



Helping people  
lead healthier,  
happier lives



Annual Report  
2019





When others can't, we can  
When others won't, we will

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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 2018 (April 1, 2018–March 31, 2019). Some sections of the report also discuss initiatives from April 2019 onwards.

#### Companies Covered

Information in this report pertains to Nippon Shinyaku Co., Ltd. and its Japanese and overseas consolidated subsidiaries within the Nippon Shinyaku Group. 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, 2019. 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.



## 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.

## 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.

At Nippon Shinyaku, we have embarked on our 6th Five-Year Medium-term Management Plan (FY2019-FY2023), which aims for sustainable growth through the pursuit of further originality. We urge all of our employees to boldly embrace the six actions outlined in this plan, with a view to enhancing our global presence and further strengthening our management base to support sustainable growth.

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

September 2019



Shigenobu Maekawa  
President





# Nippon Shinyaku's Business Segments

Nippon Shinyaku has two business segments: Pharmaceuticals and Functional Food. In each of these businesses we identify fields of focus into which we pour management resources, with a view to achieving further originality and differentiating ourselves from rivals.

## Pharmaceuticals

The thrill of delivering new medicines to those who need them

Net Sales **¥100,223 million**  
(Up 14.6% year on year)

## Functional Food

Firm in the belief that medicine and food share the same importance in maintaining good health

Net Sales **¥14,492 million**  
(Up 3.3% year on year)

### Business Domains: **Four** Fields of Focus

#### Urological Diseases



Zalutia improves quality of life (QOL) for individuals with benign prostatic hypertrophy, by alleviating urinary disorders and difficulty urinating. The anticancer drug Erleada is contributing to the treatment of prostate cancer patients, having won approval for the treatment of castration-resistant prostate cancer without distant metastases.

• Erleada • Zalutia • Cialis  
• Estracyt • Bladderon • Eviprostat

#### Intractable and Rare Diseases



Nippon Shinyaku markets three drugs—Opsumit, Upravi, and Adcirca—for the treatment of pulmonary arterial hypertension (PAH), designated in Japan as an intractable disease. Combination therapies featuring these drugs in different permutations gradually are gaining traction, contributing to the treatment of PAH patients.

• Upravi • Opsumit  
• Adcirca

#### Otorhinolaryngology



The allergic rhinitis drug Erizas is a once-daily dry powder steroid nasal spray that alleviates the three major symptoms of allergic rhinitis (sneezing, nasal discharge and nasal congestion). Nippon Shinyaku also offers a number of other drugs helping patients achieve better health, including the vertigo remedies Cephadol and Isobide, and Azunol Gargle Liquid.

• Erizas • Azunol Gargle Liquid • Livostin  
• Cephadol • Isobide

#### Hematology



Launched in August 2018, Gazyva provides medical professionals with a new treatment option for follicular lymphoma. Another drug, Vidaza, is making an important contribution to patients with myelodysplastic syndrome, as the world's first drug known to extend survival time for such patients.

• Gazyva • Vidaza • Amnolake  
• Trisenox • Cyclocide N • Cyclocide

#### Gynecology



Lunabell Tablets LD are a low-dose estrogen and progesterone compounded agent, the first product indicated for treatment of dysmenorrhea associated with endometriosis to be covered by health insurance in Japan. In Lunabell Tablets ULD, the amount of estrogen is further reduced to lessen the risk of thrombosis. Together, these remedies will help improve QOL for many women who suffer from menstrual pain.

• Lunabell Tablets ULD  
• Lunabell Tablets LD

#### Other



• Onetram • Tramal  
• Regtect

### Business Domains: **Four** Fields of Focus

#### Health Food Ingredients



In our Functional Food business, we leverage the expertise in safety and quality control developed in our Pharmaceuticals business to provide health food ingredients that are beneficial to maintaining and improving human health, with assured quality and evidence of efficacy.

• Mangosteen Aqua • Hyaluronic Acid 3000  
• Garcinia Powder J • NS Amla Extract Powder

#### Protein Preparations



We provide ingredients such as sodium caseinate and soy protein for use in processed meat products, fish-paste products, and other general food products, and ingredients such as milk proteins and peptides for use in nutritional foods for therapeutic and sports purposes.

• Lactocrystal plus • PROGEL800  
• Enlacto HG • Fitness S

#### Spices and Condiments



We utilize the extraction and formulation technologies developed in our Pharmaceuticals business to make chili pepper extracts and onion concentrate, as well as juice products using haskap berries (Japanese blue honeysuckle) and cantaloupes grown in Hokkaido.

• Kenda – chili pepper extract • New Onion Concentrate  
• Haskap Concentrate H • Hokkaido Cantaloupe Melon Extract

#### Preservatives



We supply preservatives of consistent quality that both extend the shelf life of various foods and minimize the impact on flavor by using proprietary formulation techniques. Our Mikaku Fine series and other products can be used for a wide range of applications, enhancing both the taste of food and its longevity.

• Mikaku Fine NT • Mikaku Fine S • Mikaku Fine L  
• Mikaku Fine BK • Mikaku Fine W • Mikaku Fine Z • Glycine GX-2

#### Supplements



We want to help people lead healthier, happier lives through diet. We communicate this directly to consumers by supplying unique health foods for the sports and aging care markets, which we develop in-house drawing on our R&D capabilities as a maker of original pharmaceuticals.

• Sports supplements (WINZONE series)  
• Aging care supplements (AGE-SHUT, etc.)

# Our Value Creation Model

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





## Financial and Non-Financial Highlights

### Summary of Consolidated Financial Indicators

(FY)

	2014	2015	2016	2017	2018	2018
					Millions of Yen	Thousands of U.S. Dollars
<b>For the year</b>						
Net sales	79,991	84,209	98,781	101,448	114,716	1,033,477
Pharmaceuticals	66,340	70,489	85,315	87,416	100,223	902,909
Functional food	13,651	13,720	13,466	14,031	14,492	130,558
Operating income	8,562	8,549	15,280	17,079	20,644	185,981
Net income attributable to owners of the parent	5,882	6,340	11,749	12,953	16,302	146,864
Depreciation and amortization	2,665	2,452	2,648	2,773	3,418	30,792
Capital investment	1,239	3,554	3,949	2,811	1,242	11,189
R&D expenses	8,968	9,739	14,903	13,221	16,701	150,459

					Millions of Yen	Thousands of U.S. Dollars
<b>End of the year</b>						
Total assets	129,757	135,370	150,905	155,887	168,763	1,520,387
Net assets	101,207	102,762	114,316	125,689	135,190	1,217,927

					Yen	U.S. Dollars
<b>Financial information per share</b>						
Earnings per share	87.26	94.10	174.42	192.31	242.04	2.18
Dividend per share	25	28	48	52	70	0.63

					%	%
<b>Principal financial indicators</b>						
Equity ratio	77.8	75.8	75.6	80.5	80.0	—
Return on equity	6.1	6.2	10.8	10.8	12.5	—
Payout ratio	28.7	29.8	27.5	27.0	28.9	—

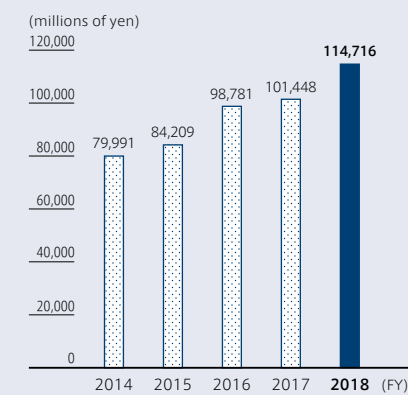
### Summary of ESG Indices

Total energy consumption (thousands of GJ)	194	193	199	209	212	—
CO <sub>2</sub> emissions (t)	10,183	10,059	10,165	10,609	10,129	—
CO <sub>2</sub> per unit of revenue (t/million yen)	0.128	0.119	0.103	0.104	0.089	—
Number of employees (people)	1,885	1,914	1,934	1,962	1,998	—

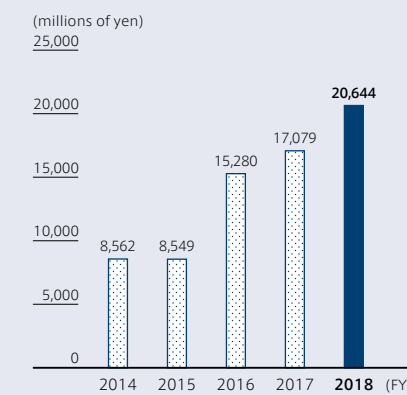
\* Employee numbers for FY2014–2017 differ from those shown in the Nippon Shinyaku Annual Report 2018 and earlier reports, due to a change in calculation method.

### Financial Highlights

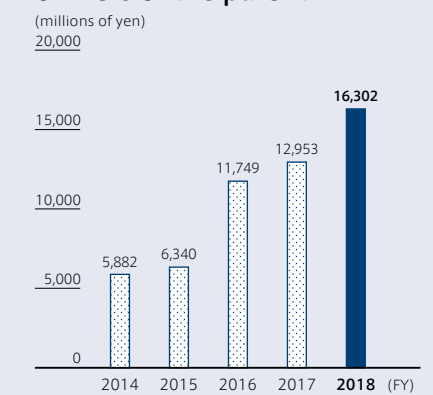
#### Net sales



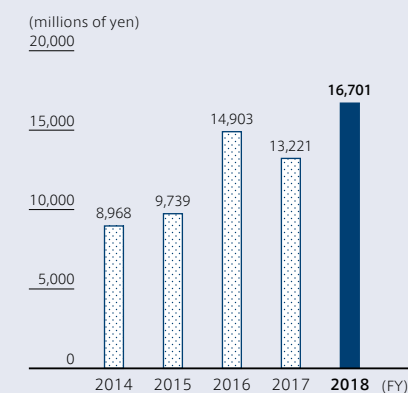
#### Operating income



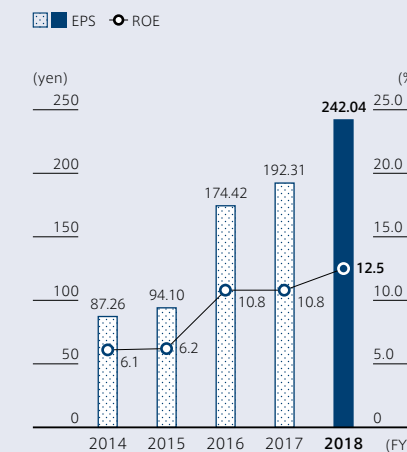
#### Net income attributable to owners of the parent



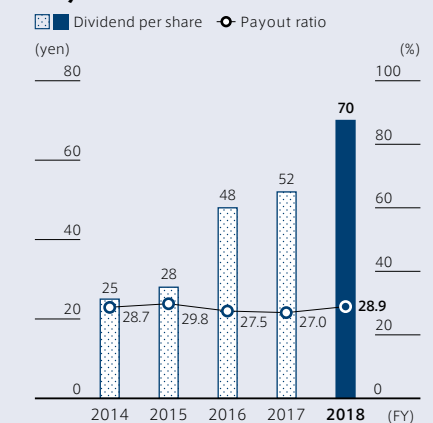
#### R&D expenses



#### EPS / ROE

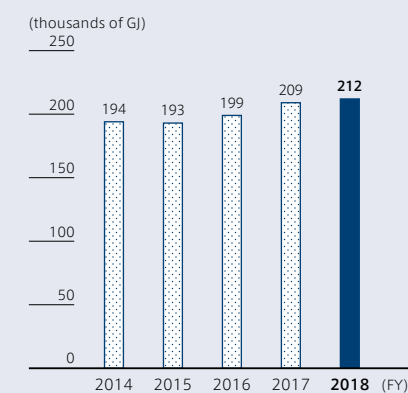


#### Dividend per share / Payout ratio

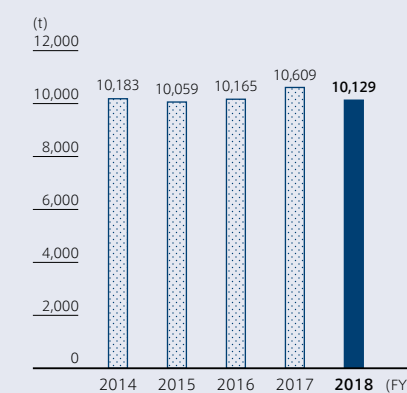


### Non-Financial Highlights

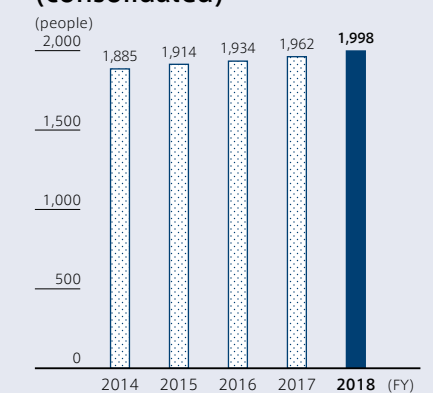
#### Total energy consumption



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



#### Number of employees (consolidated)



## Message from the President



Shigenobu Maekawa  
President

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

### Six actions

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

### Numerical targets for FY2023

(Consolidated)	FY 2018 results	FY 2023 plan	CAGR <sup>*1</sup>
Net sales	¥114,716 million	¥150,000 million	5.5%
Pharmaceuticals	¥100,223 million	¥133,000 million	5.8%
Functional food	¥14,492 million	¥17,000 million	3.4%
Operating income	¥20,644 million	¥40,000 million	14.2%
Net income attributable to owners of the parent	¥16,302 million	¥30,000 million	13.0%
EPS <sup>*2</sup>	¥242	¥445	13.0%
ROE <sup>*3</sup>	10% or more throughout the term of the 6th Plan		

<sup>\*1</sup> CAGR: Compound Annual Growth Rate

<sup>\*2</sup> EPS: Earnings Per Share

<sup>\*3</sup> ROE: Return On Equity

## Nippon Shinyaku helps people lead healthier, happier lives through the supply of unique and high-quality products

### 1 Review of the 5th Five-Year Medium-term Management Plan

During the 5th Five-Year Medium-term Management Plan, sales and all levels of profit scaled new heights, and we were able to achieve tangible results in our bid to build a clearly differentiated platform for growth.

#### 1 Situation in FY2018

In fiscal 2018, the Nippon Shinyaku Group's net sales increased 13.1% year on year to ¥114,716 million. The Pharmaceuticals business experienced growth in sales of new products including Upravi (a proprietary treatment for pulmonary arterial hypertension (PAH)), Zalutia (a drug for urinary disorders caused by benign prostatic hypertrophy), and Cialis (a remedy for erectile dysfunction), and in Upravi's case there was also growth in royalty income from overseas sales, as well as in income from co-promotion. The business saw further contributions from sales of Gazyva, a treatment for CD20-positive follicular lymphoma launched in August 2018 in conjunction with Chugai Pharmaceutical and milestone payments for Upravi, leading to net sales of ¥100,223 million (a year-on-year increase of 14.6%). In the Functional Food business, net sales increased 3.3% year on year to ¥14,492 million, due to increased sales of health food ingredients, protein preparations, and preservatives.

In terms of profits, R&D expenditure increased owing to upfront payments associated with in-licensing agreements and advances in clinical development, and sales promotion costs for new products also rose, but higher sales ensured that operating income increased year on year by 20.9% to ¥20,644 million. Ordinary income was ¥21,540 million (a year-on-year increase of 23.4%). Net income attributable to owners of the parent was ¥16,302 million (a 25.9% year-on-year increase). In short, profits rose by a large margin in all cases.

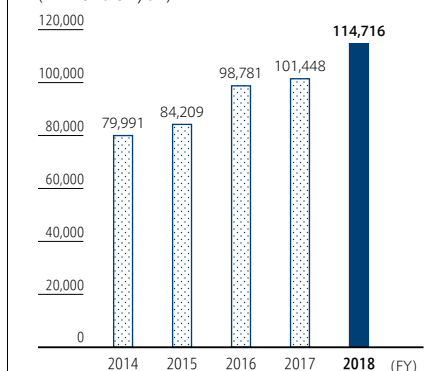
#### 2 Progress toward numerical targets

Looking back over the period covered by the 5th Five-Year Medium-term Management Plan, the Pharmaceuticals business was affected by government measures to promote greater use of generics and drastic reforms to the National Health Insurance drug price system. However, royalty income from overseas sales of our original product Upravi grew more than we had expected, and there was a further contribution from reinforcement of our sales organization, in response to change in the operating environment for our domestic Pharmaceuticals business. Consequently, both sales and operating income exceeded the plan. By promoting stable revenue management, we also were able to bring forward growth investments aimed at enhancing our R&D pipeline.

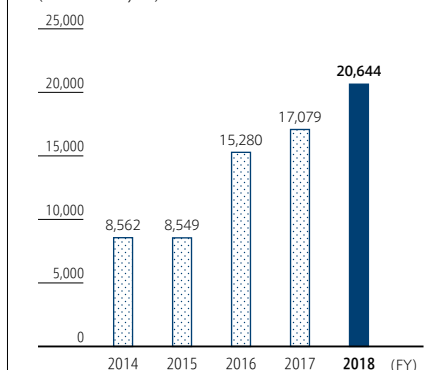
In the Functional Food business, sales were slightly lower than planned owing to fiercer competition. Nonetheless, we were able to transform the business into a highly profitable entity.

In fiscal 2018, the final year of the 5th Plan, we accordingly achieved all numerical goals (sales of ¥110,000 million, operating income of ¥18,000 million, net income attributable to owners of the parent of ¥12,000 million, EPS of ¥180, and ROE of 10.0%) and set record highs for sales and all levels of profit.

Net sales  
(millions of yen)



Operating income  
(millions of yen)



### Numerical target assessment for FY2018

	Targets	Results
Net sales	¥110,000 million	¥114,716 million
Pharmaceuticals	¥95,000 million	¥100,223 million
Functional food	¥15,000 million	¥14,492 million
Operating income	¥18,000 million	¥20,644 million
Net income attributable to owners of the parent	¥12,000 million	¥16,302 million
EPS	¥180	¥242
ROE	10.0%	12.5%

Message from the President



3 Functional-level strategy

We positioned the 5th Five-Year Medium-term Management Plan as a blueprint for building our own platform for new growth. Over the course of this plan, we pursued a six-pronged functional-level strategy.

1. R&D strategy

To facilitate regular launches of new drugs in our five areas of focus (urology, hematology, intractable and rare diseases, gynecology, and otorhinolaryngology), we fleshed out our development pipeline through the three pillars of in-house drug discovery, in-licensing, and product life cycle management (PLCM). We sought to expand market share by debuting one or more products each year on average and continuing to foster each drug post-launch. We used in-house drug discovery and PLCM to bring a total of seven new drugs to market, including Zalutia and Upravi, and further enhanced our pipeline by inking in-licensing agreements for six products including NS-73 (generic name: defibrotide sodium) and NS-32. In addition, in March 2016 we completed construction of a new manufacturing facility for active pharmaceutical ingredients (APIs) for use in clinical trials. This building has helped expedite our R&D programs,

by speeding up production of nucleic acid and other APIs for clinical trials.

2. Marketing strategy

Vidaza and Zalutia matured into key growth drivers, recording sales in excess of ¥10 billion. Moreover, the PAH treatments Upravi, Adcirca, and Opsumit (licensed from Actelion Pharmaceuticals for co-promotion with Actelion Japan) all posted stronger-than-expected sales growth, and have evolved into products held in high regard by medical professionals.

3. Supply chain strategy (pharmaceuticals)

With the July 2017 completion of a new manufacturing plant for highly active solid formulations at the Odawara Central Factory, we were able to commence in-house production of Upravi.

4. Overseas business strategy

Upravi was launched in many countries around the world and sales have been growing strongly, contributing greatly to earnings expansion. In addition, we proceeded with preparations for a U.S. NDA and business operations for the antisense oligonucleotide NS-065/NCNP-01 (generic name: viltolarsen).

5. Functional Food business

We built a platform for transformation of the Functional Food business by pursuing reforms aimed at rendering it highly profitable, also launching a supplement business to add further value.

6. Human resource strategy

We became the first Japanese pharmaceutical company to introduce a flextime system for medical representatives (MRs), in our effort to create an environment enabling employees to fulfill their professional potential while at the same time finding a balance between work and physical and mental rejuvenation. To advance our cause overseas, we recruited individuals with in-depth expertise in such areas as global development, the law, and intellectual property. Furthermore, we were certified by the Ministry of Economy, Trade and Industry (METI) as a White 500 company in the Certified Health and Productivity Management Organization Recognition Program 2019. This was in recognition of our initiatives to maintain and promote employees' health and wellbeing, in line with our view that safeguarding employee health is a key issue for management.

For further details, see the Pharmaceuticals Sales section on page 25.

