ¥5,458 million. As a result, total equity increased by ¥10,570 million to ¥145,760 million.

The equity ratio was 83.1%.

Net cash provided by operating activities amounted to ¥12,737 million. The main cash inflows were ¥22,442 million from income before income taxes; depreciation and amortization of ¥3,468 million; and a decrease of ¥5,033 million in trade receivables. The main cash outflows were an increase in inventories of ¥10,521 million and income tax payments of ¥6,235 million.

Net cash used in investing activities amounted to ¥2,339 million. The main components of net cash outflow were expenditures of ¥1,817 million for property, plant and equipment and of ¥1,315 million for long-term prepaid expenses.

Net cash used in financing activities amounted to ¥5,660 million, primarily comprising cash dividends paid.

As a result, cash and cash equivalents as of March 31, 2020 increased by ¥4,665 million compared to the previous fiscal year-end, to ¥44,298 million.

### 4. Fundamental Policy Regarding Profit Sharing

Under our strategy to maximize corporate value, we strive to bolster R&D to expand our product development pipeline, while further strengthening our business foundations by striking a balance between investment in establishing a corporate structure that can withstand intensifying competition, and the return of profits.

We return profits to shareholders in the form of performance-linked dividends. During the 6th Five-year Medium-term Management Plan (April 2019 to March 2024), we aim to raise the consolidated payout ratio to around 35%. Extraordinary gains and losses can be excluded when calculating the payout ratio.

For fiscal 2019, we issued an annual cash dividend of ¥86 per share, comprising an interim dividend of ¥43 per share and year-end dividend of ¥43 per share. As a result, we had a dividend payout ratio of 34.3% in fiscal 2019.

For fiscal 2020, we are projecting an annual dividend of ¥99 per share, comprising an interim dividend of ¥49 per share and year-end dividend of ¥50 per share.

# Consolidated Financial Statements

## Consolidated Balance Sheet

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
March 31, 2020

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2020	2019	2020
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents (Note 10)	¥ 44,298	¥ 39,632	\$ 406,403
Time deposits (Note 10)	807	987	7,403
Marketable securities (Notes 3 and 10)	2,010	1,520	18,440
Notes and accounts receivables (Note 10):			
Trade notes	599	696	5,495
Trade accounts	40,923	45,859	375,440
Other	890	591	8,165
<b>Total notes and accounts receivables</b>	<b>42,412</b>	<b>47,147</b>	<b>389,100</b>
Inventories (Note 4)	29,894	19,373	274,256
Other current assets	2,502	2,060	22,954
<b>Total current assets</b>	<b>121,925</b>	<b>110,720</b>	<b>1,118,577</b>
<b>PROPERTY, PLANT, AND EQUIPMENT:</b>			
Land	7,459	7,463	68,431
Buildings and structures	27,792	27,428	254,972
Machinery, equipment, and vehicles	12,444	12,277	114,165
Tools, furniture, and fixtures	8,955	8,842	82,155
Construction in progress	305	199	2,798
<b>Total</b>	<b>56,957</b>	<b>56,211</b>	<b>522,541</b>
Accumulated depreciation	(36,012)	(35,635)	(330,385)
<b>Net property, plant, and equipment</b>	<b>20,944</b>	<b>20,575</b>	<b>192,146</b>
<b>INVESTMENTS AND OTHER ASSETS:</b>			
Investment securities (Notes 3 and 10)	18,909	23,460	173,477
Long-term prepaid expenses	8,631	8,765	79,183
Deferred tax assets (Note 9)	1,726	2,330	15,834
Other assets	2,878	2,910	26,403
<b>Total investments and other assets</b>	<b>32,146</b>	<b>37,466</b>	<b>294,917</b>
<b>TOTAL</b>	<b>¥ 175,017</b>	<b>¥ 168,763</b>	<b>\$ 1,605,660</b>

See notes to consolidated financial statements.