2 6th Five-Year Medium-term Management Plan

We acknowledge that the operating environment is changing, and under the 6th Five-year Medium-term Management Plan we aim to continue pursuing originality through initiatives that are not bound by the old ways of working or thinking.

We expect to encounter heightened uncertainty in business amid unprecedented change in the operating environment around us, typified by

government measures to promote greater use of generics, drastic reform of the healthcare system aimed at further reining in medical expenditure, ongoing technological innovation including new modalities in drug discovery, a decline in the working population, and diversification of working styles. We accordingly think that actions outside the existing framework are needed for sustainable growth.

In the 6th Five-year Medium-term Management Plan, we will further

develop our management base into a platform for sustainable growth, taking the following "six actions" to realize our corporate vision.

1. Creation of new value through R&D

In order to continue providing patients with high-quality and unique products, we will further build on the R&D capabilities we have cultivated thus far, and proactively pursue new modalities in drug discovery, including nucleic acid medicine and gene therapy.

In the Pharmaceutical business (particularly in our four areas of focus—namely, urology, hematology, intractable and rare diseases and gynecology), we will draw on internal and external management resources to flesh out our R&D pipeline and continuously bring new products to market, harnessing the drug discovery platform technologies developed to date while also adding new modalities through in-house drug discovery, in-licensing, and PLCM. We will continue enhancing our pipeline via in-house drug discovery, in-licensing, and PLCM, with a view to launching three original products, four in-licensed products, and four PLCM products by fiscal 2023, and further advancing development of drugs for which we aim to win accelerated approval in fiscal 2024 or later.

In the Functional Food business,

too, we will utilize internal and external management resources to continuously launch high-value-added products that address market needs, in the form of functional food ingredients with a level of quality and originality only a pharmaceutical company could provide.

2. Development of global business

With a view to delivering unique products to countries around the world, we will build an organizational structure worthy of a global business in all phases from R&D to manufacturing, distribution, and sales, and further accelerate the global expansion undertaken during the 5th Plan.

We will look to maximize the value of our original product, Upravi, by cooperating with licensing partner Actelion Pharmaceuticals, part of the Janssen Pharmaceutical Companies of Johnson & Johnson, to expand

indications. Profits generated by existing drugs including Upravi will be reinvested into viltolarsen and other exon skipping nucleic acids in development, as well as NS-018, NS-580, and others.

At the U.S. business we are continuing to recruit relevant personnel, chiefly for our U.S. subsidiary NS Pharma, as we step up our business operations for viltolarsen. Through this program, and the development and commercialization of subsequent exon skipping drugs, we seek to build a platform for sustainable growth.

At our European and Chinese operations, we aim to win early approval for NS-065/NCNP-01, and will consider whether to keep sales in-house or enter into a strategic alliance with a partner company.

For further details, see the Feature: Global Expansion section on pages 20 to 21.

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

Products of which we aim for approval by FY2023

Original	NS-065/NCNP-01 Duchenne muscular dystrophy	in Japan and overseas	Exon 44 skipping drug Duchenne muscular dystrophy	in Japan and overseas	NS-018 Myelofibrosis	Overseas
License-in	NS-73 Sinusoidal obstruction syndrome (treatment)	in Japan	NS-73 Sinusoidal obstruction syndrome (prevention)		in Japan	
	NS-32 Iron deficiency anemia	in Japan	ZX008 Intractable epilepsy		in Japan	
PLCM	NS-304 Chronic thromboembolic pulmonary hypertension	in Japan	NS-304 Arteriosclerosis obliterans		in Japan	
	Macitentan Chronic thromboembolic pulmonary hypertension	in Japan	NS-17 Acute myeloid leukemia		in Japan	

Products of which we aim for approval in the near future after FY2024

NS-580 Endometriosis	NS-304 Lumbar spinal stenosis	NS-87 Secondary acute myeloid leukemia	NS-917 Relapsed/refractory acute myeloid leukemia
Duchenne muscular dystrophy treatments other than NS-065/NCNP-01 and Exon 44 skipping drug			

For further details, see the Feature: Delivering Innovation through R&D section on page 18.



## Message from the President

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

We seek to increase our corporate value while achieving sustainable coexistence with society, and to that end will take steps to strengthen ESG (Environment, Social and Governance) management by such means as developing treatments for intractable diseases and delivering them to patients, and coming up with high-value-added supplements that address consumers' needs.

For further detail on our ESG activities, see the ESG section on pages 30 to 51.

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

From the perspective that "unique products come from unique human resources," we respect our employees' diversity and make no distinctions between gender, nationality or cultural background, providing opportunities for each individual to proactively take on challenges and grow, and creating an organizational climate in which all employees can play a more significant role and flourish. We also intend to actively recruit new graduates and mid-career workers to participate in R&D, globalization, and other aspects

of business expansion geared toward longer-term growth.

For further details, see the Feature: Human Resources Critical to Sustainable Growth section on page 19.

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

IT has advanced rapidly in recent years, and pharmaceutical companies also are exploring the use of AI. At Nippon Shinyaku, we plan to actively use AI, RPA and other technologies and promote adoption of IT, with a view to accelerating the launch of new products, streamlining operations, and increasing productivity, and, in doing so, continuously creating value. Working hours saved through business efficiency gains can be used for new drug creation, further contributing to sustainable growth.

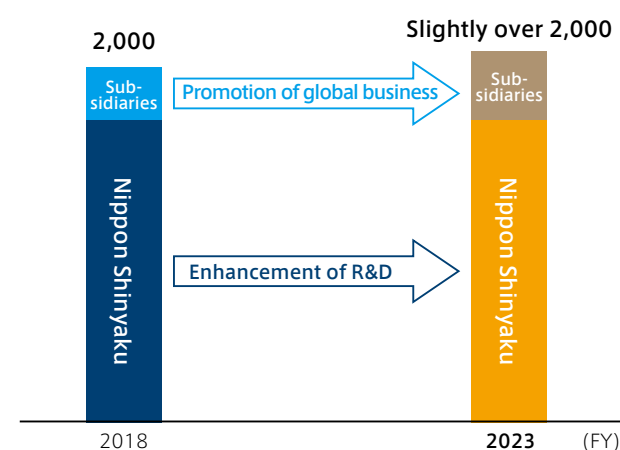
### 6. Further strengthening of management base

Predicting change is difficult at present owing to a highly uncertain business environment. To achieve sustainable growth under these circumstances, we aim to strengthen our management base by rebuilding management systems, making more effective use of management resources, improving our cost management, and pursuing greater profitability.

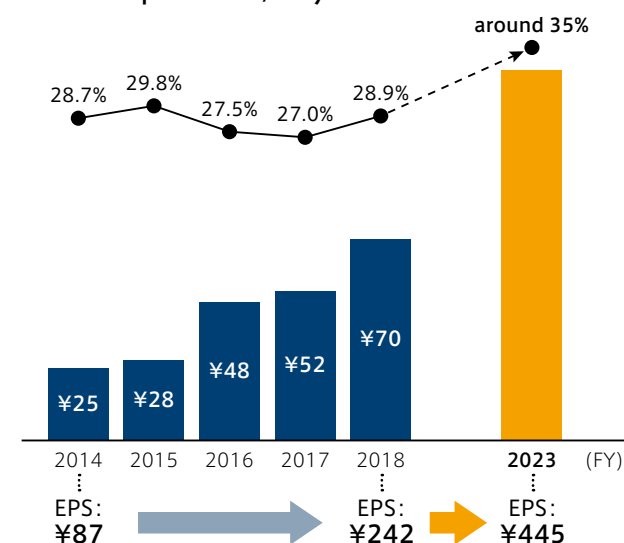
In addition to the aforementioned "six actions," we plan to invest actively in both tangible and intangible management resources (for example, personnel, knowledge, information, experience, and facilities). Through brisk investment in R&D, human resources, IT, and productivity gains, we aim to grow sustainably and be globally acclaimed as a "company with a meaningful existence in healthcare."

Through the above initiatives, we target consolidated net sales of ¥150,000 million for fiscal 2023, the final year of the 6th Five-Year Medium-term Management Plan (¥133,000 million for the Pharmaceuticals business and ¥17,000 million for the Functional Food business). For fiscal 2023 we also target operating income of ¥40,000 million, net income attributable to owners of the parent of ¥30,000 million, and EPS of ¥445. We aim to maintain ROE of 10% or more throughout the period of the 6th Plan. Furthermore, we seek to increase the consolidated payout ratio to around 35%, raising annual cash dividends per share by increasing EPS.

### Manpower planning



### Dividend per share / Payout ratio



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

**In fiscal 2019 we aim to continue growing both sales and profits. By building social value through our business activities we also look to enhance corporate value while realizing sustainable growth and achieving our vision.**

### 1 FY2019 outlook

In the Pharmaceuticals business in fiscal 2019, the first year of the 6th Plan, we anticipate an increase in sales of 0.9% year on year to ¥101,100 million due to growth in new product suites such as Upravi, Gazyva, and Zalutia, and growth in royalty income from Upravi's overseas sales, despite the scheduled revision of the National Health Insurance drug prices in October 2019. In the Functional Food business, we will focus further on developing and introducing new products, and by strengthening our efforts for priority items, we expect sales to be ¥14,900 million (a year-on-year increase of 2.8%). As a conse-

quence, we see the Nippon Shinyaku Group's net sales increasing 1.1% year on year to ¥116,000 million.

In terms of profits, we expect operating income to increase 1.7% year on year to ¥21,000 million, ordinary income to increase 2.1% year on year to ¥22,000 million, and net income attributable to owners of the parent to reach ¥16,500 million (a 1.2% year-on-year increase). In all cases, we look for profits to increase year on year, and we aim to set record highs in earnings as we expand sales.

### 2 Toward sustainable growth

The purpose of our business is to protect people's lives and health. We are concentrating in particular on the development of therapeutic agents for a small population of patients with intractable and rare diseases, through which we aim to offer unique value. In addition to fulfilling our mission toward patients and medical professionals, we plan also to contribute to the achievement

of SDGs (Sustainable Development Goals) and improve our ESG practices. By creating social value in this manner via our business activities, we believe we also enhance corporate value.

In this era of great transformation within the pharmaceutical industry, we think sustainable growth cannot be attained without the pursuit of further originality and continued rollout of highly distinctive products. By encouraging each and every employee to engage boldly in the company's mission of creating unique products, we seek to sustain growth over the longer term and become a "company with a meaningful existence in healthcare."



As a pharmaceutical maker determined to keep putting smiles on people's faces, Nippon Shinyaku aspires to become a global company using our 100th anniversary as an opportunity to shape further growth.

えがおとずっと  
100<sup>th</sup>  
ANNIVERSARY

# Special Feature: Looking Back Over Nippon Shinyaku's First 100 Years

## Celebrating 100 Years Since Founding

In the nearly 100 years since its establishment in 1919, Nippon Shinyaku has committed itself, as an R&D-based producer of new medications, to a distinctive kind of drug discovery. Here, we look back over Nippon Shinyaku's first 100 years, and identify the strengths it has nurtured in that time.

Strengths nurtured by Nippon Shinyaku



### Delivering Innovation through R&D

Building a platform for discovery of innovative new drugs



### Human Resources Critical to Sustainable Growth

Initiatives for developing human resources to drive sustainable growth



### Global Expansion

Developing global business, with a presence in 49 countries around the world, and ties with 165 companies

1962

Completed construction of Research Laboratory (first phase; now Building 3 of Discovery Research Laboratories) at the head office

1970

Completed construction of Food Development Laboratory at the head office

1982

Completed construction of main building of Central Research Laboratories (now Building 1 of Discovery Research Laboratories) at the head office

1972

Completed construction of employee welfare and training facility, Hoyu Kaikan hall

1979

Began introductory education for medical representatives (MRs)

1958

Stepped up pursuit of overseas alliances

1994

Completed construction of Building 2 of Discovery Research Laboratories at the head office



Building 2 of Discovery Research Laboratories

1997

Completed construction of Discovery Research Laboratories in Tsukuba



Discovery Research Laboratories in Tsukuba

2016

Completed construction of active pharmaceutical ingredient manufacturing building at the head office



Active pharmaceutical ingredient manufacturing building

1997

Initiated qualifying examinations for MRs



2003

Completed construction of Training Center at the head office



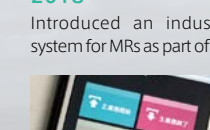
2007

Introduced Next-Generation Leader Development Program



2008

Introduced Career Support Academy (CASA)



2018

Introduced an industry-first flextime system for MRs as part of work-style reforms



2019

Selected as White 500 company in Certified Health and Productivity Management Organization Recognition Program 2019



1991

Opened Dusseldorf Office (now London Office)



1997

Opened New York Office (now U.S. subsidiary NS Pharma, Inc.)



2011

Opened Beijing Representative Office



2016

Launch of Uptravi in Japan, U.S., and Europe



2019

Established the Global Business Division



Established  
1919

Launch of products contributing to society

- Pharmaceuticals business
- Functional Food business

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

1961

- Start of Functional Food business

1967

- Eviprost, treatment for benign prostatic hypertrophy

1984

- Estracyt, treatment for prostate cancer

1989

- Gaslon N, treatment for gastric ulcers and gastritis

1992

- Selectol, treatment for hypertension and angina pectoris

1994

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

1998

- Garcinia extract, health food ingredient

2002

- Odric, ACE inhibitor

2006

- Baynas, treatment for allergic rhinitis



Santonin



Eviprost



Estracyt



Selectol



Hypen

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

2010

- Tramal, treatment for cancer pain and chronic pain

2011

- Vidaza, treatment for myelodysplastic syndrome

2013

- Regect, aid for maintaining alcohol abstinence

2014

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



Adcirca



Erizas



Zalutia

2015

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

2016

- Launched Functional Food mail-order business
- Uptravi, treatment for pulmonary arterial hypertension
- WINZONE ENERGY × ENERGY

2017

- AGE-SHUT Beauty Jelly (glycation care supplement)

2018

- Gazyva, treatment for CD20-positive follicular lymphoma



Onetram



Uptravi



WINZONE





## Delivering Innovation through R&D

### 1 Origins of Nippon Shinyaku's R&D

#### Launch of Brovarin in 1915

Nippon Shinyaku's R&D story traces back to the company's predecessor, Kyoto Shinyakudo, which was founded in 1911. Subsequently, the outbreak of the First World War led to shortages of critical supplies. Until then, the nation had relied largely on imports for its supply of pharmaceuticals and dyestuffs, however the war caused serious shortages, which became a grave issue for Japan. In addition to establishing "national policy companies" to promote domestic production of pharmaceuticals, the Japanese government also enacted the Wartime Law on Industrial Property, which effectively invalidated patents that were hindering development. These changes encouraged the

commercialization of drug manufacturing, with companies originally founded as pharmaceutical wholesalers also venturing into production. In essence, modern pharmaceutical production in Japan originated at this time.

In response to the demands of the times, Kyoto Shinyakudo hastened development of new drugs, and in 1914 it launched the Ninzerin pregnancy test and other urine dipstick tests. In 1915, Kyoto Shinyakudo went on to release a number of new drugs, including the hypnotic and sedative Brovarin, the skin ointment Pityrol, and the anemia treatment Neohe-matopan and, in doing so, progressively growing its pharmaceutical business.

Nippon Shinyaku has throughout its history adhered to this idea of tailoring R&D to answer the needs of the time, and the R&D competencies acquired over the past 100 years or so constitute a core strength for the company.



An early Kyoto Shinyakudo laboratory

### 2 Development of Nucleic Acid Drug

#### Development of NS-065/NCNP-01

In our R&D, we strive to create highly original drugs. A prime example is the nucleic acid medicine in development at the Discovery Research Laboratories in Tsukuba. Nucleic acid drugs act directly on the genes that cause diseases, making it possible to treat illnesses that previously have been difficult to treat with conventional small molecule drugs. For this reason, people all over the world believe that nucleic acid drugs will be the next generation of medicines after antibody therapies. At Nippon Shinyaku, we expect demand for nucleic acid drugs to continue growing accordingly.

In our work on nucleic acid medicines, Nippon Shinyaku has been developing a new drug that we hope will offer an effective treatment option for Duchenne muscular dystrophy (DMD). DMD is caused by mutations to the dystrophin gene, dystrophin being a protein that is indispensable in constructing the

framework of muscle cells. DMD is a serious genetic disorder in which patients experience a severe loss of muscle power due to a deficiency of normal dystrophin. Nippon Shinyaku's NS-065/NCNP-01 (generic name: viltolarsen) is a DMD treatment that can skip over exons, an ability that is unique to nucleic acid medicines, and in February 2019 the company commenced a rolling submission of a New Drug Application in the U.S. In Japan, the company has begun consultations with the Ministry of Health, Labour and Welfare with a view to filing as soon as possible under Japan's new conditional early approval system introduced in October 2018.

In our 6th Five-Year Medium-term Management Plan, we have outlined six actions needed for sustainable growth, one of which is "creation of new value through R&D." Our plan is to create pharmaceuticals with new value by adding

new modalities in drug discovery, such as gene therapy, and new technologies, such as nucleic acid drug delivery systems, to the drug discovery platform that already has produced viltolarsen as well as the small molecule drug, Upravi. We aim to draw on our R&D capabilities to pursue business activities that deliver effective drugs even one day earlier to as many patients as possible around the world.



Discussion at research laboratory



## Human Resources Critical to Sustainable Growth

### 1 Leading the Way in MR Education

#### Launch of MR introductory education in 1979

At Nippon Shinyaku, we believe that our personnel are a key management resource, without whom growth could not be sustained. We accordingly have implemented a range of initiatives related to human resources, one of which was the 1979 introduction of education and training for our medical representatives (MRs).

In 1979, the Japan Pharmaceutical Manufacturers Association (JPMA) compiled the "Education and Training Guidelines for Medical Representatives," and from 1980 the JPMA began offering introductory and ongoing education, for some 30,000 MRs. Nippon Shinyaku participated in every aspect of the JPMA's work to put together a training curriculum and basic schedule.

By that time, though, Nippon Shinyaku already had started offering basic sales education for new sales personnel, also annually conducting group training at the head office and training at individual business locations for employees in their first, third, and seventh years at the company. Nippon Shinyaku also had been planning more specialized education geared toward improving the quality of its MRs. Against this backdrop, and one year ahead of a simultaneous start across the industry, Nippon Shinyaku adopted the JPMA's Education and Training Guidelines as soon as they were formulated, when in 1979 we began offering sales education for new employees that extended over six months. We also established an internal

committee for the promotion of MR education and training, which formulated a curriculum and textbooks for continued education and drew up a plan for the implementation that followed in 1980. In this manner, Nippon Shinyaku was a step ahead of peers in directing resources into MR education.



Introductory education for MRs

### 2 Redoubling Efforts to Promote Advancement of Women in the Workplace

#### Ratio of women in management up to 13%

In our pursuit of further growth, Nippon Shinyaku is committed to developing an environment and organizational culture that enables employees to balance life events with careers. We are particularly determined to support women in this respect.

As part of this effort, we have established an "engagement system" enabling registered female employees to retain their MR qualifications and return to work as MRs after interrupting their careers due to life events such as marriage and childbirth. In our support of a greater work-life balance, we also have made it possible for employees to take cumulative paid leave in single- or even half-day units, as well as creating a contact point for inquiries on how to navigate systems pertaining to marriage, childbirth, and child-rearing.

To promote workplace reform for women and raise employee awareness, in 2011 we formed the "Maruenu Supplement" internal committee, whose activities include meetings at which MRs can exchange opinions, career seminars at the company's head office, and roundtable discussions at the Odawara site. What's more, with an eye to improving productivity through promotion of job efficiency gains and sharing, in 2013 we introduced a "Positive Off" holiday program encouraging employees to take cumulative paid leave in three-to-five-day blocks.

At Nippon Shinyaku, the number of female MRs is increasing year by year. As of March 2019 we had 108 female MRs, amounting to just over 16% of the total. The ratio of women in management positions also has risen from 9% at the

beginning of the 5th Five-Year Medium-term Management Plan, to 13% when the plan ended in fiscal 2018. Furthermore, the ratio of female executives has increased from 4.5% in 2014 to 7.9% in fiscal 2018.

For details of other initiatives related to human resources, see Pharmaceuticals Sales on pages 24-25, and Human Resources on pages 34-37.