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2020	2019	2020
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Notes and accounts payables (Note 10):			
Trade notes	¥ 1,777	¥ 1,798	\$ 16,302
Trade accounts	9,435	6,188	86,559
Other	4,831	6,924	44,321
<b>Total notes and accounts payables</b>	<b>16,045</b>	<b>14,910</b>	<b>147,201</b>
Income taxes payable (Note 10)	2,081	3,597	19,091
Accrued expenses	4,492	4,382	41,211
Deposits from customers	209	257	1,917
Other current liabilities	2,137	2,259	19,605
<b>Total current liabilities</b>	<b>24,965</b>	<b>25,406</b>	<b>229,036</b>
<b>LONG-TERM LIABILITIES:</b>			
Liability for retirement benefits (Note 5)	3,956	7,843	36,293
Deferred tax liabilities (Note 9)	9	2	82
Other long-term liabilities	324	320	2,972
<b>Total long-term liabilities</b>	<b>4,290</b>	<b>8,165</b>	<b>39,357</b>
<b>EQUITY (Notes 6 and 13):</b>			
Common stock, authorized: 200,000,000 shares; issued: 70,251,484 shares	5,174	5,174	47,467
Capital surplus	4,445	4,445	40,779
Retained earnings	132,886	121,677	1,219,137
Treasury stock – at cost: 2,897,768 shares in 2020 and 2,897,365 shares in 2019	(2,473)	(2,469)	(22,688)
Accumulated other comprehensive income:			
Unrealized gain on available-for-sale securities	6,929	9,440	63,568
Deferred gain (loss) on derivatives under hedge accounting	7	(5)	64
Foreign currency translation adjustments	(3)		(27)
Defined retirement benefit plans	(1,475)	(3,326)	(13,532)
<b>Total</b>	<b>145,491</b>	<b>134,936</b>	<b>1,334,779</b>
Noncontrolling interests	269	253	2,467
<b>Total equity</b>	<b>145,760</b>	<b>135,190</b>	<b>1,337,247</b>
<b>TOTAL</b>	<b>¥ 175,017</b>	<b>¥ 168,763</b>	<b>\$ 1,605,660</b>



## Consolidated Financial Statements

## Consolidated Statement of Cash Flows

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Year Ended March 31, 2020

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2020	2019	2020
<b>OPERATING ACTIVITIES:</b>			
Income before income taxes	¥ 22,442	¥ 21,540	\$ 205,889
Adjustments for:			
Income taxes—paid	(6,235)	(4,355)	(57,201)
Depreciation and amortization	3,468	3,418	31,816
Changes in assets and liabilities:			
Decrease (increase) in trade notes and trade accounts receivables	5,033	(6,391)	46,174
(Increase) decrease in inventories	(10,521)	972	(96,522)
Increase in other current assets	(442)	(508)	(4,055)
Increase (decrease) in trade notes and trade accounts payables	3,227	(653)	29,605
Decrease in other current liabilities	(116)	(808)	(1,064)
Decrease in liability for retirement benefits	(1,222)	(1,124)	(11,211)
Other—net	(2,895)	3,220	(26,559)
<b>Total adjustments</b>	<b>(9,704)</b>	<b>(6,230)</b>	<b>(89,027)</b>
<b>Net cash provided by (used in) operating activities</b>	<b>12,737</b>	<b>15,310</b>	<b>116,853</b>
<b>INVESTING ACTIVITIES:</b>			
Purchase of property, plant, and equipment	(1,817)	(1,351)	(16,669)
Purchases of investment securities	(62)	(102)	(568)
Purchases of software	(319)	(107)	(2,926)
Purchase of long-term prepaid expenses	(1,315)	(962)	(12,064)
Other—net	1,176	3,035	10,788
<b>Net cash provided by (used in) investing activities</b>	<b>(2,339)</b>	<b>511</b>	<b>(21,458)</b>
<b>FINANCING ACTIVITIES:</b>			
Cash dividends paid	(5,651)	(3,698)	(51,844)
Increase in treasury stock	(3)	(5)	(27)
Other—net	(5)	(4)	(45)
<b>Net cash provided by (used in) financing activities</b>	<b>(5,660)</b>	<b>(3,708)</b>	<b>(51,926)</b>
<b>FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS</b>	<b>(72)</b>	<b>9</b>	<b>(660)</b>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>4,665</b>	<b>12,122</b>	<b>42,798</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	<b>39,632</b>	<b>27,510</b>	<b>363,596</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>¥ 44,298</b>	<b>¥ 39,632</b>	<b>\$ 406,403</b>

See notes to consolidated financial statements.

## Notes to Consolidated Financial Statements

## 1. BASIS OF PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

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

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form that is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2019 consolidated financial statements to conform to the classifications used in 2020.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Nippon Shinyaku Co., Ltd. (the "Company") is incorporated and operates. Japanese yen figures of less than one million yen are rounded down to the nearest million, except for per share data. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥109 to \$1, the approximate rate of exchange at March 31, 2020. U.S. dollar figures of less than one thousand dollars are rounded down to the nearest thousand, except for per share data. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**a. Consolidation** - The consolidated financial statements as of March 31, 2020 and 2019, include the accounts of the Company and its three domestic subsidiaries and one overseas subsidiary (collectively, the "Companies").

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

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

**b. Cash Equivalents** - Cash equivalents are short-term investments that are readily convertible into cash and that are exposed to insignificant risk of changes in value. Cash equivalents include time deposits, certificates of deposit, and commercial paper, all of which mature or become due within three months of the date of acquisition.

**c. Marketable and Investment Securities** - Marketable and investment securities are classified and accounted for, depending on management's intent, as follows: i) held-to-maturity debt securities, which management has the positive intent and ability to hold to maturity, are reported at amortized cost; and ii) available-for-sale securities that are not classified as held-to-maturity securities and are reported, except for nonmarketable

available-for-sale securities, at fair value, with unrealized gains and losses, net of applicable taxes, are reported as a separate component of equity. Realized gains and losses on available-for-sale securities are included in earnings and are calculated by using the moving-average method to determine the cost of securities sold. Nonmarketable available-for-sale securities are stated at cost, cost being determined principally by the moving-average method. Write-downs are recorded in earnings for securities with a significant decline in value that is considered to be other than temporary.

**d. Inventories** - Inventories held for sale in the ordinary course of business are measured at the lower of cost, determined mainly by the average cost method, or net selling value, which is defined as the selling price, less additional estimated manufacturing costs and estimated direct selling expenses. The replacement cost may be used in place of the net selling value, if appropriate.

**e. Property, Plant, and Equipment** - Property, plant, and equipment are stated at cost. Depreciation of property, plant, and equipment of the Companies is computed by the straight-line method based on the estimated useful lives of the assets. The range of useful lives is principally from 10 to 50 years for buildings and structures, from 8 to 10 years for machinery, equipment, and vehicles, and from 4 to 6 years for tools, furniture, and fixtures.

**f. Long-term Prepaid Expenses** - Long-term prepaid expenses are amortized by the straight-line method principally over 5 to 20 years, based on the term of validity of contracts.

**g. Long-Lived Assets** - The Companies review their long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss would be measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from the continued use and eventual disposition of the asset or the net selling price at disposition.

**h. Retirement and Pension Plans** - The Company has contributory funded defined benefit pension plans, unfunded retirement benefit plans and a defined contribution pension plan for employees. Certain subsidiaries use a simplified method for calculating pension liabilities.

The Company accounts for the liability for retirement benefits based on the projected benefit obligations and plan assets at the balance sheet date. The projected benefit obligations are attributed to periods on a benefit formula basis. Actuarial gains and losses and past service costs that are yet to be recognized in profit or loss are recognized within equity (accumulated other comprehensive income), after adjusting for tax effects and are recognized in profit or loss over 15 years within the average remaining service period of the employees. The discount rate is determined using a single weighted-average discount rate reflecting the estimated timing and amount of benefit payment.

**i. Allowance for Doubtful Accounts** - The allowance for doubtful accounts is stated at an amount considered to

## Notes to Consolidated Financial Statements

be appropriate based on the Companies' past credit loss experience and an evaluation of potential losses in receivables outstanding.

- j. **Leases** - Finance lease transactions are capitalized by recognizing lease assets and lease obligations in the consolidated balance sheet. All other leases are accounted for as operating leases.
- k. **Allowance for Bonuses** - To prepare for the payment of employee bonuses, an amount corresponding to the current portion of estimated bonus payments to employees is recorded.
- l. **Income Taxes** - The provision for income taxes is computed based on the pretax income included in the consolidated statement of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted income tax rates to the temporary differences.
- m. **Foreign Currency Transactions** - All short- and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statement of income to the extent that they are not hedged by forward exchange contracts.
- n. **Foreign Currency Financial Statements** - The balance sheet accounts of the consolidated foreign subsidiary are translated into Japanese yen at the current exchange rate as of the consolidated balance sheet date except for equity, which is translated at the historical rate. Differences arising from such translation are shown as "Foreign currency translation adjustments" under accumulated other comprehensive income in a separate component of equity. Revenue and expense accounts of consolidated foreign subsidiaries are translated into yen at the average exchange rate.
- o. **Derivative Financial Instruments** - The Company uses foreign currency forward contracts as a means of hedging exposure to foreign currency exchange risks related to the procurement of merchandise from overseas suppliers. The Company does not enter into derivatives for trading or speculative purposes. Derivative financial instruments and foreign currency transactions are classified and accounted for as follows: a) all derivatives are recognized as either assets or liabilities and measured at fair value, and gains or losses on derivative transactions are recognized in the consolidated statement of income; and b) for derivatives used for hedging purposes, if such derivatives qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are deferred until maturity of the hedged transactions. The foreign currency forward contracts are utilized to hedge foreign currency exposures in procurement of raw materials from overseas suppliers. Trade payables denominated in foreign currencies are translated at the contracted rates if the forward contracts qualify for hedge accounting.
- p. **Per Share Information** - Basic net income per share (EPS) is computed by dividing net income attributable to common shareholders by the weighted-average number of

common shares outstanding for the period.

Cash dividends per share presented in the accompanying consolidated statement of income are dividends applicable to the respective fiscal years, including dividends to be paid after the end of the year.