Activities of the Maruenu Supplement internal committee





# Global Expansion

## 1 Full-Fledged Global Expansion Driven by In-House Drug Discovery

**Uptravi: Global product sales of some ¥80 billion as of 2019**

Nippon Shinyaku's global expansion began with out-licensing of the in-house developed oral quinolone antibiotic, prulifloxacin. In Japan, the then Meiji Seika Kaisha (now Meiji Seika Pharma), launched prulifloxacin in 2002, under the brand name Sword. Globally, Nippon Shinyaku out-licensed prulifloxacin to Italy's Angelini S.p.A. in 1993, and as of 2019 Angelini is marketing the drug in seven European countries and six Latin American nations. Nippon Shinyaku also forged a licensing agreement in 2010 with Lebanon's Algorithm SAL, while in Asia we inked an agreement in 2009 with the Hong Kong-based Lee's Pharmaceutical Holdings Limited.

Also, among drugs discovered in-house, one of the most important is NS-304 (generic name: selexipag).

In 2008, we entered into a licensing agreement with Swiss company Actelion Pharmaceuticals,\* a global leader in the field of pulmonary arterial hypertension (PAH), which stipulated that Actelion would be responsible for global development and commercialization of selexipag outside Japan, while Nippon Shinyaku and Actelion's Japanese subsidiary, Actelion Pharmaceuticals Japan, would co-develop and co-commercialize the drug in Japan. Subsequently, Actelion filed for marketing approval in the U.S. and Europe in 2014, and it launched the drug in both markets in 2016, under the brand name Uptravi. After selexipag was granted orphan drug designation by the MHLW in September 2014, Nippon Shinyaku launched it as Uptravi in Japan in 2016, thereby providing PAH patients with a long-awaited new

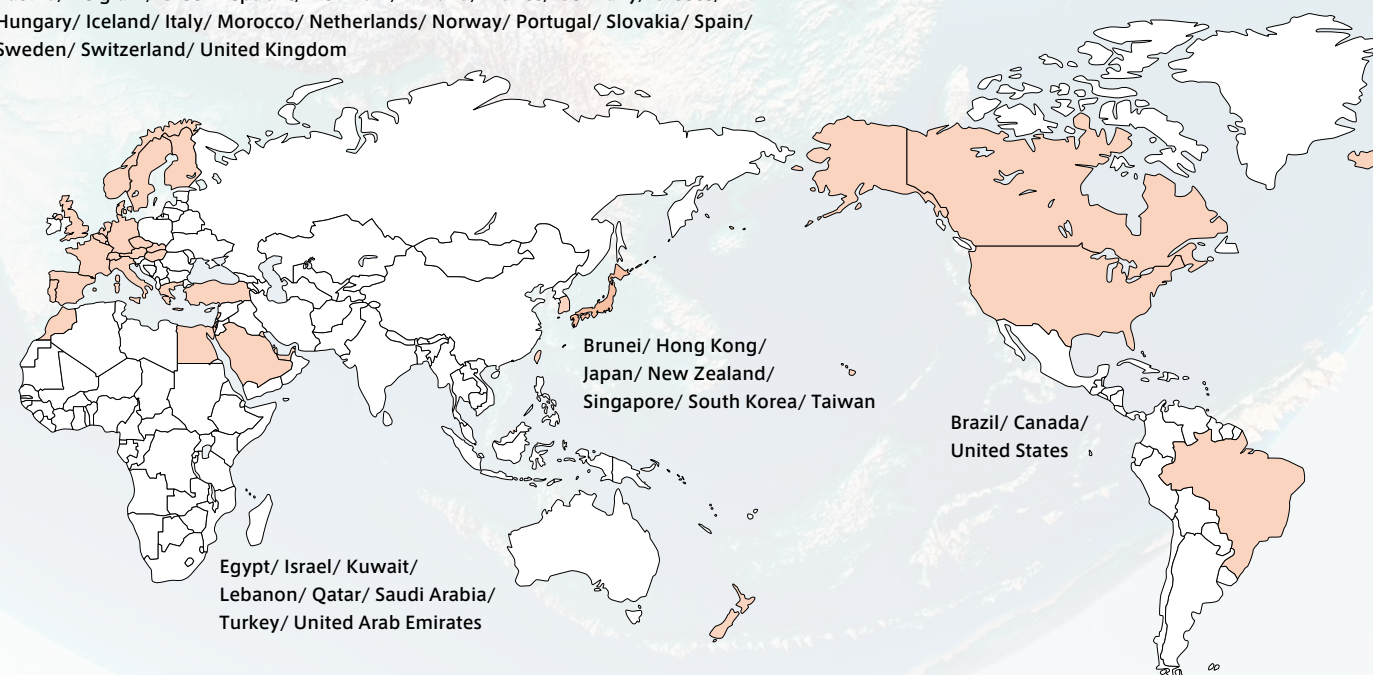
treatment option. Since then, Uptravi has been rolled out progressively across Asia and Oceania. Prescription numbers are growing steadily in each market, and the drug has evolved into a global strategic product.

Our growth strategy for drugs discovered in-house sees us continuing to expand exports of original products primarily to Asia, where demand for pharmaceutical products is rising in tandem with economic development. In other regions, we will take each country's circumstances into account when making the decision whether to keep sales in-house or enter into out-licensing agreements, selecting the option most likely to maximize product value.

\* Johnson & Johnson acquired Actelion Pharmaceuticals in 2017 and remains an important partner for Nippon Shinyaku.

### Countries in which Uptravi is sold

Austria/ Belgium/ Czech Republic/ Denmark/ Finland/ France/ Germany/ Greece/ Hungary/ Iceland/ Italy/ Morocco/ Netherlands/ Norway/ Portugal/ Slovakia/ Spain/ Sweden/ Switzerland/ United Kingdom



## 2 Actively Pursuing In-licensing in Field of Hematology

**NS-73\* commercially available in 35 countries**

\* Generic name: defibrotide sodium; from Jazz Pharmaceuticals

Since around 2012, we have licensed in a number of products in the hematology field in the search for a new blockbuster drug to follow Vidaza, which in fiscal 2017 became the first Nippon Shinyaku product to reach sales of ¥15 billion.

The first drug to be licensed in after Vidaza was the CD20-positive follicular lymphoma treatment Gazyva (generic name: obinutuzumab). Swiss pharmaceutical company Roche is conducting clinical trials overseas, while Roche group company Chugai Pharmaceutical is responsible for clinical trials in Japan, and in November

2012 we entered into an agreement to co-develop and co-market Gazyva with Chugai, as we looked to expand our offerings in the hematological field. Since then, Nippon Shinyaku also has been participating in Gazyva's development. In July 2018, Chugai obtained MHLW approval to manufacture and market Gazyva in Japan, and Nippon Shinyaku began marketing the drug in conjunction with Chugai. Sales are increasing steadily, and together we aim to grow Gazyva into a blockbuster drug.

Also, in 2017 we entered into a licensing agreement with Ireland's Jazz Pharmaceuticals,

through which we licensed in the sinusoidal obstruction syndrome (SOS) treatment NS-73 (generic name: defibrotide sodium). Jazz obtained regulatory approval in Europe in 2013 and in the U.S. in 2016, and NS-73 is now available in 35 countries around the world (including several European nations as well as the U.S., Israel, and South Korea), with plans for a Japan launch in 2019. At the same time, we also inked a licensing agreement with Jazz through which we licensed in NS-87, for the treatment of secondary acute myeloid leukemia. Preparations for development currently are under way.

## 3 Building Production Infrastructure Supporting Globalization

**Production capacity increased by 30%**

In 2000 or thereabouts, Nippon Shinyaku embarked on a realignment of production facilities geared toward improving productivity, adapting to change in the operating environment and supporting business globalization. Key to this effort was a massive project to recreate a manufacturing facility conforming to international standards of good manufacturing practice (GMP) while also realizing high productivity and increasing capacity by 30%, through the transfer of

production from the existing Kyoto Factory to a new site for pharmaceuticals formulation production at the Odawara Factory, construction of which commenced in 1999. This facility covers 16,529m<sup>2</sup> of floor space, and at the time of construction it boasted one of the highest production capacities in Japan's pharmaceutical sector. It features cutting-edge automated production lines and manufacturing software, supporting high-mix manufacturing.

After completion of this new building, Nippon Shinyaku closed the Kyoto Factory and consolidated production at the Odawara Factory, now known as the Odawara Central Factory. Following the 2017 completion of a manufacturing plant for highly active solid formulations, the Odawara Central Factory has a crucial role to play in our plans for globalization.

## A Director's Comments

### Boldly Embracing Challenge of Globalization by Forming Global Business Division to Strengthen Organizational Structure

Aided by the 2016 launch of the PAH treatment Uptravi, in fiscal 2018 Nippon Shinyaku achieved overseas sales in excess of ¥20 billion, amounting to 20% of overall sales. Uptravi is available in 38 countries globally, and I take great pride in the fact that a Nippon Shinyaku product is helping people around the world achieve better health. Going forward, our goal is to further expand overseas sales and associated royalty income by deepening our ties with Johnson & Johnson, with whom we have a license and supply agreement concerning Uptravi. With NS-065/NCNP-01 and subsequent exon skipping drugs, we will step up efforts to grow global sales by practicing in-house sales, starting in the U.S. and from there expanding our reach to include Europe and China.

In fiscal 2019, we established a Global Business Division with a view to building an organization robust enough to underpin global expansion. As Head of Global Business, my role naturally is to strengthen the division's organizational structure, although I think it is also important that I exercise leadership in pursuing global growth through cooperation with other Nippon Shinyaku divisions (that is, R&D, manufacturing, distribution, sales, and administration), and working toward greater competitiveness for the Nippon Shinyaku Group as a whole. Amid great change in the business climate in Japan, I plan to boldly embrace globalization to ensure that Nippon Shinyaku can continue to grow.

Toru Nakai

Director,  
Head of Global  
Business





# Pharmaceuticals R&D

## Providing patients with unique medications in main fields of focus, even if only one day earlier

### Situation in FY2018

#### Continuing developmental progress in main fields of focus

In fiscal 2018, we continued to engage in R&D, especially in our main fields of focus. In August 2018, Nippon Shinyaku and Chugai Pharmaceutical commenced sales in Japan of GA101 (product name: Gazyva, generic name: obinutuzumab), a CD20-positive follicular lymphoma treatment for which Chugai Pharmaceutical originally won domestic manufacturing and marketing approval in July 2018. We are endeavoring to deliver this product to patients and medical professionals without delay, with a view to providing patients with new treatment opportunities.

In October 2018, we sought manufacturing and marketing approval in Japan for NS-73 (generic name: defibrotide sodium), a sinusoidal obstruction syndrome (SOS) treatment licensed in

from Jazz Pharmaceuticals in March 2017. We gained approval for NS-73 in June 2019. Furthermore, since June 2018 we have been participating in a Phase III global study initiated by Jazz Pharmaceuticals, investigating NS-73 in the prevention of SOS.

A Phase III trial for the additional indication of chronic thromboembolic pulmonary hypertension (CTEPH) is under way with Actelion Pharmaceuticals Japan for NS-304 (product name: Upravi, generic name: selexipag), a product launched in 2016 for pulmonary arterial hypertension (PAH). NS-304 has been granted orphan drug designation by the Ministry of Health, Labour and Welfare (MHLW) for the indication of CTEPH. Nippon Shinyaku also is independently investigating NS-304 in a late Phase II clinical trial covering arteriosclerosis obliterans, and an early Phase II study targeting lumbar spinal stenosis.

- Pharmaceuticals R&D
- Pharmaceuticals Sales
- Pharmaceuticals Production
- Functional Food



We completed a Phase I/II trial in Japan for the Duchenne muscular dystrophy treatment NS-065/NCNP-01 (generic name: viltolarsen), the first antisense oligonucleotide discovered in Japan. We also conducted a Phase II trial in the U.S., where we have commenced a rolling submission of a New Drug Application (NDA). In Japan, NS-065/NCNP-01 has received “Sakigake” designation from the MHLW, enabling accelerated regulatory approval, while in the U.S. it was granted fast track designation status by the U.S. Food and Drug Administration (FDA), and has received orphan drug designation and rare pediatric disease designation status.

### Our Future Growth Strategy

**Nippon Shinyaku aims to continually enhance its development pipeline through in-house drug discovery incorporating new drug discovery modalities, as well as in-licensing, and product life cycle management (PLCM).**

Under the 6th Five-Year Medium-term Management Plan, we seek to further enhance the R&D capabilities we have built thus far, while also actively incorporating new drug discovery modalities including nucleic acid drugs and gene therapy.

With a focus on the four key areas of urology, hematology, intractable and rare diseases, and gynecology, we plan to flesh out our development pipeline through in-house drug discovery, in-licensing, and PLCM, utilizing both internal and external resources, and ultimately targeting global expansion.

Through these R&D activities, we seek to create new value and provide a steady stream of innovative new drugs for diseases with significant unmet medical needs.

Akira Matsuura  
Managing Director,  
Head of R&D

### Pipeline

#### Japan

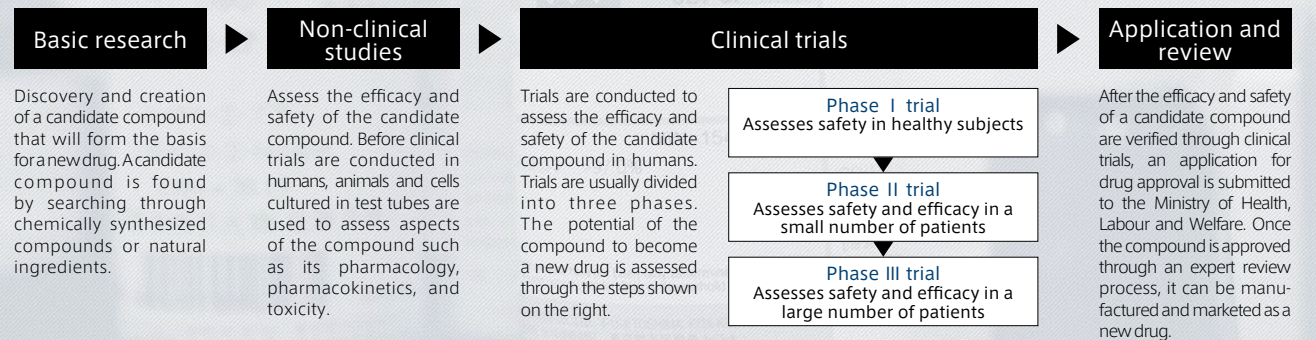
As of July 1, 2019

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase			NDA filing	Preparation for launching
						I	II	III		
NS-73 (Defibrotide sodium)	Preparation for launching	Hematologic malignancies	Sinusoidal obstruction syndrome (treatment)	Licensed-in from: Jazz Pharmaceuticals PLC	Nippon Shinyaku					
	PⅢ (Global clinical trials)		Sinusoidal obstruction syndrome (prevention)	Licensed-in from: Jazz Pharmaceuticals PLC	Co-development: Jazz Pharmaceuticals PLC					
NS-17 (Azacitidine)	PⅡ		Acute myeloid leukemia	Licensed-in from: Celgene Corporation	Nippon Shinyaku					
NS-917	Preparation for development		Relapsed/refractory acute myeloid leukemia	Licensed-in from: Delta-Fly Pharma, Inc.	Nippon Shinyaku					
NS-87	Preparation for development		Secondary acute myeloid leukemia	Licensed-in from: Jazz Pharmaceuticals PLC	Nippon Shinyaku					
ZX008	PⅢ	Intractable disease/ orphan disease	Dravet syndrome/ Lennox-Gastaut syndrome	Licensed-in from: Zogenix, Inc.	Zogenix, Inc.					
NS-065/ NCNP-01 (Viltolarsen)	PⅠ/Ⅱ		Duchenne muscular dystrophy	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku					
	PⅢ		Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Co-development: Actelion Pharmaceuticals Japan Ltd.					
NS-304 (Selexipag)	PⅡ	Cardiovascular	Arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku					
	PⅡ	Orthopedics	Lumbar spinal stenosis	Nippon Shinyaku	Nippon Shinyaku					
NS-32	PⅢ	Gynecology	Iron deficiency anemia	Licensed-in from: Pharmacosmos A/S	Nippon Shinyaku					
NS-580	PⅡ		Endometriosis	Nippon Shinyaku	Nippon Shinyaku					

#### Overseas

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase			NDA filing	Preparation for launching
						I	II	III		
NS-018	PⅠ/Ⅱ	Hematologic malignancies	Myelofibrosis	Nippon Shinyaku	Nippon Shinyaku					
NM441 (Prulifloxacin)	NDA filing	Anti-infection	Bacterial infections	Nippon Shinyaku	Licensed-out to: Lee's Pharmaceutical Holdings Ltd.					
NS-304 (Selexipag)	PⅢ	Intractable disease/ orphan disease	Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Licensed-out to: Johnson & Johnson					
NS-065/ NCNP-01 (Viltolarsen)	Rolling submission for NDA		Duchenne muscular dystrophy	Co-development: National Center of Neurology and Psychiatry	Nippon Shinyaku					

### Main steps of new drug development





# Pharmaceuticals Sales

## Contributing to patient care by providing accurate information addressing medical professionals' needs

### Situation in FY2018

#### Contributing to patient care in our main fields of focus

We strive to provide high-quality information in the three areas we have identified as core areas of focus: urology, hematology, and pulmonary arterial hypertension (PAH).

In the urology field, we have committed to providing information on proper usage of Zalutia since its launch in 2014. When the Japanese Urological Association released new clinical guidelines for male lower urinary tract symptoms and benign prostatic hypertrophy in April 2017, it positioned Zalutia as first-line therapy, and in fiscal 2018, Zalutia accordingly has made further inroads into the market for benign prostatic hypertrophy therapies.

In the field of hematology, the CD20-positive follicular lymphoma treatment Gazyva was launched in Japan in August 2018. In the marketing of this drug as well as the myelodysplastic syndrome remedy Vidaza, we are contributing to patient care by providing information that leads to better treatment for bone marrow disease, lymphatic system disease, and other forms of blood cancer.

In the PAH field, Nippon Shinyaku is the only company in the world to offer oral preparations with three different action mechanisms: Adcirca, Opsumit, and Uptravi. By providing accurate information on these three agents to medical specialists, we are making a contribution to PAH treatment.

- Pharmaceuticals R&D
- Pharmaceuticals Sales
- Pharmaceuticals Production
- Functional Food



### Our Future Growth Strategy

#### Building and enhancing an academic support system that addresses diverse medical needs, providing information contributing to regional healthcare visions and comprehensive regional care

The government has put in place a system that encourages collaboration in healthcare between companies and medical providers in local communities. This has brought variation in healthcare delivery between regions, and heightened the importance of information-supplying activities that match communities' diverse needs. At the same time, gathering and providing information in a more efficient manner is critical to achieving improved productivity via workplace reforms.

Our Sales and Marketing Division accordingly is transitioning to a model whereby medical representatives (MRs) take responsibility for all medical institutions in a particular area, with no differentiation between hospitals and private practitioners. In this manner, we are building a system that reduces duplication in MR visits, and helps us disseminate information more efficiently. We also are striving to ensure that in providing information we are better meeting the diversifying medical needs of individual communities. In addition to recruiting already-qualified individuals, Nippon Shinyaku also appoints MRs to as the Pharmaceutical Information Department members in each area after they have gained specialized knowledge by undertaking extensive training and sitting in-house qualification exams.

Our Sales and Marketing Division remains committed to day-to-day information-sharing activities aimed at delivering appropriate medications to patients even just one day earlier, and putting smiles on more patients' faces each day.



Shouzou Sano  
Managing Director,  
Head of Sales and Marketing

### Key Topics for FY2018

#### Introduction of flextime system for MRs

In the Sales and Marketing Division we seek to facilitate diverse working styles as part of our commitment to workplace reforms. We believe MRs are at their most efficient when given responsibility for their own time management, rather than following hours set by the company. To that end, in fiscal 2018 we introduced a flextime system without core time that enables MRs to adapt break times as well as starting and ending times to their individual circumstances.

This system allows MRs to effectively utilize times when they are not meeting with medical professionals, for example for self-improvement, a lunch break, or the pursuit of hobbies. More and more MRs are taking advantage of this system, which also lets employees adjust the hours at which they begin and finish work, enabling a more equal distribution of household chores between husband and wife, and drawing a clear distinction between on- and off-time.

To help this system gain traction, in fiscal 2018 the Sales and Marketing Division strove to improve time management, introducing greater flexibility to MR planning for visits to doctors, and eliminating waste time. By leveraging this system we aim to carry out information-supplying activities in an efficient manner while at the same time effecting workplace reforms.



Adoption of time attendance management system as part of commitment to workplace reforms

#### Team-based marketing and business process monitoring

In Japan, the government has put in place a system that encourages collaboration in healthcare among medical providers (both hospitals and private practitioners) in local communities, which increases the importance of local area marketing. We accordingly have rejigged our sales organization, introducing a team structure in fiscal 2017. In fiscal 2018, we subdivided our sales force into 13 business offices, 43 business branches, and 115 sales teams across the country. In addition to a top-down strategy from head office, we set up a system that will allow us to formulate and execute strategy in a way that matches needs in each locality.