- q. **Accounting Changes and Error Corrections** - Under ASBJ Statement No. 24, "Accounting Standard for Accounting Changes and Error Corrections," and ASBJ Guidance No. 24, "Guidance on Accounting Standard for Accounting Changes and Error Corrections," accounting treatments are required as follows: (1) Changes in Accounting Policies—When a new accounting policy is applied following revision of an accounting standard, the new policy is applied retrospectively unless the revised accounting standard includes specific transitional provisions, in which case the entity shall comply with the specific transitional provisions. (2) Changes in Presentation—When the presentation of financial statements is changed, prior-period financial statements are reclassified in accordance with the new presentation. (3) Changes in Accounting Estimates—A change in an accounting estimate is accounted for in the period of the change if the change affects that period only, and is accounted for prospectively if the change affects both the period of the change and future periods. (4) Corrections of Prior-Period Errors—When an error in prior-period financial statements is discovered, those statements are restated.
- r. **New Accounting Pronouncements** - On March 30, 2018, the ASBJ issued ASBJ Statement No. 29, "Accounting Standard for Revenue Recognition," and ASBJ Guidance No. 30, "Implementation Guidance on Accounting Standard for Revenue Recognition." The core principle of the standard and guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity should recognize revenue in accordance with that core principle by applying the following steps: Step 1: Identify the contract(s) with a customer Step 2: Identify the performance obligations in the contract Step 3: Determine the transaction price Step 4: Allocate the transaction price to the performance obligations in the contract Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation The accounting standard and guidance are effective for annual periods beginning on or after April 1, 2021. Earlier application is permitted for annual periods beginning on or after April 1, 2018. The Company expects to apply the accounting standard and guidance for annual periods beginning on or after April 1, 2021, and is in the process of measuring the effects of applying the accounting standard and guidance in future applicable periods. On July 4, 2019, the ASBJ issued ASBJ Statement No. 30, "Accounting Standard for Fair Value Measurement" and ASBJ Guidance No. 31, "Implementation Guidance on Accounting Standard for Fair Value Measurement," and revised related ASBJ Statements and ASBJ Guidance (the "New Accounting Standards"). Under the New Accounting Standards, nonmarketable available-for-sale equity securities are stated at cost, while under the

current accounting standards, nonmarketable available-for-sale securities are stated at cost. The New Accounting Standards are effective for the annual periods beginning on or after April 1, 2021.

## 3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2020 and 2019, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Current:			
Government and corporate bonds	¥ 2,010	¥ 1,520	\$ 18,440
Total	¥ 2,010	¥ 1,520	\$ 18,440
Noncurrent:			
Equity securities	¥ 18,317	¥ 22,918	\$ 168,045
Government and corporate bonds	562	511	5,155
Other	29	29	266
Total	¥ 18,909	¥ 23,460	\$ 173,477

The costs and aggregate fair values of marketable and investment securities at March 31, 2020 and 2019, were as follows:

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

March 31, 2019	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	9,637	13,280		22,918
Held-to-maturity	2,061			2,061

March 31, 2020	Thousands of U.S. Dollars			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	\$ 78,678	\$ 89,366		\$ 168,045
Held-to-maturity	23,871		\$ 36	23,834

## 4. INVENTORIES

Inventories at March 31, 2020 and 2019, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Finished products and merchandise	¥ 15,179	¥ 14,064	\$ 139,256
Work in process	4,618	1,362	42,366
Raw materials and supplies	10,096	3,946	92,623
Total	¥ 29,894	¥ 20,345	\$ 274,256

## 5. RETIREMENT AND PENSION PLANS

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

## 1. Defined Benefit Pension Plan

(1) The changes in defined benefit obligation for the years ended March 31, 2020 and 2019, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Balance at beginning of year	¥ 29,601	¥ 29,020	\$ 271,568
Current service cost	1,141	1,091	10,467
Interest cost	164	212	1,504
Actuarial (gains) losses	(3,659)	1,054	(33,568)
Benefits paid	(1,680)	(1,777)	(15,412)
Balance at end of year	¥ 25,567	¥ 29,601	\$ 234,559

(2) The changes in plan assets for the years ended March 31, 2020 and 2019, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Balance at beginning of year	¥ 21,758	¥ 21,597	\$ 199,614
Expected return on plan assets	870	863	7,981
Actuarial losses	(1,452)	(955)	(13,321)
Contributions from the employer	2,112	2,017	19,376
Benefits paid	(1,677)	(1,765)	(15,385)
Balance at end of year	¥ 21,610	¥ 21,758	\$ 198,256

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

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Defined benefit obligation	¥ 23,075	¥ 27,161	\$ 211,697
Plan assets	(21,610)	(21,758)	(198,256)
	1,465	5,403	13,440
Unfunded defined benefit obligation	2,491	2,439	22,853
Net liability arising from defined benefit obligation	¥ 3,956	¥ 7,843	\$ 36,293