Furthermore, in 2015 we switched our MR evaluation system from a performance-based system to a business process monitoring system that puts more weight on MRs' day to day activities. This new system is built on the principle of valuing those who contribute to patient care by acting as a treatment partner for medical professionals, with a view to providing information that ensures patients receive the drug therapy best suited to their circumstances. As a result, we are progressively generating heightened awareness among MRs tasked with marketing our products, resulting in steady growth in earnings.



Team structure introduced as part of reforms to sales organization

### Human Resource Initiatives

#### Cultivating human resources capable of supplying high-quality information

In order to improve the quality of information provided to medical professionals, Nippon Shinyaku emphasizes employees' academic levels and meeting skills, working to strengthen both. For MRs to supply high-quality information to medical providers, they must be able to ascertain the true needs of medical professionals and convey their academic knowledge accurately.

In 2013, Nippon Shinyaku introduced an in-house qualification system testing MRs' knowledge regarding our three main fields of focus: urology, hematology, and PAH. These examinations are graded according to level of knowledge, and those passing each test are qualified accordingly. As the names suggest, the Basic test evaluates MRs' basic product knowledge, the Advanced test identifies MRs with advanced product expertise and peripheral knowledge, and the Specialist test singles out MRs capable of discussing individual cases with medical specialists, and providing information appropriate to each case. In this manner, the company is building an internal culture that encourages employees to aspire to higher-stage qualifications, and we have found that MRs are keen to pursue self-improvement and improve their academic knowledge.

On the subject of meeting skills, we put high priority on the ability to accurately grasp the needs of medical



MR training

professionals and provide information addressing those needs. To that end, we work constantly to improve the quality of MR activities, including via external training from time to time. As a consequence, MRs' focus is shifting from merely introducing products, to supplying the information needed by medical professionals to support patient care.

External research has shown that as a result of these endeavors, Nippon Shinyaku's MRs are earning higher commendations from specialists in the fields of urology, hematology, and PAH, enabling the company to grow its presence in each area.

#### Nurturing human resources able to fulfill their role in various environments

Nippon Shinyaku employees are required to respond flexibly to increasingly rapid change in both the internal and external environment. With that in mind, our Sales and Marketing Division holds diversity management training aimed at invigorating the organization via such means as promoting further activity by women, in a bid to develop employees capable of holding their own in a changing business environment. The company will continue working proactively to cultivate MRs who can act on behalf of medical professionals and patients.



Training in diversity management



# Pharmaceuticals Production



## Expanding business globally to ensure steady supply of high-quality pharmaceuticals

### Situation in FY2018

#### Raising productivity and enhancing stable product supply system

In fiscal 2018, the final year of our 5th Five-Year Medium-term Management Plan, we strove to improve productivity across the supply chain through tighter cost management and initiatives to provide a stable supply of products while also enhancing efficiency at every stage—procurement, manufacturing, and logistics. As in fiscal 2017, we provided an e-learning program on cost control to raise awareness of costs among employees working across the supply chain. We also put a quality management system in place to ensure the quality, efficacy, and safety of active pharmaceutical ingredients and pharmaceutical products. Furthermore, we actively pursued business continuity planning (BCP) to ensure the supply of products

was not disrupted, by such means as establishing and maintaining target inventory levels, reducing risk via oversight of suppliers, and regularly revising emergency operations manuals. We also worked to lower logistics costs through a reexamination of business practices.

#### Pursuing originality with view to enhancing customer satisfaction

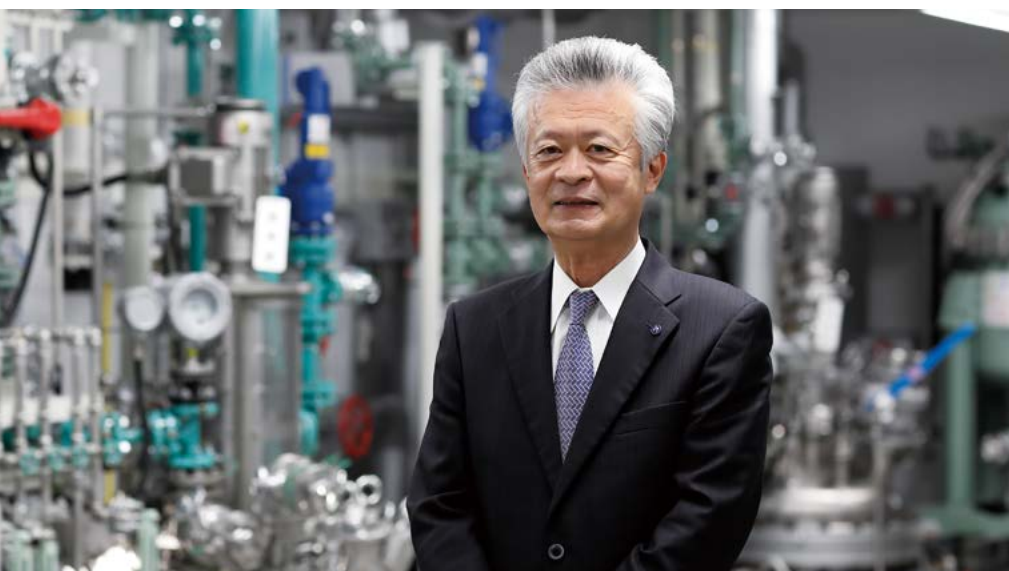
As a result of the Japanese government putting in place a policy to promote generic medicines, production volume of long-listed products has been declining at the Odawara Central Factory. Lower output can lead to higher manufacturing costs, in light of which we are cross-training workers and re-employing seniors, enabling us to carry out manufacturing with fewer capable workers. We are working to further reduce manufacturing costs by streamlining production and

focusing on the acquisition of new manufacturing contracts. In July 2017, a facility for highly active solid formulations was constructed on the premises of the Odawara Central Factory, and in fiscal 2018 this facility began serving as an integrated production center for the company's highly active solid formulations. We seek to ensure that the Odawara Central Factory maintains a high degree of customer satisfaction, through the pursuit of originality leveraging the factory's existing technological prowess alongside this new capacity for producing highly active solid formulations.

### Our Future Growth Strategy

#### Establishing global supply system and reliability assurance framework

We think proactive globalization is critical in laying the groundwork needed for sustained growth. To ensure confidence in the quality, efficacy, and safety of our pharmaceutical products, it is essential in our view to establish a supply system and reliability assurance framework that are compliant with global standards. In addition to building a global supply system, we are committed also to operating a logistics division compliant with Good Distribution Practice (GDP) for medicinal products, toward which end we seek to establish a reliability assurance framework that stands up to overseas audits and regulations, and foster the personnel required to achieve this.



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

### Quality Assurance and Supply Stability

#### Reliability assurance from the R&D stage to post-marketing

Under the leadership of the Regulatory Affairs Supervision and Assurance Division, Nippon Shinyaku strives to unfailingly secure the quality, efficacy, and safety that are indispensable to pharmaceutical products.

At the R&D stage of product development, we carry out clinical and non-clinical tests, and prepare application documents for manufacture and marketing approval. Our Regulatory Affairs Supervision and Assurance Division audits these documents at the appropriate stage to ensure the reliability of data from non-clinical testing and clinical trials.

Once manufacture and marketing approval is received, the three key administrators required by legislation (general marketing supervisor, quality assurance manager, and safety manager) work in tandem to fulfill the company's responsibilities to the market by maintaining and managing such approvals as well as Nippon Shinyaku's license for marketing authorization and license for manufacturing, thereby assuring the quality of products being manufactured and sold, and affirming their safety.

#### 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-manufacture 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 manufacture and marketing approval and license for marketing authorization, etc.

#### Pharmaceutical risk management

We carry out risk management in accordance with a pharmaceutical risk management plan (RMP)<sup>1</sup>. The RMP's purpose is to maintain the safety of post-market drugs by evaluating the benefits and risks through all periods from the development phase to post-marketing; we carry out necessary safety measures based on the results. At present, Nippon Shinyaku has created RMPs for the tramadol formulations Tramal OD and Onetram, as well as Uptravi. This information is made public on the websites of both the Pharmaceuticals and Medical Devices Agency (PMDA) and Nippon Shinyaku.

To ensure that the RMP is put into practice, the Safety Management Department prepares manuals aimed at enhancing the response capabilities of persons in charge, also encouraging cross-departmental division of duties across the group.

<sup>1</sup> Risk Management Plan: A document that defines critical risks with post-marketed pharmaceuticals and outlines the efforts made by the company to reduce those risks

#### Establishing a pharmaceutical quality assurance system

The Quality Assurance Department is charged with ensuring adherence to GQP and GMP and establishing a pharmaceutical quality assurance system. Through management reviews, the department strives to maintain vigilance over suppliers and continually improve product quality and resource allocation. As the company expands its footprint in the U.S., we are also committed to establishing a world-class quality assurance system, through a focus on communication skills in English, and the recruitment and further training of personnel with knowledge of quality assurance practices overseas.

#### Stable supply of products

At the Odawara Central Factory, we introduced an original qualification certification system in fiscal 2014, and are working to enhance the versatility of employees' skills. With the vision of becoming a factory that is competitive in terms of cost and quality, we have implemented the balanced scorecard (BSC<sup>2</sup>) management method, under which we establish strategy from a multifaceted perspective that incorporates financials, customers, business processes, human resources, innovation, and more, also setting KPIs<sup>3</sup> to manage progress toward achievement of our strategy and vision. Our distribution framework is configured not only to help maintain quality, for instance through temperature control during transit and storage, but also incorporates ideas such as use of multiple storage sites to minimize loss risks in contingencies such as disasters.

<sup>2</sup> Balanced Scorecard: A method for comprehensively measuring the extent to which corporate strategy has been implemented

<sup>3</sup> Key performance indicators: Particularly important indicators among the business process monitoring indicators set under the BSC to achieve corporate goals

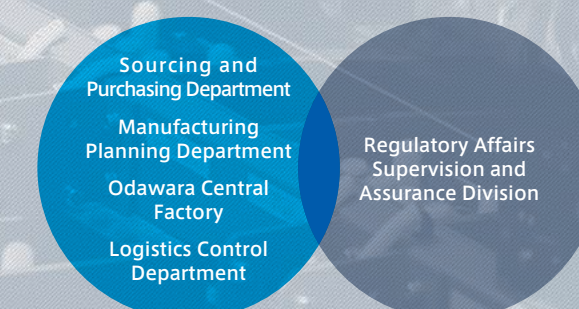
#### Framework for supplying products

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





## Functional Food



### Aspiring to be a manufacturer strong in the healthcare field, with developmental capabilities sufficient to create new markets with in-house-developed products

#### Situation in FY2018

#### Selecting and focusing on high-value-added product lines

Against the backdrop of a shrinking population and transition toward a super-aging society, people are becoming more interested in health, and in the processed foods market in Japan there is an increasing push to maintain and improve health through daily eating habits, with a view to contributing to healthy longevity and aging care. In particular, increasing demand for food with function claims is helping drive expansion in the health food market as a whole.

In fiscal 2018, we continued to pour management resources into R&D, with a focus on the core areas of health food ingredients, preservatives,

and protein preparations. In addition, in the supplement business established in 2016, we emphasized sales of high-value-added products.

In the field of health food ingredients, we concentrated on expanding sales of aging care ingredients such as hyaluronic acid. We also sought to actively research and develop products in collaboration with users.

In the field of preservatives, we strengthened our engagement in processed foods for convenience stores and commercial use, with a focus on our Mikaku Fine series, which extends shelf life with minimal impact on flavor.

In the field of protein preparations, we aim to become the most important protein product manufacturer for the processed food and nutrition markets, utilizing our strength in

research to supply a wide range of items and develop unique, high-value-added products.

Finally, in the supplement business that directly delivers value to consumers, we steadily expanded our lineup, including the WINZONE series of sports supplements and AGE-SHUT aging care supplement, also progressively building a presence in the mail-order market for health foods.

These initiatives were particularly useful in boosting sales of health food ingredients and protein preparations, contributing to year-on-year growth in profits from functional food.

#### Our Future Growth Strategy

#### Seeking to increase earnings from supplement business while also addressing social issues

Our mission is to contribute to people's healthy longevity and active living through food. We plan to transform functional food into a more profitable operation by positioning the relatively new supplement business as a growth driver.

We regard food safety as an important responsibility, alongside reduction in food losses. With food waste constituting a major challenge to society in recent years, in our food ingredient business including preservatives, we develop original technologies to further extend the recommended best-before date of foods while maintaining their flavor, thereby helping to reduce the amount of food that goes to waste. In this manner, we seek to contribute to resolving social issues at the same time as growing earnings from functional food.



Kenro Kobayashi  
Director,  
Head of Functional Food

#### Main Products

#### Bacopa extract recognized by Japan's Consumer Affairs Agency as active ingredient in a food with function claims

In Japan, Ginkgo biloba leaf is well known as a food with function claim for cognitive function. In recent years, a number of other products including plasmalogens and phosphatidylserine have been marketed for this purpose, and in view of Japan's aging society and increasing interest in preventive medicine, it seems likely there will be further expansion in the market for ingredients associated with cognitive function. Against this backdrop, in December 2018 a Nippon Shinyaku supplement with Bacopa extract as the active ingredient was recognized by the Consumer Affairs Agency as a food with function claim\*. This was a first for Nippon Shinyaku.

Bacopa's full name is *Bacopa monnieri*, while its Japanese name is otomeazena. In India, Bacopa has been prized for three thousand years among practitioners of traditional Ayurvedic medicine, as a nootropic (substance that supports mental performance).

This product is slated for release during fiscal 2019, and Nippon Shinyaku is permitted to say on the label that the product includes Bacopa saponins, which are reported to aid in enhancing memory (the cognitive function that enables us to remember and recall information pertinent to daily life, with diminishing success as one ages).

In the functional food segment, we remain committed to developing products worthy of the Nippon Shinyaku name, including foods in the motion and muscle space, currently headlined by the WINZONE series, and in the realm of aging care, adding to the AGE-SHUT supplement already on the market and the Bacopa supplement scheduled for launch in fiscal 2019.

\* Under the responsibility of food business operators, such products are submitted to the Consumer Affairs Agency as products that can be labeled with function claims based on scientific evidence.



Bacopa

#### Brand recognition elevated by WINZONE booth

During the February 15–16 check-in period for the 2019 Kyoto Marathon, we operated a WINZONE booth at the Okoshiyasu Welcome Square, an event held in support of the actual running of the marathon on February 17. Some 26,400 people attended Okoshiyasu Welcome Square, including 16,000 or so runners planning to participate in the Kyoto Marathon, as well as personnel running the event's 33 corporate booths (including those showcasing sponsors) and a number of very popular stalls representing famous Kyoto restaurants. Visitors to our own booth were able to purchase WINZONE supplements as well as limited-edition marathon completion sets, providing an ideal opportunity for large numbers of runners to sample WINZONE. Many of the marathon runners professed to be fans of WINZONE already, and from the comments made on-site by those having their first experience of WINZONE, it seems clear that the product's user base is growing.

Three years have passed since the launch of the WINZONE brand, which is now widely recognized, particularly among marathon runners. In fiscal 2018, we set up WINZONE booths not just at the Kyoto Marathon, but also at the Osaka Marathon in November 2018 and the Nagoya Marathon in March 2019, where we engaged in assertive promotional activities aimed at further increasing brand recognition.

We will continue to expand the WINZONE brand lineup and work toward greater recognition, with a view to establishing WINZONE as a brand much loved by marathon runners.



Image of WINZONE booth



## Related SDGs



## Environmental Management

### Nippon Shinyaku Basic Environmental Policy

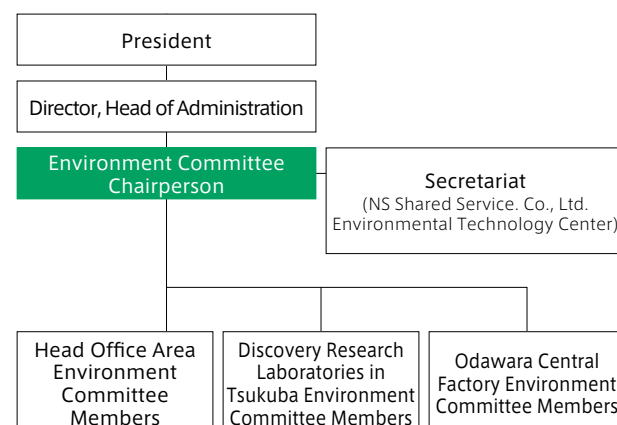
**At Nippon Shinyaku, our mission is to help people lead healthier, happier lives. When we seek growth, it should be growth in harmony with the natural environment. That is why we strive to protect, sustain, and improve the environment through eco-considerate business activities.**

- 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 obtained ISO 14001 certification for its environmental management system in August 2004 as a mechanism for promoting continuous improvement of environmental performance, and it remains engaged in environmental management activities. In June 2012, we acquired KES Environmental Management System Standard Step 2 (hereinafter KES\* Step 2) certification for the head office, our site for research and development, which also is engaged in environmental management activities.

In fiscal 2018, 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 2018.

#### Environmental conservation costs

(thousands of yen)		
Costs	Investments	Expenses
Costs within our business areas	132,244	341,093
Pollution prevention costs	42,217	77,754
Global environmental conservation costs	90,027	183,146
Resource recycling costs	0	80,193
Upstream & downstream costs	0	4,957
Management activity costs	5,783	86,592
R&D costs	0	0
Social activity costs	0	2,598
Environmental remediation costs	0	0
<b>Total</b>	<b>138,027</b>	<b>435,240</b>

(excluding our sales offices)

#### Environmental conservation benefits

Benefit verification	Units	FY2018 results	Year-on-year change
CO <sub>2</sub> emissions	Tons	12,638	-676
Electricity usage	1,000 kWh	15,058	109
Heavy oil & kerosene usage	kl	3	0
City gas & LPG usage	1,000 m <sup>3</sup>	1,641	19
Gasoline & diesel usage	kl	900	-49
Water consumption (main business locations)	1,000 m <sup>3</sup>	204	-71
Waste substances generated (main business locations)	Tons	522	14
Final amount of landfilled waste (main business locations)	Tons	1.5	-0.5

### 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 2018 we continued working toward the targets set in the 5th Nippon Shinyaku Environmental Targets Plan.

The 5th Nippon Shinyaku Environmental Targets Plan <sup>*1</sup>		Numerical Targets	Results in FY2018	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: 212,329 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: 0.089 ▶ 60% 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: 1.52 tons ▶ 89% 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: 0.46 ▶ 51% reduction from FY2005 level	Reached
	Keep the waste recycling rate at 55% or more by FY2019.	55% or more	Waste recycling rate: 42%	Not 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 FY2018
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.	Consumption of PRTR substances compared with FY2017 Dichloromethane: 7% reduction N-hexane: 8% reduction Acetonitrile: 35% increase Companies are newly required to report the amounts of toluene and DMF <sup>*5</sup> used.
Promote an Environmental Management System (EMS)	Effectively improve the results of our environmental performance by maintaining certifications for environmental management systems (ISO 14001 and KES).	Environmental management system certification was carried forward. • 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)

<sup>\*5</sup> N,N-dimethylformamide

## Environmental Performance

### Promotion of Energy Conservation and Global Warming Countermeasures

Nippon Shinyaku has established guidelines for saving electricity and energy to continuously promote power savings among all employees. The guidelines cover, for example, appropriate indoor temperature settings, turning off unnecessary lighting, and recommending the use of stairs. A “year-round no-necktie” policy\* was introduced in April 2018 to further promote energy conservation.

On the facility side, we are endeavoring to make more efficient use of electricity, by such means as upgrading air conditioning equipment and fitting heat insulating sheets to roofs and heat-reducing coatings to windows. In lighting equipment, we have been sequentially replacing existing light bulbs 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 2018.

\* We do not set seasonal dress codes such as Cool Biz or Warm Biz, but allow employees to wear a jacket as practical, or a necktie or other wear as desired, to promote a flexible business style throughout the year.

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

Nippon Shinyaku secured an Honorable Mention at the Kyoto Environment Award ceremony in fiscal 2018, and also was recognized by Kyoto City for excellence in industrial waste disposal and promotion of the 3Rs.



Kyoto Environment Award ceremony



Kyoto City ceremony for recognizing excellence in industrial waste disposal and promotion of 3Rs

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

In fiscal 2018 we achieved the targets of reduction in the final amount of landfilled waste and improvement in the basic unit of waste generated; however, at 42% the waste recycling rate was 13% below our 55% goal. This was because we had to appropriately dispose of non-recyclable waste generated in the process of starting up a facility to manufacture active pharmaceutical ingredients (APIs) for clinical trials, and a facility for producing highly active solid formulations, on the premises of the Odawara Central Factory. If this factor is excluded, the waste recycling rate was 76%, which is 21% above our target.