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Liability for retirement benefits	¥ 3,956	¥ 7,843	\$ 36,293
Net liability arising from defined benefit obligation	¥ 3,956	¥ 7,843	\$ 36,293

## Notes to Consolidated Financial Statements

(4) The components of net periodic benefit costs for the years ended March 31, 2020 and 2019, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Service cost	¥ 1,141	¥ 1,091	\$ 10,467
Interest cost	164	212	1,504
Expected return on plan assets	(870)	(863)	(7,981)
Amortization of prior service cost	456	443	4,183
Recognized actuarial losses		20	
Others	58	41	532
Net periodic benefit costs	¥ 950	¥ 947	\$ 8,715

(5) Amounts recognized in other comprehensive income (before income tax effect) in respect of defined retirement benefit plans for the years ended March 31, 2020 and 2019, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Prior service cost		¥ (20)	
Actuarial (gains) losses	¥ (2,663)	1,566	\$(24,431)
Total	¥ (2,663)	¥ 1,545	\$(24,431)

(6) Amounts recognized in accumulated other comprehensive income (before income tax effect) in respect of defined retirement benefit plans as of March 31, 2020 and 2019, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Unrecognized actuarial losses	¥ 2,122	¥ 4,786	\$ 19,467
Total	¥ 2,122	¥ 4,786	\$ 19,467

(7) Plan assets

a. Components of plan assets  
Plan assets as of March 31, 2020 and 2019, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Domestic bonds	14.5%	15.1%	
Domestic stocks	8.0	12.8	
Foreign bonds	13.1	11.2	
Foreign stocks	5.7	9.2	
General accounts	37.8	34.7	
Alternative	13.9	13.8	
Others	7.0	3.2	
Total	100.0%	100.0%	

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

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

(8) Assumptions used for the years ended March 31, 2020 and 2019, are set forth as follows:

	2020	2019
Discount rate	0.2-0.6%	0.1-0.8%
Expected rate of return on plan assets	4.0	4.0

2. Defined Contribution Pension Plan

Premiums for the defined contribution pension plan were ¥89 million (\$816 thousand) and ¥81 million for the years ended March 31, 2020 and 2019, respectively.

## 6. EQUITY

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

### (a) Dividends

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

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

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

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

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

### (c) Treasury stock and treasury stock acquisition rights

The Companies Act also provides for companies to purchase treasury stock and dispose of such treasury stock by resolution of the Board of Directors. The amount of treasury stock purchased cannot exceed the amount available for distribution to the shareholders, which is determined by a specific formula.

Under the Companies Act, stock acquisition rights are presented as a separate component of equity.

The Companies Act also provides that companies can purchase both treasury stock acquisition rights and treasury stock. Such treasury stock acquisition rights are presented as a separate component of equity or deducted directly from stock acquisition rights.

## 7. RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥13,994 million (\$128,391 thousand) and ¥16,701 million for the years ended March 31, 2020 and 2019, respectively.

## 8. LEASES

The companies leases certain machinery, computer equipment, office space and other assets.

Total rental expenses including lease payments under finance leases for the years ended March 31, 2020 and 2019, were ¥1,289 million (\$11,831 thousand) and ¥1,433 million, respectively.

Future minimum payments under noncancelable operating leases were as follows:

	Operating Leases	
	2020	
	Millions of Yen	Thousands of U.S. Dollars
Due within one year	¥ 39	\$ 357
Due after one year	109	1,000
Total	¥ 149	\$ 1,366

## 9. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in the aggregate, resulted in a normal effective statutory tax rate of approximately 30.5% for the years ended March 31, 2020 and 2019, respectively.

The tax effects of significant temporary differences that resulted in deferred tax assets and liabilities at March 31, 2020 and 2019, are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Deferred tax assets:			
Retirement benefits	¥ 1,210	¥ 2,396	\$ 11,100
Accrued expenses	1,117	1,107	10,247
Property, plant, and equipment	30	31	275
Supplies	1,505	1,861	13,807
Other	1,946	2,065	17,853
Less valuation allowance	(295)	(309)	(2,706)
Deferred tax assets	5,514	7,151	50,587
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	2,811	3,839	25,788
Deferred gains on sales of property	961	966	8,816
Other	24	17	220
Deferred tax liabilities	3,797	4,823	34,834
Net deferred tax assets	¥ 1,717	¥ 2,328	\$ 15,752

A reconciliation between the normal effective statutory tax rates and the actual effective tax rates reflected in the accompanying consolidated statement of income for the year ended March 31, 2020, with the corresponding figures for 2019, is as follows:

	2020	2019
Normal effective statutory tax rate	30.5%	30.5%
Expenses not deductible for income tax purposes	0.5	0.5
Income not taxable for income tax purposes	(0.5)	(0.5)
Tax credits for research and development costs	(5.7)	(6.9)
Inhabitant tax on per capita basis	0.3	0.3
Other—net	(0.4)	0.3
Actual effective tax rate	24.7%	24.2%

## Notes to Consolidated Financial Statements

## 10. FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

## (1) Group policy for financial instruments

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

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

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

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

The Company's derivative transactions are comprised of specific foreign exchange forward contracts. The Company has entered into foreign exchange forward contracts, as requested by customers or based on the judgment of the purchase department, to hedge foreign currency exchange risk specifically associated with imported merchandise. Such derivative transactions are entered into to hedge foreign currency exposures occurring within the Company's business.

## (3) Risk management for financial instruments

## Credit risk management

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

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

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

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

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

## Liquidity risk management

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

## (4) Fair values of financial instruments

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

## (a) Fair value of financial instruments

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

March 31, 2019	Millions of Yen		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	¥ 39,632	¥ 39,632	
Time deposits	987	987	
Notes and accounts receivables	47,147	47,147	
Marketable and investment securities	24,651	24,651	
<b>Total</b>	<b>¥ 112,418</b>	<b>¥ 112,418</b>	
Notes and accounts payables	¥ 14,910	¥ 14,910	
Income taxes payable	3,597	3,597	
<b>Total</b>	<b>¥ 18,507</b>	<b>¥ 18,507</b>	

March 31, 2020	Thousands of U.S. Dollars		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	\$ 406,403	\$ 406,403	
Time deposits	7,403	7,403	
Notes and accounts receivables	389,100	389,100	
Marketable and investment securities	188,899	188,862	\$(36)
<b>Total</b>	<b>\$ 991,816</b>	<b>\$ 991,780</b>	<b>\$(36)</b>
Notes and accounts payables	\$ 147,201	\$ 147,201	
Income taxes payable	19,091	19,091	
<b>Total</b>	<b>\$ 166,293</b>	<b>\$ 166,293</b>	

## Cash and Cash Equivalents

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

## Marketable and Investment Securities

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

## Notes and Accounts Payables and Income Taxes Payable

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

## Derivatives

Fair value information for derivatives is omitted because fair values and unrealized gains were immaterial for the years ended March 31, 2020 and 2019.

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

	Carrying Amount		
	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Investments in equity instruments that do not have a quoted market price in an active market	¥ 329	¥ 329	\$ 3,018

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

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

March 31, 2019	Millions of Yen			
	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years	Due after 10 Years
Cash and cash equivalents	¥ 39,632			
Time deposits	987			
Notes and accounts receivables	47,147			
Marketable and investment securities:				
Held-to-maturity securities	1,520	¥ 240		¥ 300
<b>Total</b>	<b>¥ 89,287</b>	<b>¥ 240</b>		<b>¥ 300</b>

March 31, 2020	Thousands of U.S. Dollars			
	Due in 1 Year or Less	Due after 1 Year through 5 Years	Due after 5 Years through 10 Years	Due after 10 Years
Cash and cash equivalents	\$ 406,403			
Time deposits	7,403			
Notes and accounts receivables	389,100			
Marketable and investment securities:				
Held-to-maturity securities	18,440	\$ 2,660	\$ 2,752	
<b>Total</b>	<b>\$ 821,357</b>	<b>\$ 2,660</b>	<b>\$ 2,752</b>	

## 11. OTHER COMPREHENSIVE INCOME (LOSS)

The components of other comprehensive income (loss) for the years ended March 31, 2020 and 2019, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2020	2019	2020
Unrealized gain (loss) on available-for-sale securities:			
Gains arising during the year	¥ (3,261)	¥ (2,911)	\$(29,917)
Reclassification adjustments to profit or loss	(277)		(2,541)
Amount before income tax effect	(3,539)	(2,911)	(32,467)
Income tax effect	1,028	882	9,431
<b>Total</b>	<b>¥ (2,510)</b>	<b>¥ (2,028)</b>	<b>\$(23,027)</b>
Deferred gain (loss) on derivatives under hedge accounting:			
Gains arising during the year	¥ 17		\$ 155
<b>Total</b>	<b>¥ 12</b>		<b>\$ 110</b>
Foreign currency translation adjustments:			
Adjustments arising during the year	¥ (3)	¥ (4)	\$ (27)
<b>Total</b>	<b>¥ (3)</b>	<b>¥ (4)</b>	<b>\$ (27)</b>
Defined retirement benefit plan (s):			
Adjustments arising during the year	¥ 2,207	¥ (2,009)	\$ 20,247
Reclassification adjustments to profit or loss	456	464	4,183
Amount before income tax effect	2,663	(1,545)	24,431
Income tax effect	(812)	471	(7,449)
<b>Total</b>	<b>¥ 1,851</b>	<b>¥ (1,074)</b>	<b>\$ 16,981</b>
<b>Total other comprehensive income (loss)</b>	<b>¥ (650)</b>	<b>¥ (3,107)</b>	<b>\$ (5,963)</b>

## Notes to Consolidated Financial Statements

## 12. NET INCOME PER SHARE

Reconciliation of the differences between basic and diluted net income per share ("EPS") for the years ended March 31, 2020 and 2019, is as follows:

	Millions of Yen	Thousands of Shares	Yen	Dollars
	Net Income Attributable to Owners of the Parent	Weighted-Average Shares		EPS
For the year ended March 31, 2020-				
Basic EPS				
Net income available to common shareholders	¥16,866	67,353	¥250.42	\$2.30
For the year ended March 31, 2019-				
Basic EPS				
Net income available to common shareholders	¥16,302	67,354	¥242.04	

## 13. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 26, 2020, the Company's shareholders approved the following:

Payment of a year-end cash dividend of ¥43 (\$0.39) per share to holders of record at March 31, 2020, for a total of ¥2,896 million (\$26,568 thousand).

## 14. SEGMENT INFORMATION

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

## 1. Description of Reportable Segments

The Companies' reportable segments are those for which separate financial information is available and regular evaluation by the Company's management is performed in order to decide how resources are allocated among the Companies. As such, the Companies' reportable segments consist of the 'Pharmaceuticals' industry and the 'Functional Food' industry. The 'Pharmaceuticals' industry consists of the manufacturing and sale of drugs for urological diseases, inflammation and allergies, hematologic malignancies, cardiovascular and metabolic diseases, gastrointestinal disorders, and other diseases. The 'Functional Food' industry consists of the manufacturing and sale of health food ingredients, preservatives, protein preparations, nutritional ingredients, seasonings and spices, sterilization cleaning agents, and others.

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

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

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

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

	Millions of Yen				
	2019				
	Reportable Segments			Reconciliations	Consolidated
Pharmaceuticals	Functional Food	Total			
Sales:					
Sales to external customers	¥100,223	¥14,492	¥114,716		¥114,716
Total	¥100,223	¥14,492	¥114,716		¥114,716
Segment profit	¥19,679	¥965	¥20,644		¥20,644
Segment assets	93,772	10,879	104,651	¥64,111	168,763
Other:					
Depreciation	3,232	148	3,380	37	3,418
Increase in property, plant, and equipment and intangible assets	1,180	61	1,242		1,242

	Thousands of U.S. Dollars				
	2020				
	Reportable Segments			Reconciliations	Consolidated
Pharmaceuticals	Functional Food	Total			
Sales:					
Sales to external customers	\$932,504	\$137,559	\$1,070,064		\$1,070,064
Total	\$932,504	\$137,559	\$1,070,064		\$1,070,064
Segment profit	\$189,779	\$9,009	\$198,788		\$198,788
Segment assets	906,495	102,917	1,009,412	\$597,935	1,607,357
Other:					
Depreciation	30,394	1,082	31,477	339	31,816
Increase in property, plant, and equipment and intangible assets	21,467	1,440	22,917	18	22,935

Note: Unallocated corporate assets included in "Reconciliations" for 2020 and 2019 are ¥65,175 million (\$597,935 thousand) and ¥64,111 million, respectively, and consisted primarily of funds, such as cash equivalents, investment securities, assets for administrative functions, and deferred tax assets.

## Related Information

## 1. Information about Products and Services

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

	Millions of Yen		
	2019		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	¥100,223	¥14,492	¥114,716

	Thousands of U.S. Dollars		
	2020		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	\$932,504	\$137,559	\$1,070,064

## 2. Information about Geographical Areas

## (1) Sales

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

	Millions of Yen				
	2019				
	Europe			Other	Total
Japan	Switzerland	Other			
	¥91,817	¥21,827	¥633	¥437	¥114,716

	Thousands of U.S. Dollars				
	2020				
	Europe			Other	Total
Japan	Switzerland	Other			
	\$866,724	\$198,018	\$2,908	\$2,403	\$1,070,064

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

## (2) Property, plant, and equipment

Information about geographical areas is omitted, as property, plant, and equipment located in Japan accounted for more than 90% of property, plant, and equipment presented in the consolidated balance sheet as of March 31, 2020 and 2019.