We carried out final disposal of waste with low PCB concentrations in accordance with all applicable laws. In fiscal 2018 we similarly followed appropriate disposal protocols for waste with high PCB concentrations in the head office area and at the Odawara Central Factory.



Details on environmental data are on our website (Japanese only).  
[http://www.nippon-shinyaku.co.jp/csr/environment\\_manage.html](http://www.nippon-shinyaku.co.jp/csr/environment_manage.html)

### Proper Management of Chemical Substances

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, under the Act on Confirmation, etc., of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (Law concerning Pollutant Release and Transfer Register/PRT). At Nippon Shinyaku, this applies to acetonitrile, n-hexane, toluene, and DMF at the head office, and dichloromethane at the Discovery Research Laboratories in Tsukuba. All were reported appropriately.

The amounts of n-hexane and dichloromethane used decreased by 8% and 7%, respectively, compared to fiscal 2017. The amount of acetonitrile used increased by 35% owing to the start-up of our new facility for manufacturing APIs for clinical trials. However, this new facility is equipped with solvent adsorption devices that minimize the release into the atmosphere of chemical substances generated during production of APIs.

### 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. At the Yamashina Botanical Research Institute, we practice conservation of many plants on the Japanese Ministry of the Environment's endangered plants list, as well as plants, such as tree tumbo (*Welwitschia mirabilis*), that are recognized the world over as endangered. We also offer tours.



Yamashina Botanical Research Institute

For further details, see the Activities that Benefit Society section on page 38.

### 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 scraps 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

### School Workshops

- Two workshops on the Environment and Medicine: Connected by Plants lecture for 4th and 6th graders at Syoho Elementary and other schools

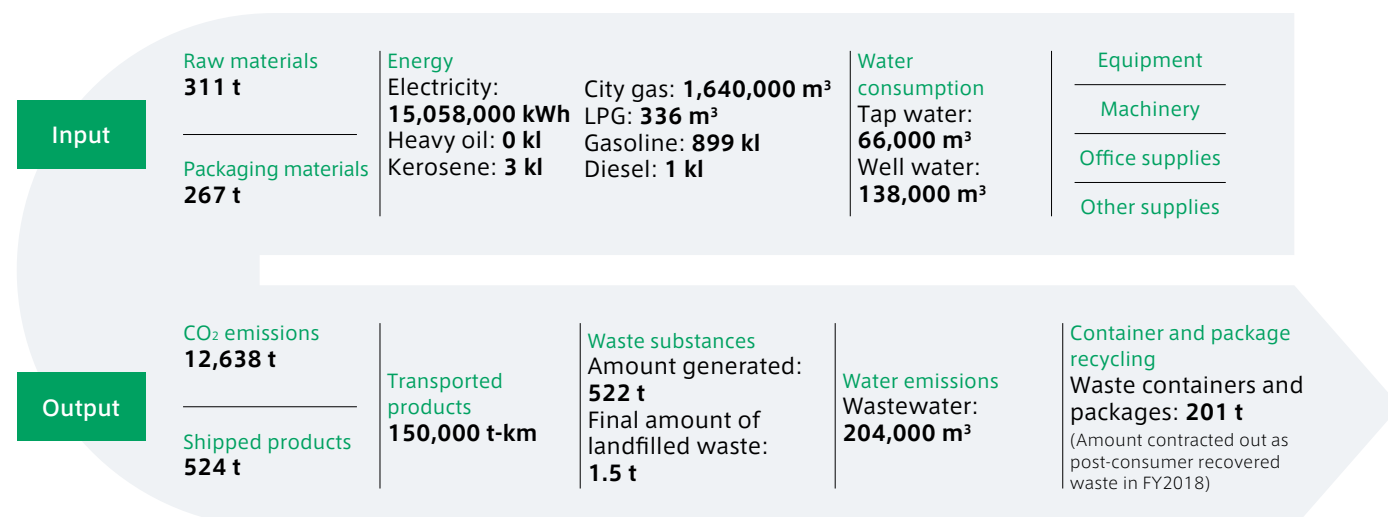
### Research Laboratory Tours

- Head Office's Discovery Research Labs: Five 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

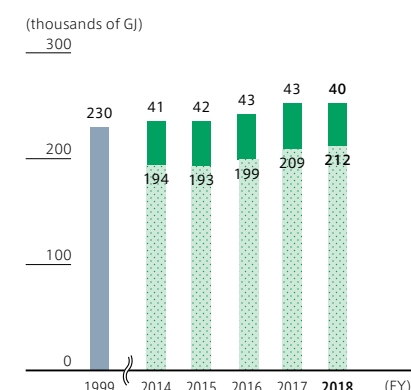
- Conservation of tree tumbo (*Welwitschia mirabilis*) and other endangered plants
- Raising Japanese wild ginger (*Asarum caulescens*) for the Aoi Festival (Kamigamo Shrine, Kyoto Prefecture)
- Raising *Chrysanthemum seticuspe* for the Green Water Corridor (Kyoto Station) and Kikutani Forest of Flowering 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

### Material Balance of Our Business Activities



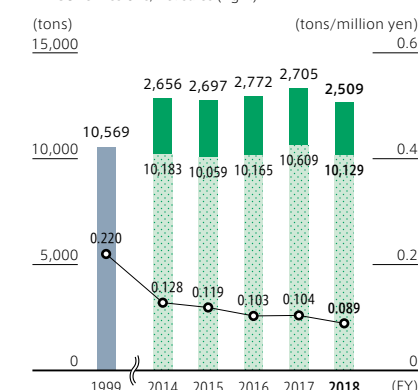
### Total energy consumption

- Sales offices, etc.
- Main business locations: Head Offices, Odawara Central Factory, Discovery Research Laboratories in Tsukuba



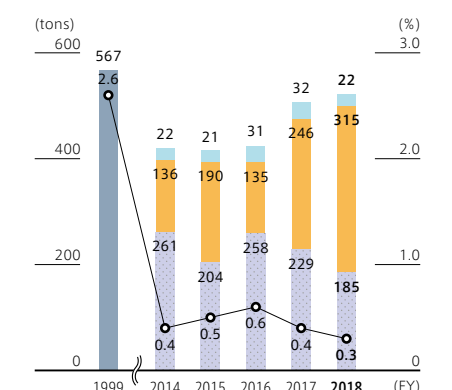
### CO<sub>2</sub> emissions

- Sales offices, etc. (left)
- Main business locations: Head Offices, Odawara Central Factory, Discovery Research Laboratories in Tsukuba (left)
- Emissions per unit of sales at main business locations CO<sub>2</sub> emissions/net sales (right)



### Waste substances generated

- Discovery Research Laboratories in Tsukuba (left)
- Odawara Central Factory (left)
- Head Offices (left)
- Final landfill waste ratio (right)





Related SDGs



# Human Resources

## Basic View on Human Resources 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



Specially selected employees undergoing English training

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.

## 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 2018, we held the 5th Next-Generation Leader Challenge Program. We sought nominations from within the company, either via self-recommendation or recommendation by others, and selected 13 participants from several departments. Between September 2018

Type of Training	New employees	J3	J2	J1	Executives
Basic	Department-based training				
	Level of training				
	Training for new employees	J3 training	J2 training	J1 training	Executive training
					Training for newly promoted managers
	"Brother" system	"Brother" training			
	Training for individuals being appraised				Training for individuals doing appraising
Skill Up	Career support (distance education, e-learning, external seminars, etc.), KYO Academy				
	Language learning support (distance education, supplemental English conversation classes, programs to improve English conversation skills)				
Challenge		Terakoya Academy			
			Next-generation Leader Challenge Program		Next-generation Leader Development Program
		Training to improve business English skills			
		PhD, MBA support program			
		Overseas training support program			

and February 2019 these employees undertook group training as well as attending external education programs, where they acquired the knowledge and skills expected of next-generation leaders, in areas including corporate accounting, marketing theory, and human resource and organization theory.



5th Next-Generation Leader Challenge Program

## Training for Managers

Approaches to dealing with subordinates also are evolving as employees become increasingly diverse in such terms as gender, age, values, and lifestyle. In fiscal 2018 we accordingly framed our thoughts concerning handling of subordinates, and in order to inculcate these ideas in our work force we organized training for managers in how to nurture their subordinates, who are mostly young and/or female. We used instructors on loan from the Japan Institute for Women’s Empowerment & Diversity Management, and the training drew praise from participants, who acknowledged the existence of unconscious bias in the notion that men should be the breadwinners while women take responsibility for child-rearing and housework, and regarded this as motivation to transform their own management styles. It would seem that diversity awareness gradually is increasing across the company, with participants commenting, for example, that it is time to move on from a focus on women, toward support for work practices affording both men and women time for child-rearing, home care, and so forth.



Training for managers in how to nurture subordinates, who are mostly young and/or female

## 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 2018, we held “Happy Career Seminars” for women who work as production engineers and who aspire to be future leaders. These seminars were designed to draw attention to unconscious bias, stereotyping, and preconceptions surrounding gender, age, post, and other differences in the workplace. Female management candidates also participated in a seminar sponsored by the Japan Institute for Women’s Empowerment & Diversity Management—A 21st Century Women’s Empowerment Tutorial—and were given an opportunity to build an external network as well as personal skills.

In addition to the above, we continue to engage in information exchange regarding diversity promotion through participation in a cross-industry social event dubbed “Team Spring!,” conceived as a forum for interaction between Kyoto companies’ employees in charge of promoting women’s advancement.

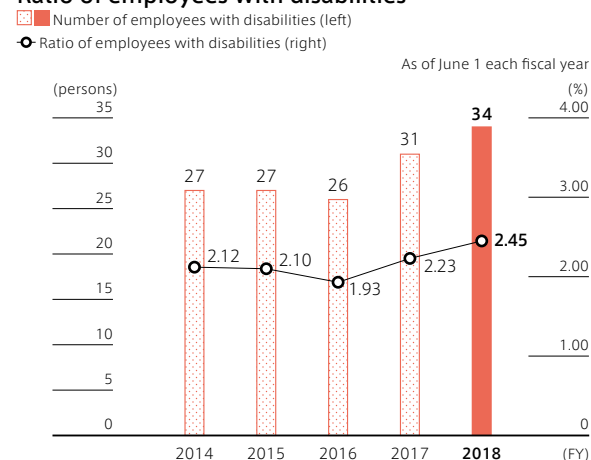
As of March 31 each fiscal year					
	FY2014	FY2015	FY2016	FY2017	FY2018
Number of employees (parent company) (persons)	1,707	1,739	1,727	1,753	1,761
Number of female employees (persons)	466	480	478	488	494
Ratio of female employees (%)	27.3	27.6	27.7	27.8	28.1
Number of executives (persons)	590	577	555	566	555
Number of female executives (persons)	62	66	65	69	72
Ratio of female executives (%)	10.5	11.4	11.7	12.2	13.0
Number of managers (persons)	308	311	285	319	321
Number of female managers (persons)	15	18	14	17	25
Ratio of female managers (%)	4.9	5.8	4.9	5.3	7.8
Number of recruits (persons)	68	79	68	74	72
Number of female recruits (persons)	23	23	24	22	25
Ratio of female recruits (%)	33.8	29.1	35.3	29.7	34.7
Average number of years of service of female employees (years)	17.8	18.0	17.3	17.4	17.3
Average number of years of service of male employees (years)	18.0	17.8	17.4	17.6	17.5
Difference in average length of service for female and male employees (years)	-0.2	0.2	-0.1	-0.2	-0.2



### 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 terms of creating new job opportunities, we have made efforts to simplify and standardize various routine tasks, with a view to shifting employees with disabilities into roles that they can undertake, and enabling work-sharing. Furthermore, a number of consultants are stationed in the workplace to help promote an environment where those with disabilities will be able to productively work side by side with others. This is one example of how we are working to create comfortable work environments.

#### Ratio of employees with disabilities



In addition to the above, since fiscal 2016 we have taken steps to eliminate obstacles to persons with disabilities in the workplace, in line with provisions in the Act on the Elimination of Discrimination against Persons with Disabilities and Revised Act on Employment Promotion, etc., of Persons with Disabilities (both enacted in April 2016), that explicitly require businesses to provide reasonable accommodation to employees with disabilities. When employing such persons, we conduct short-term practical training to ascertain each individual's daily rhythm and the nature of their disability, before progressively moving on to long-term practical training aimed at familiarizing employees with specific tasks. In this manner, we seek to provide 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.

### Work-Life Balance

As part of work-life balance promotion efforts for employees, in accordance with our business philosophy of "helping people lead healthier, happier lives," Nippon Shinyaku conducts the "Good Job Initiative." We envision the goals of the Good Job Initiative as: working productively, resting regularly, and leading a fruitful lifestyle that increases one's satisfaction and zest for life. Without changing fixed monthly working hours, we have eliminated fixed break times and fixed starting and ending times to the work day. By thus enabling flexible working hours, we aim to increase work productivity and enable working styles that can be adapted to individual lifestyles. To that end, in January 2018 we introduced a flextime system for MRs. Many MRs working under this system have said that drawing a clear distinction between on- and off-time has enabled them to adjust the cycles of their workdays, using time more effectively whether it be at work or during private time.

### Shaping the Work Environment

#### Occupational Health and Safety Selected as White 500 company in Certified Health and Productivity Management Organization Recognition Program 2019

Nippon Shinyaku is committed to securing employee health and safety, and complying with the Industrial

Safety and Health Law in order to create comfortable working conditions. We are committed to pursuing unified initiatives for health and safety.

In October 2018, Nippon Shinyaku issued a "Health Declaration" proclaiming that the company will work together with its health insurance association to engage actively in the health and wellbeing of employees and their families, delivering a working environment and employment conditions contributing to health and productivity management. In February 2019, Nippon Shinyaku was selected as a White 500 company in the Certified Health and Productivity Management Organization Recognition Program. In April 2019 we established a Health Promotion Office responsible for health and productivity management and occupational health and safety, to further support our employees and their families in the pursuit of better health.

### Mental Healthcare

Nippon Shinyaku introduced an externally developed Employee Assistance Program (EAP) in March 2003, and has been carrying out stress checks once a year for prevention, early detection, and early intervention in mental illness, in compliance with a mandatory occupational health policy called the Stress Check Program, introduced in 2015. Furthermore, in fiscal 2018 we began offering an on-site counselling service to make it easier for employees to communicate their concerns. Looking ahead we plan to continue fine-tuning our approach to mental health management.

### Voice of the Stakeholder Promoting Women in the Workplace



**Miki Isshiki**  
Leader, Tokorozawa Team,  
Kawagoe Business Branch,  
Saitama Business Office

#### Pursuing my own leadership vision, leveraging insights from training

When I was appointed team leader, I was performing MR duties while also being involved in child-rearing. I was simultaneously overjoyed that my efforts to date had been recognized, and concerned that I might not be up to the job. Around that time, I attended a seminar sponsored by the Japan Institute for Women's Empowerment & Diversity Management—A 21st Century Women's Empowerment Tutorial—where I learned that changes in the social climate and workstyles in fact provide a perfect opportunity to recognize differences in others as strengths, and to develop my own management style. These words are a source of daily motivation for me in my quest to become the kind of leader who enables as many people as possible to work more productively and fruitfully, regardless of personal attributes such as gender and age.

### Voice of the Stakeholder Cultivating Global Talent



**Takashi Homan**  
Section 2, Licensing  
Department, Licensing and  
Alliance Division

#### English-language training enhances skills, facilitating personal growth

The main task of the Licensing and Alliance Division is to seek out and evaluate drug seeds in development at pharmaceutical companies around the world, and to negotiate for the development and marketing rights (license) for drug candidates deemed attractive. English-language skills are of course essential for performing this task, and with that in mind I have attended several of the training sessions offered by the company to improve employees' English, where I was able to acquire a range of business skills including email-writing, how to conduct meetings, and how to make a persuasive presentation. The skills I acquired have proven useful in many business settings, and I am now able to convey my opinions to others with confidence. Through my engagement with people from overseas I am reminded on a daily basis of the importance of thinking laterally and flexibly, and I am sure that these experiences have aided my personal growth.



## Social Contribution

### Activities that Benefit Society

#### Nippon Shinyaku Children's Literary Awards

We created the Nippon Shinyaku Children's Literary Awards to commemorate our 90th anniversary in 2009, with the support of the Japan Juvenile Writers Association and Kyoto City. Our future lies in the hands of our children, and these awards were created with the hope of giving wings to young children's dreams and nurturing their minds and spirits through picture books. The Nippon Shinyaku Children's Literary Awards has two divisions, for stories and artwork, and the first-prize winners from each division collaborate to produce a picture book. In 2016, the Nippon Shinyaku Children's Literary Awards won the Minister of State for Special Missions' Award in the Development and Support for Children and Young People category of the Cabinet Office's Awards for Supporters of Children/Family and Youth.

To commemorate the 10th anniversary of the Awards' creation, in fiscal 2018 we invited many people, chiefly local children and their families, to attend the 10th Nippon Shinyaku Children's Literary Awards ceremony, where the winning picture book *Ofuro ni Hairu Tokiwa* (the tale of a young boy's imagined adventures when alone in the bath) was unveiled. We entertained those attending with the ceremonial donation of an oversized picture book, and a live sand art display by the performance group, SILT, commemorating the Awards' 10th year.

Winning books are distributed to children nationwide through medical institutions such as children's hospitals and via public facilities. Also, visitors to our Japanese-only special website (<http://kodomo-bungaku.jp/>) are able to see electronic versions of past and present books, and hear them read aloud as they browse the pages.



Picture books produced to date



10th Nippon Shinyaku Children's Literary Awards ceremony

#### Nippon Shinyaku & Seitaro Kuroda Smiles Art Project

In March 2013 we launched the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project, a nationwide campaign that encourages locals to band together and create art on the walls of hospitals and nursing facilities. Spearheaded by illustrator Seitaro Kuroda, this initiative kicked off at the Public Ono Town General Hospital in Fukushima Prefecture, and since then it has been rolled out across the country. Two hospitals had their walls painted in fiscal 2018: the Saitama Children's Medical Center and Public Toyooka Hospital.

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



Activity at Toyooka Hospital

#### 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. Moreover, the institute is a proud participant in Kyoto-based activities to preserve rare plants, helping to protect and propagate plants such as Japanese wild ginger (*Asarum caulescens*) and Kikutani-giku (*Chrysanthemum seticuspe*).

In the spring and autumn of fiscal 2018, the institute held four tours on national holidays, as well as tours for the general public, pharmacist training courses, seminars for medicinal plant specialists, field trips for local elementary school students, summer-vacation indigo dyeing workshops, and various other events. Last year the institute welcomed approximately 1,700 visitors.



Touring Yamashina Botanical Research Institute

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

For more than half a century Nippon Shinyaku has annually produced hand towels and calendars with pictures made by using *Kataezome*, a traditional stencil dyeing technique unique to Kyoto. These works feature Kyoto's seasonal scenery, customs, and historical events. Also, we publish a quarterly magazine called *Kyo*, the inaugural edition of which came out in 1967. This publication showcases the profound appeal of Kyoto—from its wealth of cultural assets including shrines and temples, to the city's cuisine and famous local products—and is always well received by medical professionals.



Calendar and quarterly magazine *Kyo*



Hand towel featured by pictures made by using *Kataezome*

### Supporting Education through Sports

The Nippon Shinyaku amateur baseball team offers baseball clinics for elementary, junior and senior high school students in order to raise the level of local baseball. In November 2018, the team hosted winter training sessions for the Kyoto High School Baseball Federation at Wakasa Stadium Kyoto. There we provided coaching for about 300 team members from 74 high school teams in Kyoto Prefecture. We also held several baseball workshops for elementary and junior high school students. Through these we are working to improve the baseball skills and physical strength of these children, while increasing our interaction with local communities.



Coaching high school students

### Elementary School Workshops

Since 2008 we have sent employees to conduct workshops at elementary schools\* in Kyoto City, as part of the children's practical environment studies. Our employees teach these children not only about the importance of global environmental conservation, but also about the correct way to consume medicines. In fiscal 2018, we held workshops at two schools in Kyoto, which we kept very hands-on in order to keep the children interested. Experiments included measuring how much carbon dioxide plants absorb through photosynthesis, and studying the way pills dissolve (using mock pills containing no active pharmaceutical ingredients).

\* Elementary school workshops: Environmental instruction for elementary school students



An elementary school workshop

### Contributing to the Field of Medicine

#### Promoting Understanding of Rare and Intractable Diseases

To coincide with Rare Disease Day, an observance on the last day of February to raise global awareness of rare and intractable diseases, we conduct our own awareness-raising activities. In fiscal 2018, we interviewed specialists on the subject of rare blood cancers, later publishing the content in the form of newspaper articles.



Interviewing specialists

#### Launch of Public Research Grant Scheme

As part of our 100th anniversary celebrations in 2019, Nippon Shinyaku has initiated a "Public Research Grant Scheme" aimed at contributing to the advancement of science in medical and pharmacological spheres where the company is active. Under this scheme, Nippon Shinyaku looks to support young researchers by offering grants to successful applicants. For fiscal 2019, 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 for five research projects in each field.



Award ceremony for Nippon Shinyaku public research grants for fiscal 2019

### Voice of the Stakeholder

#### Yamashina Botanical Research Institute Contributes to Society by Cultivating Great Variety of Medicinal and Useful Plants



Professor Hisashi Matsuda

Department of Pharmacognosy  
Kyoto Pharmaceutical University

On my first visit to the Yamashina Botanical Research Institute, I was impressed by the fact that despite its urban location, the institute preserves and cultivates some 3,000 varieties of medicinal and useful plants from around the world, including more than 160 plant sources for crude drugs listed in the Japanese Pharmacopoeia. I believe the institute also should be proud of its contribution to developing high-grade mibuyomogi cultivars.






The Garden of Medicinal Plants adjoining Kyoto Pharmaceutical University contributes to society and supports students' education and research. While I understand that the Yamashina Botanical Research Institute similarly attaches great importance to social contributions, in addition to hosting tours of its own grounds I would like to see the institute plan initiatives that also would lead to research and business collaboration with our university and other educational institutions.



Engagement with Stakeholders

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 of 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.



 Business partners	<div>Policy</div> <p>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 fulfil our social responsibilities.</p> <div>Responsible Procurement Guidelines</div> <ul style="list-style-type: none"><li>•Stringent legal compliance<p>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.</p></li><li>•Confidentiality<p>We take thoroughgoing measures to prevent leaks of confidential information concerning business partners, also eschewing fraudulent transactions.</p></li><li>•Equitable business practices<p>In our dealings with all business partners, Nippon Shinyaku offers transparent, fair, and equitable transactions based on free competition principles.</p></li><li>•Rational selection of suppliers<p>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.</p></li><li>•Consideration for the environment<p>We comply with laws and regulations pertaining to the environment and undertake environmentally friendly procurement in adherence to our Basic Environmental Policy.</p></li></ul>													
 Users	<div>Policy</div> <p>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> <div>Engagement</div> <ul style="list-style-type: none"><li>•Information site on supplement business, accessed through company website Nippon Shinyaku Official Healthcare Shop <b>Updated as necessary</b></li><li>•Booths at domestic marathon competitions <b>Six times</b> in fiscal 2018</li></ul>													
 Shareholders and Investors	<div>Policy</div> <p>We strive to meet the expectations of shareholders and investors by securing reasonable profits through capital-conscious management and returning them to shareholders, while also promoting constructive communication via fair management practices emphasizing timely and appropriate disclosure of corporate information, and proactive dialog.</p> <div>Engagement</div> <table><tr><td>•Individual meetings with institutional investors and analysts (<b>roughly 150</b> in fiscal 2018)</td><td>•Results briefings (in May and November)</td><td>•Earnings calls (in August and February)</td><td>•General Meeting of Shareholders (in June)</td></tr><tr><td colspan="4">•Delivery of information via IR site and response to inquiries (<b>as needed</b>)</td></tr></table>	•Individual meetings with institutional investors and analysts ( <b>roughly 150</b> in fiscal 2018)	•Results briefings (in May and November)	•Earnings calls (in August and February)	•General Meeting of Shareholders (in June)	•Delivery of information via IR site and response to inquiries ( <b>as needed</b> )								
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•Delivery of information via IR site and response to inquiries ( <b>as needed</b> )														
 Employees	<div>Policy</div> <p>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> <div>Engagement</div> <table><tr><td colspan="4">Participant numbers for various training programs in fiscal 2018</td><td rowspan="3">Ratio of employees with disabilities: <b>2.45%</b></td></tr><tr><td>•Training for newly hired employees: <b>64</b></td><td>•Training for newly promoted employees: <b>187</b></td><td>•Training for executives: <b>33</b></td><td>•Training for newly appointed managers: <b>40</b></td></tr><tr><td>•“Brother” training: <b>64</b></td><td>•Next-generation Leader Challenge Program: <b>13</b></td><td colspan="2">•English-language training for elite employees: <b>17</b></td></tr></table>	Participant numbers for various training programs in fiscal 2018				Ratio of employees with disabilities: <b>2.45%</b>	•Training for newly hired employees: <b>64</b>	•Training for newly promoted employees: <b>187</b>	•Training for executives: <b>33</b>	•Training for newly appointed managers: <b>40</b>	•“Brother” training: <b>64</b>	•Next-generation Leader Challenge Program: <b>13</b>	•English-language training for elite employees: <b>17</b>	
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•“Brother” training: <b>64</b>	•Next-generation Leader Challenge Program: <b>13</b>	•English-language training for elite employees: <b>17</b>												
 Community Groups and Environment	<div>Policy</div> <p>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> <div>Engagement</div> <ul style="list-style-type: none"><li>•Activities that benefit society (Nippon Shinyaku Children’s Literary Awards, Smiles Art Project, activities at Yamashina Botanical Research Institute (tours, seminars, etc.), children’s baseball clinics hosted by Nippon Shinyaku amateur baseball team, environmental instruction for elementary school students, Yancha Fiesta, Kyo Aruki in Tokyo 2019, etc.)</li><li>•Contributions in medical field (taking applications for public research grants)</li></ul>													



Patients

Policy

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.

Engagement

- Disease awareness-raising via website

Information sites on alcohol dependence, erectile dysfunction and its treatments, period pain, pulmonary arterial hypertension (PAH), hay fever and allergic rhinitis.
- Patient education via smartphone apps

PAH Care Notebook for PAH patients
- Inquiries regarding medicines

Healthcare consumers, **2,632**; healthcare professionals, **16,147**; other, **180**





# Corporate Governance

As of July 2019

## Basic Concepts of Corporate Governance

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.

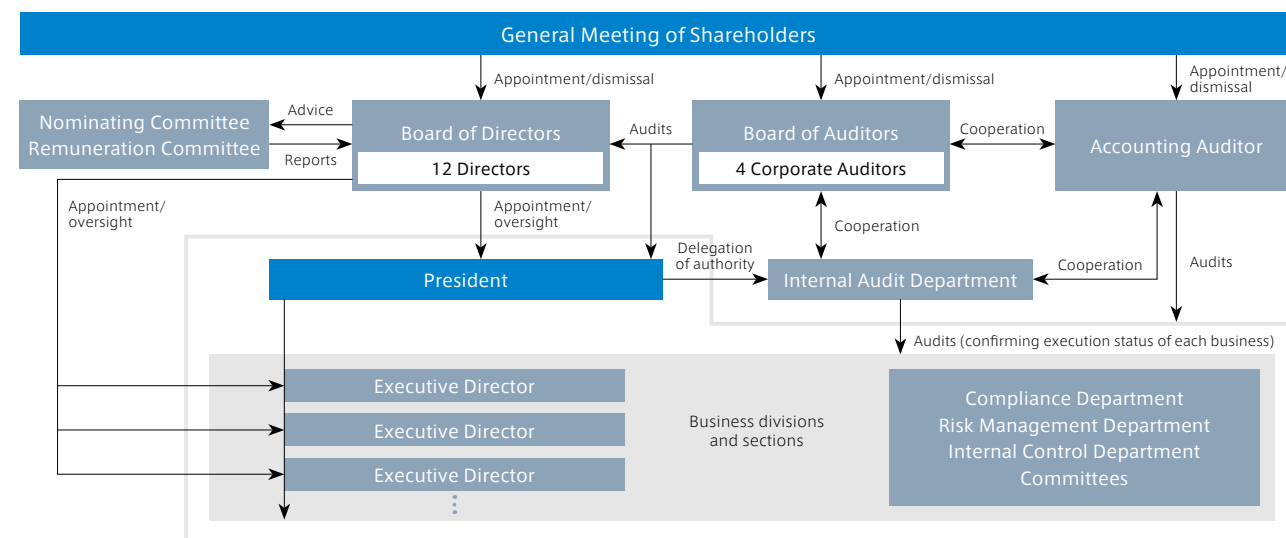


**Corporate Governance Basic Policy**  
[http://www.nippon-shinyaku.co.jp/english/img/company\\_profile/CorporateGovernanceBasicPolicy\\_December17\\_2018.pdf](http://www.nippon-shinyaku.co.jp/english/img/company_profile/CorporateGovernanceBasicPolicy_December17_2018.pdf)

## Compliance with Corporate Governance Code

Adhering to the essence and spirit of the Corporate Governance Code spelled out by the Tokyo Stock Exchange in June 2015, Nippon Shinyaku assessed the state of our efforts to implement the code’s principles, for the sake of sustainable growth and improved corporate value over the medium and long term. In our June 2019 Corporate Governance Report, we carried out “Disclosure Based on the Principles of the Corporate Governance Code,” and divulged “Reasons for Non-compliance with the Principles of the Corporate Governance Code.”

## 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

In response to inquiries by the Board of Directors, the Nominating Committee deliberates on matters concerning the appointment and dismissal, etc., of directors and corporate auditors, whereas the Remuneration Committee

deliberates on matters concerning the remuneration, etc., of directors and corporate auditors. Both Committees subsequently report back to the Board of Directors with the results of their deliberations.

## 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

## External Directors and Auditors

Nippon Shinyaku has four external directors and two external auditors, none of whom have any special interest in the company. When selecting outside officers (external directors and external auditors), in principle

Nippon Shinyaku chooses candidates on the basis of their independence from the company, as we put great stock in the ability to oversee corporate governance from an objective, third-party standpoint.

## External Directors

Name	Reasons for Appointment	Attendance at Board of Directors meetings (Fiscal 2018: 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 <small>(newly appointed)</small>	Appointed because he is expected to offer advice to management from a practical perspective, based on his expertise and insight from an independent standpoint as a physician.	—

## External Auditors

Name	Reasons for Appointment	Attendance at Board of Directors meetings (Fiscal 2018: 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.	(11/12)
Sumitaka Maruyama <small>(newly appointed)</small>	Appointed because he is expected to offer 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.	—

## Steps taken to strengthen corporate governance

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

	2011	2012	2013	2014	2015	2016	2017	2018	2019
Number of directors	7			9			10		12
(of whom, inside)	7			7			7		8
(of whom, external)				2			3		4
(of whom, female)							1		
Number of auditors					4				
(of whom, standing)					2				
(of whom, external)					2				
Committees							Existence of Nominating Committee		
							Existence of Remuneration Committee		



### Evaluating Board of Directors' Effectiveness

Our policy on the analysis and evaluation of the Board of Directors' effectiveness is detailed in the "Corporate Governance Basic Policy" (see Article 33). In order to analyze and evaluate the overall effectiveness of the Board of Directors, we implemented a self-evaluation survey for all directors. We were able to confirm that as before, each executive director and external director on the Board continues to actively voice their opinion and engage in free-spirited, broad-minded and constructive discussion from multiple perspectives, supporting management in making appropriate judgments. From this we determined that the Board of Directors remains effective overall.

Based on the results of this analysis and evaluation, the Board of Directors will focus on further invigorating and enhancing discussions at Board meetings, with a view to ensuring and improving the effectiveness of the Board moving forward.

### 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

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

As of March 31, 2019

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)	363	186	177	9*
Auditors (excl. External Auditors)	34	34	—	2
External Directors/ Auditors	50	50	—	5

\* Includes directors who were in office between July 2017 and June 2018

### ■ 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.

### 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.

Nippon Shinyaku employs Deloitte Touche Tohmatsu LLC as its accounting auditor, to help ensure the observance of proper accounting procedures and secure transparent management through internal control auditing.

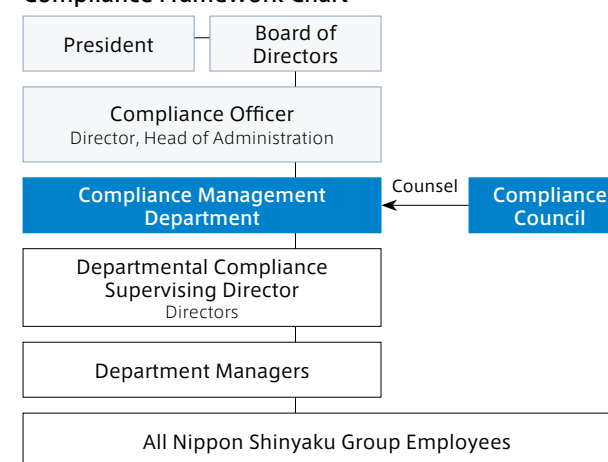
The Internal Audit Department examines the processes behind risk management, control and governance of the entire group and assesses their effectiveness. The results are reported to the President and conveyed in detail to the Board of Directors, shared also with the Board of Auditors and the accounting auditor.

## 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.

In April and October of 2018, the President announced an appeal for the strengthening of compliance implementation and the establishment of a corporate

culture where no compliance breach would be ignored or condoned. Throughout the year, we also implemented the training and education activities outlined below.

### Compliance Training in Fiscal 2018

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 newly promoted managers (March, October)	Training that focuses on teaching compliance to newly promoted managers.
Enhanced Training (October–November)	Departmental compliance training in October followed-up by supplemental training through e-learning in November; the theme for fiscal 2018 was "Targeted Email Attacks."
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.

### Education Initiatives

- Conducted e-learning concerning compliance for employees in their second year at the company.
- Conducted e-learning concerning "power harassment" prevention for all managers.
- Prepared compliance education posters for display in each department, with slogans that were selected as winners in an internal competition.
- Created compliance cards combined with safety contact cards and distributed these to new employees among others.

### 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.

The security of reporting employees is clearly specified in the guidelines to ensure that the person will not be transferred against his or her interests and that such a transfer and other prejudicial measures are not imposed.

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

### Responsible Procurement

Companies have much greater responsibilities than simply providing products to consumers. Corporate social responsibility requires that a company protect human rights, comply with laws and regulations, and protect the environment throughout its supply chain.

At Nippon Shinyaku, our policies, including our desire to earn the trust of society at large, are promoted by, and enshrined in, our Responsible Procurement Guidelines.

The Responsible Procurement Guidelines are a statement of our dedication to stringent legal compliance, confidentiality, equitable business practices, rational selection of suppliers, and consideration for the environment. We are determined to uphold our responsibility to society by pursuing such responsible procurement policies together with our business partners.



The Responsible Procurement Guidelines can be viewed at the Nippon Shinyaku website (Japanese only).  
<http://www.nippon-shinyaku.co.jp/csr/>



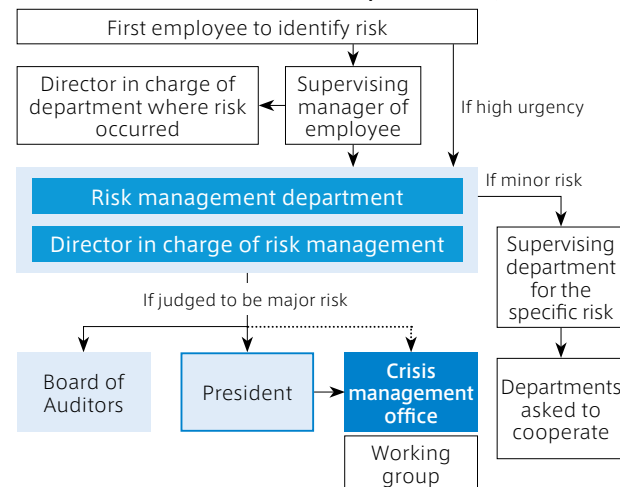
## Risk Management

### 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 2018, 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, 2019)



### 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.

In fiscal 2018 we engaged in employee awareness-raising and dissemination of information focused on the corruption and leakage of electronic data caused by cyberattacks. In particular, we gave education and training to employees concerning the troubling recent development of targeted email attacks. Furthermore, we established the NS-Computer Security Incident Response Team (NS-CSIRT) to deal with crises caused by cyberattacks in an organized and timely fashion. In the future we will continue to strengthen our information security.

### Anti-Harassment Action

We consider harassment a serious issue that disrespects individuals and infringes upon their human rights. In addition to establishing the Harassment Prevention Committee (renamed from the Workplace Improvement & Human Rights Awareness Committee in April 2019) to prevent harassment in all forms and maintain a positive working environment, we have written and enforce our own Harassment Prevention Rules. There are other measures we use to prevent harassment, such as compliance training, as well as the production of a pamphlet about our anti-harassment policy which we distribute to all employees.

### Disaster Countermeasures (Formulating a BCP)

To ensure the supply of medicines to patients is not disrupted in emergency situations such as earthquakes and other disasters, we have established a Business Continuity Plan (BCP) aimed at keeping the Odawara Central Factory running even in the event of an earthquake measuring in the upper-six range on Japan’s seismic scale. We revise the BCP every three years, and the most recent revision was in fiscal 2018. Meanwhile, we continue to bolster readiness in other areas, such as inventory storage facilities and support for partner companies, and are prepared to invoke the BCP whenever required.

### Respect for and Protection of Intellectual Property Rights

In recognizing the importance of intellectual property, the Nippon Shinyaku Group’s Patent Strategy Committee formulates global patent application strategies for intellectual property created during the various stages from early R&D to post-marketing, as well as devising and implementing measures to address any associated issues. To ensure we are able to conduct our business freely, we properly secure intellectual property rights, including patents and trademarks, related to our proprietary drugs and functional foods.

Our basic stance is to also respect the intellectual property rights of third parties, which we ensure by carefully managing intellectual property risks through rights investigations and other means.

## Roundtable Discussion Among External Directors

### Focus on strengthening governance, with eye on the next 100 years



As we celebrate our 100th anniversary in 2019, Nippon Shinyaku is working to improve corporate governance with a view to achieving further sustainable growth. We invited three external directors to participate in a roundtable talk, to express their views on the current state of governance as well as possible future challenges and means of strengthening governance.

### How the Board of Directors operates

**Sugiura:** In my six years as an external director for Nippon Shinyaku, I have dedicated myself to bringing a breath of fresh air to Board discussions, with a view to enlivening debate. Over the years directors have come to enjoy a free and open exchange of opinions, facilitating active debate, and I think the Board of Directors is now functioning reasonably well. During that period, I have also seen an increase in questions posed from various perspectives and in constructive opinions, which I think have made the Board of Directors more effective, as has adherence to the policy of combining concise explanations with robust discussion.

**Sakata:** It has also been roughly six years since I was appointed as an external director for Nippon Shinyaku. Over that time, I feel that the atmosphere in the boardroom has changed substantially. When I first joined the Board, the President led the conversation, but in comparison with that time, external directors and auditors now are more forthright in expressing their views, and there are more opportunities for the Board of Directors to listen to the various opinions voiced by external members. Encouraged by this change, internal directors and auditors also have become active in voicing their opinions, ensuring vigorous debate among all officers, both internal and external.

**Sakurai:** I agree with Mr. Sugiura in that I believe the Board of Directors engages in vigorous discussion, but in a sincere and courteous manner with respect for multiple points of view. I think this is partly because Board members receive advance briefings to ensure they enter meetings with an adequate grasp of agenda items, as well as being given the opportunity to attend training seminars on topical themes in order to further their understanding of the company’s operations. Two new directors were appointed in fiscal 2018, and since then, the variety of questions and opinions has only increased. Some significant insights have arisen out of our discussions, which I think is extremely important to ensure



that the Board of Directors functions effectively.

## Initiatives to strengthen governance

**Sugiura:** My role is to draw on the expertise and insight I have gained as a pharmacologist to aid Nippon Shinyaku in its quest to develop innovative new drugs, while at the same time strengthening management and improving profitability. I consider it important to ensure that corporate governance is functioning effectively in order to enhance the company's value, and to that end I strive to make my opinions heard at Board meetings. There are many ways for a company to improve compliance, including regularly preparing compliance and internal control reports for submission to the Board, having the Internal Control Department perform internal audits of domestic business locations, providing employees with compliance training, constructing and utilizing an internal whistleblowing system, and having management perform regular site inspections. Nippon Shinyaku already follows these practices, and in my view the company's compliance system operates effectively.

**Sakata:** I have much the same opinions concerning compliance. I applaud Nippon Shinyaku for the serious consideration it gives to various compliance and risk management issues, although I worry that the company sometimes overlooks reality in its pursuit of excessive ideals. While I think it is important to aspire to high ideals, there is little point in doing so

if employees cannot work in unison to fulfil these expectations. In my view, the company needs to be prudent in its approach to resolving compliance issues, with due consideration for employees' awareness levels and the degree of progress toward goal realization.