## (3) Information about Major Customers

Name of Customers	Sales		Related Segment Name
	Millions of Yen	Thousands of U.S. Dollars	
	2020		
Actelion Pharmaceuticals Ltd.	¥21,584	\$198,018	Pharmaceuticals
Alfresa Corporation	18,580	170,458	Pharmaceuticals
MEDICEO CORPORATION	17,526	160,788	Pharmaceuticals
Suzuken Co., Ltd.	17,326	158,954	Pharmaceuticals

Name of Customers	Sales		Related Segment Name
	Millions of Yen	Thousands of U.S. Dollars	
	2019		
Actelion Pharmaceuticals Ltd.	¥21,827		Pharmaceuticals
Alfresa Corporation	17,511		Pharmaceuticals
Suzuken Co., Ltd.	17,309		Pharmaceuticals
MEDICEO CORPORATION	16,980		Pharmaceuticals

## Independent Auditor's Report

# Deloitte.

Deloitte Touche Tohmatsu LLC  
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www.deloitte.com/jp/en

### INDEPENDENT AUDITOR'S REPORT

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

#### Opinion

We have audited the consolidated financial statements of Nippon Shinyaku Co., Ltd. and its subsidiaries (the "Group"), which comprise the consolidated balance sheet as of March 31, 2020, and the consolidated statement of income, consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies, all expressed in Japanese yen.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Group as of March 31, 2020, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

#### Convenience Translation

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

#### Basis for Opinion

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

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

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

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

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

Member of  
Deloitte Touche Tohmatsu Limited

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

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

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

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

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

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

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

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

*Deloitte Touche Tohmatsu LLC*

June 26, 2020

**Corporate Data / Investor Information** As of March 31, 2020

**Corporate Data**

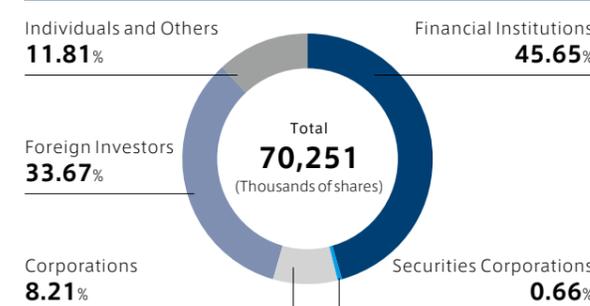
<b>Corporate Name</b>	Nippon Shinyaku Co., Ltd.	<b>Representative Director</b>	Shigenobu Maekawa, President
<b>Founded</b>	November 20, 1911	<b>Independent and Certified Public Accountants</b>	Deloitte Touche Tohmatsu Shijokarasuma FT Square 20, Naginataboko-cho, Shijo-dori Karasuma-higashiiru, Shimogyo-ku, Kyoto 600-8008, Japan
<b>Date of Incorporation</b>	October 1, 1919	<b>Issued and Outstanding Number of Shares</b>	70,251,484
<b>Head Office</b>	14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan Phone: +81-75-321-1111 Facsimile: +81-75-321-0678 <a href="http://www.nippon-shinyaku.co.jp/english/">http://www.nippon-shinyaku.co.jp/english/</a>	<b>Number of Shareholders</b>	5,025
<b>Paid-in Capital</b>	¥5.2 billion (Listed on the First Section of the Tokyo Stock Exchange)	<b>Share Registrar</b>	Mitsubishi UFJ Trust and Banking Corporation 6-3, Fushimimachi 3-chome, Chuo-ku, Osaka 541-0044, Japan



**Major Shareholders**

- Meiji Yasuda Life Insurance Company
- The Master Trust Bank of Japan, Ltd. (Trust account)
- Japan Trustee Services Bank, Ltd. (Trust account)
- MUFG Bank, Ltd.
- The Bank of Kyoto, Ltd.
- JP MORGAN CHASE BANK 380055
- STATE STREET BANK AND TRUST COMPANY 505001
- Nippon Life Insurance Company
- CHASE NOMINEES RE JASDEC TREATY CLIENT A/C (GENERAL)
- THE BANK OF NEW YORK MELLON 140044

**Distribution of Shares Issued**



**Stock Price and Trading Volumes**



**Network** As of April 1, 2020

**Main Offices**

**Tokyo Office** **Business Offices** Sapporo, Tohoku, Kanetsu, Tokyo, Saitama, Chiba, Yokohama, Nagoya, Osaka, Keiji/Hokuriku, Kobe, Chushikoku, Kyushu  
**Business Branches** Asahikawa, Kitatohoku, Fukushima, Niigata, Tochigi, Ibaraki, Koshin, Josai, Jonan, Tama, Yokohamanishi, Shizuoka, Hokuriku, Himeji, Okayama, Shikoku, Kitakyushu, Nishikyushu, Kumamoto, Minamikyushu, Okinawa, and others

Discovery Research Laboratories, Discovery Research Laboratories in Tsukuba, Food Development Laboratories, Yamashina Botanical Research Institute, Odawara Central Factory, East Logistic Center, West Logistic Center

**Domestic Subsidiaries**

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

**Overseas Offices and Subsidiary**

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