**Sakurai:** On the subject of compliance, I similarly applaud Nippon Shinyaku for its efforts under President Maekawa to update guidelines, confirm the company's basic policy, comply as appropriate with all legally necessary



investigations, and offer training aimed at maintaining and raising compliance awareness. I also think each department is adequately addressing the topic of risk management, by identifying and evaluating emerging risks, and offering risk education and training. On the other hand, reality does not always align with expectations, as Mr. Sakata suggested. I think it is important to remain conscious of whether or not those expectations really can be met, by keeping track of whether management initiatives are being put into practice at the individual employee level, whether each department is adequately adhering to the HoRenSo (report, contact, consult) mantra on a daily basis, and whether risks are being overlooked or underestimated.

**Sugiura:** Mr. Sakata and Ms. Sakurai have been praising Nippon Shinyaku for its compliance initiatives. However, I feel that more effort is required in some areas in order to further improve corporate value—for example, conducting regular compliance risk

surveys, preventing impropriety through the introduction of state-of-the-art systems, and having the Internal Audit Department and Internal Control Department perform audits of overseas bases. In my view, the company must remain aware at all times of the risk of compliance breaches, due for example to inadequate anchoring of compliance awareness or lack of a compliance audit system at overseas operations.

**Sakata:** Exactly so. It is of course important to be mindful always of the risk of compliance breaches, and to

put in place a system for managing compliance. However, it is important also to strengthen the overall organization by creating a work environment that discourages violations and endeavoring to improve working conditions. In my view, initiatives of this kind can further enhance governance. I feel it is my responsibility as an external director to monitor the organizational integrity of each department and the richness of communication, investigating whether or not the workplace atmosphere is open, ensuring that the company is not overly dependent on particular individuals to perform certain jobs, and ascertaining the degree of workplace pressure being exerted.

**Sakura:** As the only female on the Board of Directors, I strive to make remarks from broad-based viewpoints, drawing on my expertise and insight as a lawyer to leverage my own particular strengths and individuality. In fiscal 2018, I had my first opportunities to meet with the company's female managers, and I was struck by the wealth of highly motivated and

talented female employees at Nippon Shinyaku. As a female external director, I want employees to feel that I'm with them. I want to support talented employees regardless of their gender, helping them reach their full potential while respecting diverse working styles. I think these kind of activities can further improve the work environment and help prevent compliance breaches from occurring.

## Toward sustainable growth

**Sugiura:** Amid drastic reforms to the drug price system and contraction in the domestic market, I think that for pharmaceutical companies to survive they must practice "selection and concentration" and "overseas expansion." When it comes to "selection and concentration," branded drug makers are expected to hasten moves to drop long-listed products, and I consider it important for Nippon Shinyaku also to identify its strengths and market positioning, with a view to better elucidating its vision for the future. "Overseas expansion" entails considerable risk, but without it I think growth will prove difficult. I want to see

Nippon Shinyaku take this approach to business, while at the same time fulfilling its mission as a healthcare company by making endurable contributions to society and promoting fundamental research. The company celebrates its 100th anniversary this year, and I hold high hopes for its evolution over the next 100 years.

**Sakata:** If Nippon Shinyaku is to continue growing over the long term, I think it needs to strengthen the R&D department and achieve higher sales in overseas markets, and also recruit talented individuals to nurture into important management resources. In my view, it is incumbent on the company's directors not only to monitor and supervise everyday operations, but also to invest more time in discussion over Nippon Shinyaku's plans for the medium and long term, with due consideration for the above perspectives.

**Sakurai:** I believe an ESG approach is essential to a company's medium- and long-term growth, and certainly, Nippon Shinyaku has always recognized the importance of ESG management, and has included "Increase in corporate value by strengthening ESG management" as a key plank of the 6th Five-Year



Medium-term Management Plan released in May 2019. I am extremely encouraged by Nippon Shinyaku's intention of devoting further attention to ESG strategies. While I believe exhortations from management are key to promoting ESG adoption, I think it is also important for employees to exercise their individual strengths. As with the Challenge 100 push to improve productivity, I think positive results are inevitable if employees are motivated to offer ideas that then evolve into companywide initiatives with support from management.

### Miyuki Sakurai (left)

Registered with the Osaka Bar Association in 1992. Became joint owner of Hanamizuki Law Office in 2003 (position still held). Engaged in a broad range of civil and family law-related work. Appointed as an auditor at Nissay Life Foundation in 2015 (position still held) and also at Osaka University in 2016 (position still held). Other posts include domestic relations conciliation commissioner at the Osaka Family Court, and Chairperson of the Takarazuka Building Council. Appointed as external director at Nippon Shinyaku in 2017 (position still held).

### Yukio Sugiura (center)

Appointed as professor at Kyoto University's Institute for Chemical Research in 1988, becoming Director of the Institute in 1998. Pursued research activities centering on fundamental research, as well as engaging in mentoring. Also participated in joint research with overseas universities. Appointed as an emeritus professor at Kyoto University in 2005 (position still held), as well as president of The Pharmaceutical Society of Japan. Took up position of specially appointed professor at Doshisha Women's College of Liberal Arts' Faculty of Pharmaceutical Sciences in 2007. Appointed as external director at Nippon Shinyaku in 2013 (position still held).

### Hitoshi Sakata (right)

Registered with the Kyoto Bar Association in 1985. Became partner at Oike Law Office in 1995 (position still held), mainly engaging in general corporate work as well as work involving intellectual property, and international law. Authored a number of papers concerning copyright laws. Appointed as guest researcher at the University of Cambridge's Faculty of Law in 2010 and as a professor at Doshisha University's Graduate School of Law in 2011. Became an external director at Nippon Shinyaku in 2013 (position still held).

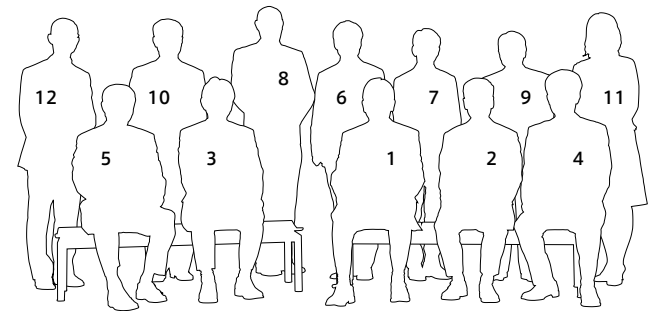




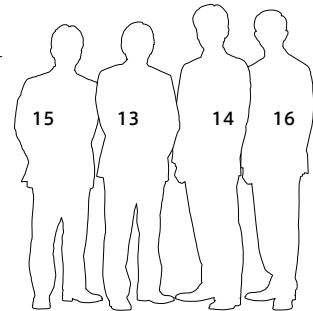
## Board of Directors, Corporate Officers and Corporate Auditors



### Directors



### Corporate Auditors



#### 1 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 (FY2018): 12/12

#### 4 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 (FY2018): 12/12

#### 7 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 (FY2018): 10/10

#### 2 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 (FY2018): 12/12

#### 5 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 (FY2018): 12/12

#### 8 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)

#### 3 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 (FY2018): 12/12

#### 6 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 (FY2018): 10/10

#### 9 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 (FY2018): 12/12

#### 10 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 (FY2018): 12/12

#### 13 Hideya Mukai Standing Corporate Auditor

1979 Joined Nippon Shinyaku Co., Ltd.  
2004 Department Manager, Pharmacokinetics Dept., Discovery Research Labs., R&D  
2008 Department Manager, Pharmaceutical Research Dept., Discovery Research Labs., R&D  
2010 Department Manager, Discovery Research Labs., R&D  
2011 Corporate Officer; Department Manager, Discovery Research Labs., R&D  
2016 Standing Corporate Auditor (current position)

Attendance at board meetings (FY2018): 12/12

#### 15 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 (FY2018): 11/12

#### 11 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)

Attendance at board meetings (FY2018): 12/12

#### 14 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)

#### 16 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)

#### 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, Osaka Medical Center for Maternal and Child Health  
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 (current position)  
2019 Director (current position)

### ■ Corporate Officers

#### Taro Sakurai

Department Manager, Finance & Accounting Dept.

#### Hirokata Harada

Head of Medical Supervisory Div.

#### Hisashi Suehara

Head of Regulatory Affairs Supervision and Assurance Div.

#### Koji Honma

Department Manager, Personnel Dept.

#### Hideki Sasaki

Department Manager, Odawara Central Factory

#### Hironaka Nakajima

Chief Medical Officer

#### Kazuya Mori

Head of R&D Administration Div., R&D

#### Kazuchika Takagaki

Department Manager, Discovery Research Labs., R&D

#### Hitoshi Ishizawa

Department Manager, Osaka Business Office, Sales and Marketing

#### Hayato Wada

Department Manager, Tokyo Business Office, Sales and Marketing

#### Noboru Nishikawa

Head of Sales and Marketing Planning Div.

#### Masaya Toda

Head of Licensing & Alliance Div.

#### Kazuyuki Yamate

Department Manager, Corporate Planning Dept.

Current as of June 27, 2019



## Ten-Year Summary

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

(FY)

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2018
<b>For the year</b>										Millions of Yen	Thousands of U.S. Dollars
Net sales	62,932	63,525	67,304	69,941	76,517	79,991	84,209	98,781	101,448	114,716	1,033,477
Pharmaceuticals	52,165	52,554	55,746	58,318	63,345	66,340	70,489	85,315	87,416	100,223	902,909
Functional food	10,767	10,970	11,558	11,622	13,172	13,651	13,720	13,466	14,031	14,492	130,558
Cost of sales	29,018	30,218	32,702	34,776	39,033	41,226	44,016	44,835	46,929	50,952	459,027
Gross profit	33,937	33,332	34,601	35,165	37,483	38,764	40,192	53,946	54,519	63,764	574,450
Total selling, general and administrative expenses	27,475	28,151	28,588	28,263	29,445	30,202	31,643	38,666	37,439	43,119	388,459
Selling, general and administrative expenses	19,035	19,184	19,174	19,214	19,914	21,233	21,904	23,762	24,217	26,418	238,000
R&D expenses	8,440	8,967	9,414	9,049	9,530	8,968	9,739	14,903	13,221	16,701	150,459
Operating income	6,461	5,181	6,012	6,901	8,038	8,562	8,549	15,280	17,079	20,644	185,981
Net income attributable to owners of the parent	4,096	3,958	3,715	4,647	5,750	5,882	6,340	11,749	12,953	16,302	146,864
Depreciation and amortization	3,078	3,116	2,948	2,759	2,704	2,665	2,452	2,648	2,773	3,418	30,792
Capital investment	1,859	1,185	967	1,332	1,072	1,239	3,554	3,949	2,811	1,242	11,189
Cash flows from operating activities	9,225	3,233	3,658	3,767	6,015	6,113	8,915	18,916	6,719	15,310	137,927
Cash flows from investing activities	(3,648)	(2,844)	(759)	(2,026)	(3,357)	(3,718)	(3,978)	(5,750)	(11,342)	511	4,603
Cash flows from financing activities	(1,318)	(1,393)	(1,341)	(1,413)	(1,606)	(1,773)	(1,907)	(2,193)	(3,787)	(3,708)	(33,405)
<b>End of the year</b>										Millions of Yen	Thousands of U.S. Dollars
Total assets	103,575	102,737	106,304	113,730	118,188	129,757	135,370	150,905	155,887	168,763	1,520,387
Interest-bearing debt	182	113	75	35	—	—	—	—	—	—	—
Net assets	80,370	81,692	84,566	89,529	93,186	101,207	102,762	114,316	125,689	135,190	1,217,927
<b>Financial information per share</b>										Yen	U.S. Dollars
Earnings per share	60.63	58.62	55.04	68.87	85.25	87.26	94.10	174.42	192.31	242.04	2.18
Net assets per share	1,187.42	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	18.05
Dividend per share	19	19	19	21	23	25	28	48	52	70	0.63
<b>Principal financial indicators</b>										%	%
Operating income to net sales	10.3	8.2	8.9	9.9	10.5	10.7	10.2	15.5	16.8	18.0	—
Equity ratio	77.4	79.3	79.4	78.5	78.7	77.8	75.8	75.6	80.5	80.0	—
Return on assets	6.4	5.0	5.8	6.3	6.9	7.0	6.5	10.8	11.2	12.7	—
Return on equity	5.2	4.9	4.5	5.4	6.3	6.1	6.2	10.8	10.8	12.5	—
Payout ratio	31.3	32.4	34.5	30.5	27.0	28.7	29.8	27.5	27.0	28.9	—



# Management’s Discussion and Analysis

## 1. Overview of Performance

For the Nippon Shinyaku Group and other members of the pharmaceutical industry, the operating environment has become very challenging owing to drastic reforms to the NHI drug price system, government initiatives to promote greater use of generics, and various other measures aimed at reining in healthcare expenditure.

Although heightened health-consciousness has created strong demand for functional food, the business climate also remains harsh for Nippon Shinyaku’s Functional Food segment, due to factors including consumer thriftiness and accompanying stagnation in household spending, as well as higher costs for transportation and labor, and a more competitive landscape.

Under these circumstances, the Nippon Shinyaku Group worked hard to realize its goal of earning society’s trust and respect as an indispensable entity in the healthcare field—in short, as a company with a meaningful role to play.

Against this backdrop, net sales increased 13.1% year on year to ¥114,716 million. Factors contributing to this increase included growth in sales of new pharmaceutical products in Japan, as well as co-promotion revenues, royalty revenues from overseas sales of Uptravi (a proprietary treatment for pulmonary arterial hypertension (PAH)), and milestone payments for Uptravi. In terms of profits, R&D expenditure increased owing to upfront payments associated with in-licensing agreements and advances in clinical development, and sales promotion costs for new products also rose, but higher sales ensured that operating income increased year on year by 20.9% to ¥20,644 million. Ordinary income was ¥21,540 million (a year-on-year increase of 23.4%), and net income attributable to owners of the parent recorded a 25.9% year-on-year increase. In short, profits rose by a large margin.

## 2. Overview by Segment

### 1 Pharmaceuticals

The Pharmaceuticals business experienced growth in sales of Uptravi (proprietary PAH treatment), Zalutia (a drug for urinary disorders caused by benign prostatic hypertrophy), and Cialis (a remedy for erectile dysfunction), and in Uptravi’s case there was also growth in royalty income from overseas sales, as well as in income from co-promotion. The business saw further contributions from sales of Gazyva, a treatment for CD20-positive follicular lymphoma launched in August 2018 in conjunction with Chugai Pharmaceutical, and milestone payments for Uptravi, leading to net sales of ¥100,223 million (a year-on-year increase of 14.6%).

### 2 Functional Food

Net sales increased 3.3% year on year to ¥14,492 million, due to increased sales of health food ingredients, protein preparations, and preservatives.

## 3. Financial Condition

Decreases in marketable securities and inventories, and increases in cash and cash equivalents and time deposits compared to the previous fiscal year-end caused current assets to total ¥110,720 million. Fixed assets totaled ¥58,042 million due to decreases in investment securities, long-term prepaid expenses and net property, plant and equipment

compared to the previous fiscal year-end. As a result, total assets increased by ¥12,876 million compared to the previous fiscal year-end, to ¥168,763 million.

Current liabilities totaled ¥25,406 million due to an increase in income taxes payable, despite a decrease in notes and accounts payables compared to the previous fiscal year-end. Long-term liabilities totaled ¥8,165 million, due to an increase in deferred tax liabilities compared to the previous fiscal year-end. As a result, total liabilities increased by ¥3,375 million compared to the previous fiscal year-end, to ¥33,572 million.

Equity increased by ¥12,593 million compared to the previous fiscal year-end, to ¥128,827 million. Accumulated other comprehensive income decreased by ¥3,107 million to ¥6,109 million. As a result, total equity increased by ¥9,501 million to ¥135,190 million.

The equity ratio was 80.0%.

Net cash provided by operating activities amounted to ¥15,310 million. The main cash inflows were income before income taxes of ¥21,540 million, depreciation and amortization of ¥3,418 million, and a decrease in inventories of ¥972 million, while the main outflows were an increase in trade notes and trade accounts receivables of ¥6,391 million, and income taxes—paid of ¥4,355 million.

Net cash provided by investing activities amounted to ¥511 million. The main cash inflow was ¥4,420 million in proceeds from redemption of marketable securities, while the main outflow was expenditure of ¥1,351 million for the purchase of property, plant and equipment.

Net cash used in financing activities amounted to ¥3,708 million, primarily comprising cash dividends paid.

As a result, cash and cash equivalents as of March 31, 2019 increased by ¥12,122 million compared to the previous fiscal year-end, to ¥39,632 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.

Our policy on returning profits to shareholders is to issue dividends linked to business performance. During the 5th Five-year Medium-term Management Plan (April 2014 to March 2019), we sought to maintain a consolidated payout ratio of around 30%, and in the period covered by the 6th Five-year Medium-term Management Plan (April 2019 to March 2024), we aim to increase the consolidated payout ratio to around 35%. In some cases, we may exclude extraordinary gains and/or losses when calculating the payout ratio.

For fiscal 2018, we issued an annual cash dividend of ¥70 per share, comprising an interim dividend of ¥29 per share and year-end dividend of ¥41 per share. As a result, we had a dividend payout ratio of 28.9% in fiscal 2018.

For fiscal 2019, we are projecting an annual dividend of ¥86 per share, comprising an interim dividend of ¥43 per share and year-end dividend of ¥43 per share.

# Business Risks

The following are some of the risks that could impact the financial position and business results of the Nippon Shinyaku Group. Forward-looking statements contained below are based on judgments made at the end of the fiscal year ended March 31, 2019.

### 1 Regulatory Control Risks

The core Pharmaceuticals and Functional Food businesses of the Nippon Shinyaku Group are strictly regulated under the Pharmaceutical and Medical Device Act (officially called the Act on Securing the Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics), and the Food Sanitation Act. In the event that changes to these laws require the Group to recall or cease the sale of products, it could impact our business performance.

### 2 Intellectual Property (IP) Risks

The Nippon Shinyaku Group practices appropriate control over intellectual property rights and is vigilant against third-party infringement of such rights. An actual infringement of IP rights could trigger a decline in Nippon Shinyaku Group sales, so in some instances the company will engage in litigation to protect its rights. While the Nippon Shinyaku Group strives to ensure that its own business activities do not infringe upon the IP rights of others, there is a risk of litigation in the event of such infringements, which could require the company to pay compensation, or cease relevant business activities. In such cases, the Group’s business performance could be adversely affected.

### 3 Litigation Risks

It is possible that the Nippon Shinyaku Group’s business activities will give rise in future to litigation, related for example to pharmaceutical side effects, product liability, environmental and labor issues, and fair trade. Such litigation also could impact business performance.

### 4 R&D Risks

Pharmaceuticals R&D is a lengthy process that requires significant capital, yet the probability that it will lead to the release or out-licensing of new pharmaceuticals is not high. If R&D is abandoned because drugs are found to lack efficacy or have safety issues, we will not be able to recover the capital that we invested, and in some instances this could affect the business performance of the Nippon Shinyaku Group.

### 5 Side Effect Risks

Pharmaceuticals are thoroughly tested for safety and strictly reviewed before they are authorized to be sold. However, if unexpected side effects arise after pharmaceuticals are placed on the market, the Group could be required to recall or cease the sale of products, which could impact business performance.

### 6 Regulatory Risks, Including Moves to Limit Healthcare Expenditures

The Pharmaceuticals business is subject to a variety of laws, regulations, and ordinances. In its bid to reduce healthcare expenditures, Japan’s government has introduced a number of policies including drug price cuts for prescription pharmaceuticals and measures to promote greater use of generics, and debate continues over how to further reform the healthcare system. Any additional reforms to the healthcare system—such as stricter regulations concerning the development, manufacture, and sale of pharmaceuticals—could have an impact on the Group’s business performance.

### 7 Manufacturing and Procurement Risks

The Nippon Shinyaku Group is improving production efficiency by consolidating its manufacturing facilities. At the same time, if operations at manufacturing facilities cease due to natural disasters or other circumstances, this could interrupt the supply of products and impact our business performance. In addition, we procure certain products and important ingredients from specific suppliers. If supply is interrupted, it could impact our business performance.

### 8 Financial Market and Foreign Exchange Rate Fluctuation Risks

There is a risk that financial market movements—including swings in share prices, interest rates, or foreign exchange rates—could lead to declines in the market value of asset holdings and corporate pension assets, or affect transactions denominated in foreign currencies. These kind of fluctuations potentially could affect the Group’s business performance.

### 9 Risks Related to IT Security and Information Management

The Nippon Shinyaku Group uses all manner of information systems, and operations could be hindered in the event of system failures or cyberattacks. The Group also holds a large amount of confidential (including personal) information, and if this information was leaked to external parties, business performance could be affected by payment of monetary damages, or erosion of public trust.



# Consolidated Financial Statements

## Consolidated Balance Sheet

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
March 31, 2019

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2019	2018	2019
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents (Note 10)	¥ 39,632	¥ 27,510	\$ 357,045
Time deposits (Note 10)	987	957	8,891
Marketable securities (Notes 3 and 10)	1,520	4,420	13,693
Notes and accounts receivables (Note 10):			
Trade notes	696	702	6,270
Trade accounts	45,859	39,462	413,144
Other	591	225	5,324
<b>Total notes and accounts receivables</b>	<b>47,147</b>	<b>40,390</b>	<b>424,747</b>
Inventories (Note 4)	19,373	20,345	174,531
Other current assets	2,060	1,551	18,558
<b>Total current assets</b>	<b>110,720</b>	<b>95,176</b>	<b>997,477</b>
<b>PROPERTY, PLANT, AND EQUIPMENT:</b>			
Land	7,463	7,463	67,234
Buildings and structures	27,428	27,178	247,099
Machinery, equipment, and vehicles	12,277	12,330	110,603
Tools, furniture, and fixtures	8,842	8,679	79,657
Construction in progress	199	67	1,792
<b>Total</b>	<b>56,211</b>	<b>55,718</b>	<b>506,405</b>
Accumulated depreciation	(35,635)	(34,616)	(321,036)
<b>Net property, plant, and equipment</b>	<b>20,575</b>	<b>21,102</b>	<b>185,360</b>
<b>INVESTMENTS AND OTHER ASSETS:</b>			
Investment securities (Notes 3 and 10)	23,460	26,309	211,351
Long-term prepaid expenses	8,765	9,621	78,963
Deferred tax assets (Note 9)	2,330	517	20,990
Other assets	2,910	3,161	26,216
<b>Total investments and other assets</b>	<b>37,466</b>	<b>39,608</b>	<b>337,531</b>
<b>TOTAL</b>	<b>¥ 168,763</b>	<b>¥ 155,887</b>	<b>\$ 1,520,387</b>

See notes to consolidated financial statements.

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2019	2018	2019
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Notes and accounts payables (Note 10):			
Trade notes	¥ 1,798	¥ 2,016	\$ 16,198
Trade accounts	6,188	6,622	55,747
Other	6,924	5,727	62,378
<b>Total notes and accounts payables</b>	<b>14,910</b>	<b>14,367</b>	<b>134,324</b>
Income taxes payable (Note 10)	3,597	2,115	32,405
Accrued expenses	4,382	4,228	39,477
Deposits from customers	257	255	2,315
Other current liabilities	2,259	1,488	20,351
<b>Total current liabilities</b>	<b>25,406</b>	<b>22,454</b>	<b>228,882</b>
<b>LONG-TERM LIABILITIES:</b>			
Liability for retirement benefits (Note 5)	7,843	7,422	70,657
Deferred tax liabilities (Note 9)	2		18
Other long-term liabilities	320	321	2,882
<b>Total long-term liabilities</b>	<b>8,165</b>	<b>7,743</b>	<b>73,558</b>
<b>EQUITY (Notes 6 and 13):</b>			
Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares	5,174	5,174	46,612
Capital surplus	4,445	4,445	40,045
Retained earnings	121,677	109,078	1,096,189
Treasury stock—at cost, 2,897,365 shares in 2019 and 2,896,632 shares in 2018	(2,469)	(2,464)	(22,243)
Accumulated other comprehensive income:			
Unrealized gain on available-for-sale securities	9,440	11,469	85,045
Deferred loss on derivatives under hedge accounting	(5)	(5)	(45)
Foreign currency translation adjustments	0	4	0
Defined retirement benefit plans	(3,326)	(2,252)	(29,963)
<b>Total</b>	<b>134,936</b>	<b>125,451</b>	<b>1,215,639</b>
Noncontrolling interests	253	237	2,279
<b>Total equity</b>	<b>135,190</b>	<b>125,689</b>	<b>1,217,927</b>
<b>TOTAL</b>	<b>¥ 168,763</b>	<b>¥ 155,887</b>	<b>\$ 1,520,387</b>



Consolidated Financial Statements

Consolidated Statement of Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Year Ended March 31, 2019

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2019	2018	2019
<b>NET SALES</b> (Note 14)	<b>¥ 114,716</b>	¥ 101,448	<b>\$ 1,033,477</b>
<b>COST AND EXPENSES:</b>			
Cost of sales	50,952	46,929	459,027
Selling, general, and administrative expenses (Notes 7 and 8)	43,119	37,439	388,459
<b>Total</b>	<b>94,071</b>	84,368	<b>847,486</b>
<b>Operating income</b> (Note 14)	<b>20,644</b>	17,079	<b>185,981</b>
<b>OTHER INCOME (EXPENSES):</b>			
Interest and dividend income	542	486	4,882
Interest expense	(3)	(3)	(27)
Other—net	357	(111)	3,216
<b>Other income—net</b>	<b>896</b>	371	<b>8,072</b>
<b>INCOME BEFORE INCOME TAXES</b>	<b>21,540</b>	17,451	<b>194,054</b>
<b>INCOME TAXES</b> (Note 9):			
Current	5,674	4,622	51,117
Deferred	(457)	(140)	(4,117)
<b>Total income taxes</b>	<b>5,217</b>	4,482	<b>47,000</b>
<b>NET INCOME</b>	<b>16,323</b>	12,969	<b>147,054</b>
<b>NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTERESTS</b>	<b>20</b>	15	<b>180</b>
<b>NET INCOME ATTRIBUTABLE TO OWNERS OF THE PARENT</b>	<b>¥ 16,302</b>	¥ 12,953	<b>\$ 146,864</b>

	Yen		U.S. Dollars
<b>PER SHARE OF COMMON STOCK</b> (Notes 2.o and 12):			
Basic net income	¥ 242.04	¥ 192.31	\$ 2.18
Cash dividends applicable to the year	70.00	52.00	0.63

See notes to consolidated financial statements.

Consolidated Statement of Comprehensive Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Year Ended March 31, 2019

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2019	2018	2019
<b>NET INCOME</b>	<b>¥ 16,323</b>	¥ 12,969	<b>\$ 147,054</b>
<b>OTHER COMPREHENSIVE INCOME (LOSS)</b> (Note 11):			
Unrealized gain (loss) on available-for-sale securities	(2,028)	2,234	(18,270)
Deferred gain (loss) on derivatives under hedge accounting			
Foreign currency translation adjustments	(4)	(6)	(36)
Defined retirement benefit plans	(1,074)	(34)	(9,675)
<b>Total other comprehensive income (loss)</b>	<b>(3,107)</b>	2,194	<b>(27,990)</b>
<b>COMPREHENSIVE INCOME (LOSS)</b>	<b>¥ 13,215</b>	¥ 15,163	<b>\$ 119,054</b>
<b>TOTAL COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO:</b>			
Owners of the parent	¥ 13,195	¥ 15,147	\$ 118,873
Noncontrolling interests	20	15	180

See notes to consolidated financial statements

Consolidated Statement of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Year Ended March 31, 2019

	Thousands	Millions of Yen											
	Outstanding Number of Shares of Common Stock	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Accumulated Other Comprehensive Income					Total	Noncontrolling Interest	Total Equity
						Unrealized Gain on Available-for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Defined Retirement Benefit Plans				
BALANCE, APRIL 1, 2017	67,357	¥ 5,174	¥ 4,445	¥ 99,897	¥ (2,450)	¥ 9,235	¥ (5)	¥ 11	¥ (2,217)	¥ 114,089	¥ 226	¥ 114,316	
Net income attributable to owners of the parent				12,953						12,953		12,953	
Cash dividends, ¥56.00 per share				(3,771)						(3,771)		(3,771)	
Purchase of treasury stock	(2)				(14)					(14)		(14)	
Net change during the year						2,234		(6)	(34)	2,194	11	2,205	
BALANCE, MARCH 31, 2018	67,354	5,174	4,445	109,078	(2,464)	11,469	(5)	4	(2,252)	125,451	237	125,689	
Net income attributable to owners of the parent				16,302						16,302		16,302	
Cash dividends, ¥55.00 per share				(3,704)						(3,704)		(3,704)	
Purchase of treasury stock					(5)					(5)		(5)	
Net change during the year						(2,028)		(4)	(1,074)	(3,107)	15	(3,091)	
BALANCE, MARCH 31, 2019	67,354	¥ 5,174	¥ 4,445	¥ 121,677	¥ (2,469)	¥ 9,440	¥ (5)		¥ (3,326)	¥ 134,936	¥ 253	¥ 135,190	

	Thousands of U.S. Dollars (Note 1)											
	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Accumulated Other Comprehensive Income					Total	Noncontrolling Interest	Total Equity
					Unrealized Gain on Available-for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Defined Retirement Benefit Plans				
BALANCE, MARCH 31, 2018	\$46,612	\$40,045	\$ 982,684	\$(22,198)	\$103,324	\$(45)	\$36	\$(20,288)	\$1,130,189	\$2,135	\$1,132,333	
Net income attributable to owners of the parent			146,864						146,864		146,864	
Cash dividends, \$0.49 per share			(33,369)						(33,369)		(33,369)	
Purchase of treasury stock				(45)					(45)		(45)	
Net change during the year					(18,270)		(36)	(9,675)	(27,990)	135	(27,846)	
BALANCE, MARCH 31, 2019	\$46,612	\$40,045	\$1,096,189	\$(22,243)	\$ 85,045	\$(45)		\$(29,963)	\$1,215,639	\$2,279	\$1,217,922	

See notes to consolidated financial statements.



## Consolidated Financial Statements

## Consolidated Statement of Cash Flows

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Year Ended March 31, 2019

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2019	2018	2019
<b>OPERATING ACTIVITIES:</b>			
Income before income taxes	¥ 21,540	¥ 17,451	\$ 194,054
Adjustments for:			
Income taxes—paid	(4,355)	(6,220)	(39,234)
Depreciation and amortization	3,418	2,773	30,792
Changes in assets and liabilities:			
Increase in trade notes and trade accounts receivables	(6,391)	(3,286)	(57,576)
Decrease (increase) in inventories	972	(1,768)	8,756
Increase in other current assets	(508)	(416)	(4,576)
(Decrease) increase in trade notes and trade accounts payables	(653)	2,407	(5,882)
Decrease in other current liabilities	(808)	(189)	(7,279)
Decrease in liability for retirement benefits	(1,124)	(692)	(10,126)
Other—net	3,220	(3,339)	29,009
<b>Total adjustments</b>	<b>(6,230)</b>	<b>(10,732)</b>	<b>(56,126)</b>
<b>Net cash provided by operating activities</b>	<b>15,310</b>	<b>6,719</b>	<b>137,927</b>
<b>INVESTING ACTIVITIES:</b>			
Purchase of property, plant, and equipment	(1,351)	(4,017)	(12,171)
Purchases of investment securities	(102)	(1,431)	(918)
Purchases of software	(107)	(160)	(963)
Purchase of long-term prepaid expenses	(962)	(4,004)	(8,666)
Other—net	3,035	(1,728)	27,342
<b>Net cash provided by investing activities</b>	<b>511</b>	<b>(11,342)</b>	<b>4,603</b>
<b>FINANCING ACTIVITIES:</b>			
Cash dividends paid	(3,698)	(3,768)	(33,315)
Purchase of treasury stock	(5)	(14)	(45)
Other—net	(4)	(4)	(36)
<b>Net cash used in financing activities</b>	<b>(3,708)</b>	<b>(3,787)</b>	<b>(33,405)</b>
<b>FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS</b>	<b>9</b>	<b>6</b>	<b>81</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>12,122</b>	<b>(8,404)</b>	<b>109,207</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	<b>27,510</b>	<b>35,914</b>	<b>247,837</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>¥ 39,632</b>	<b>¥ 27,510</b>	<b>\$ 357,045</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 2018 consolidated financial statements to conform to the classifications used in 2019.

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. 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 ¥111 to \$1, the approximate rate of exchange at March 31, 2019. 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, 2019 and 2018, 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-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.

**g. 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 of calculated 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.

**h. Allowance for Doubtful Accounts** - The allowance for doubtful accounts is stated at an amount considered to be appropriate based on the Companies' past credit loss experience and an evaluation of potential losses in receivables outstanding.

**i. 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.

**j. 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.

- k. **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.

On February 16, 2018, the Accounting Standards Board of Japan (ASBJ) issued ASBJ Statement No. 28, "Partial Amendments to Accounting Standard for Tax Effect Accounting," which requires deferred tax assets and deferred tax liabilities to be classified as investments and other assets and long-term liabilities, respectively. Deferred tax assets were previously classified as current assets and investments and other assets, and deferred tax liabilities were previously classified as current liabilities and long-term liabilities under the previous accounting standard. The revised accounting standard is effective for annual periods beginning on or after April 1, 2018. The Company retrospectively applied the revised accounting standard effective April 1, 2018, and deferred tax assets of ¥2,777 million, which was previously classified as current assets, as of March 31, 2018, have been reclassified as investments and other assets, in the accompanying consolidated balance sheet.

- l. **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.

- m. **Foreign Currency Financial Statements** - The balance sheet accounts of the consolidated foreign subsidiaries 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.

- n. **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.

- o. **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.

- p. **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.

- q. **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.

### 3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2019 and 2018, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Current:			
Equity securities			
Government and corporate bonds	¥ 1,520	¥ 4,020	\$ 13,693
Other		400	
Total	¥ 1,520	¥ 4,420	\$ 13,693
Noncurrent:			
Equity securities	¥ 22,918	¥ 25,828	\$ 206,468
Government and corporate bonds	511	451	4,603
Other	29	29	261
Total	¥ 23,460	¥ 26,309	\$ 211,351

The costs and aggregate fair values of marketable and investment securities at March 31, 2019 and 2018, were as follows:

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

	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
March 31, 2018				
Securities classified as:				
Available-for-sale:				
Equity securities	¥ 9,636	¥ 16,191		¥ 25,828
Other	400			400
Held-to-maturity	4,500		¥ 5	4,495

	Thousands of U.S. Dollars			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
March 31, 2019				
Securities classified as:				
Available-for-sale:				
Equity securities	\$ 86,819	\$ 119,639		\$ 206,468
Held-to-maturity	18,567			18,567

### 4. INVENTORIES

Inventories at March 31, 2019 and 2018, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Finished products and merchandise	¥ 14,064	¥ 14,337	\$ 126,702
Work in process	1,362	1,671	12,270
Raw materials and supplies	3,946	4,337	35,549
Total	¥ 19,373	¥ 20,345	\$ 174,531

### 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, 2019 and 2018, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Balance at beginning of year	¥ 29,020	¥ 28,662	\$ 261,441
Current service cost	1,091	1,081	9,828
Interest cost	212	236	1,909
Actuarial losses	1,054	422	9,495
Benefits paid	(1,777)	(1,381)	(16,009)
Balance at end of year	¥ 29,601	¥ 29,020	\$ 266,675

(2) The changes in plan assets for the years ended March 31, 2019 and 2018, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Balance at beginning of year	¥ 21,597	¥ 20,597	\$ 194,567
Expected return on plan assets	863	823	7,774
Actuarial losses	(955)	(152)	(8,603)
Contributions from the employer	2,017	1,666	18,171
Benefits paid	(1,765)	(1,337)	(15,900)
Balance at end of year	¥ 21,758	¥ 21,597	\$ 196,018

(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
	2019	2018	2019
Defined benefit obligation	¥ 27,161	¥ 26,415	\$ 244,693
Plan assets	(21,758)	(21,597)	(196,018)
	5,403	4,818	48,675
Unfunded defined benefit obligation	2,439	2,604	21,972
Net liability arising from defined benefit obligation	¥ 7,843	¥ 7,422	\$ 70,657

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Liability for retirement benefits	¥ 7,843	¥ 7,422	\$ 70,657
Net liability arising from defined benefit obligation	¥ 7,843	¥ 7,422	\$ 70,657



(4) The components of net periodic benefit costs for the years ended March 31, 2019 and 2018, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Service cost	¥1,091	¥1,081	\$9,828
Interest cost	212	236	1,909
Expected return on plan assets	(863)	(823)	(7,774)
Amortization of prior service cost	443	479	3,990
Recognized actuarial losses	20	45	180
Others	41	6	369
Net periodic benefit costs	¥ 947	¥1,024	\$8,531

(5) Amounts recognized in other comprehensive income (before income tax effect) in respect of defined retirement benefit plans for the years ended March 31, 2019 and 2018, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Prior service cost	¥ (20)	¥ (45)	\$ (180)
Actuarial losses	1,566	94	14,108
Total	¥1,545	¥ 49	\$13,918

(6) Amounts recognized in accumulated other comprehensive income (before income tax effect) in respect of defined retirement benefit plans as of March 31, 2019 and 2018, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Unrecognized prior service cost		¥ 20	
Unrecognized actuarial losses	¥4,786	3,220	\$43,117
Total	¥4,786	¥3,241	\$43,117

(7) Plan assets  
a. Components of plan assets  
Plan assets as of March 31, 2019 and 2018, consisted of the following:

	2019	2018
Domestic bonds	15.1%	17.2%
Domestic stocks	12.8	15.8
Foreign bonds	11.2	12.4
Foreign stocks	9.2	10.2
General accounts	34.7	31.5
Alternative	13.8	9.3
Others	3.2	3.6
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, 2019 and 2018, are set forth as follows:

	2019	2018
Discount rate	0.1-0.8%	0.1-0.6%
Expected rate of return on plan assets	4.0	4.0

2. Defined Contribution Pension Plan  
Premiums for the defined contribution pension plan were ¥81 million (\$729 thousand) and ¥73 million for the years ended March 31, 2019 and 2018, 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 cannot do so because it does not meet all the above criteria.

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

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

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

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

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

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

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

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

## 7. RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥16,701 million (\$150,459 thousand) and ¥13,221 million for the years ended March 31, 2019 and 2018, respectively.

## 8. LEASES

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

Total rental expenses including lease payments under finance leases for the years ended March 31, 2019 and 2018, were ¥1,433 million (\$12,918 thousand) and ¥1,311 million, respectively.

Future minimum payments under noncancelable operating leases were as follows:

	Operating Leases	
	2019	
	Millions of Yen	Thousands of U.S. Dollars
Due within one year	¥ 29	\$ 261
Due after one year	166	1,495
Total	¥196	\$1,765

## 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, 2019 and 2018.

The tax effects of significant temporary differences and tax loss carryforwards which resulted in deferred tax assets and liabilities at March 31, 2019 and 2018, are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Deferred tax assets:			
Retirement benefits	¥2,396	¥2,267	\$21,585
Accrued expenses	1,107	1,087	9,972
Property, plant, and equipment	31	31	279
Supplies	1,861	1,427	16,765
Other	2,065	1,729	18,603
Less valuation allowance	(309)	(309)	(2,783)
Deferred tax assets	7,151	6,231	64,423
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	3,839	4,721	34,585
Deferred gains on sales of property	966	970	8,702
Other	17	21	153
Deferred tax liabilities	4,823	5,714	43,450
Net deferred tax assets	¥2,328	¥ 517	\$20,972

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, 2019, with the corresponding figures for 2018, is as follows:

	2019	2018
Normal effective statutory tax rate	30.5%	30.5%
Expenses not deductible for income tax purposes	0.5	0.6
Income not taxable for income tax purposes	(0.5)	(0.5)
Tax credits for research and development costs	(6.9)	(6.1)
Inhabitant tax on per capita basis	0.3	0.4
Other—net	0.3	0.8
Actual effective tax rate	24.2%	25.7%



## 10. FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

### (1) Group policy for financial instruments

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

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

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

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

The Company's derivative transactions are specific foreign exchange forward contracts. The Company has entered into foreign exchange forward contracts to hedge foreign currency exchange risk specifically associated with imported merchandise, as requested by customers or based on the judgment of the purchase department. 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 on the basis of 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 comprises 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, 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	
Total	¥ 112,418	¥ 112,418	
Notes and accounts payables	¥ 14,910	¥ 14,910	
Income taxes payable	3,597	3,597	
Total	¥ 18,507	¥ 18,507	

March 31, 2018	Millions of Yen		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	¥ 27,510	¥ 27,510	
Time deposits	957	957	
Notes and accounts receivables	40,390	40,390	
Marketable and investment securities	30,399	30,394	¥ 5
Total	¥ 99,258	¥ 99,252	¥ 5
Notes and accounts payables	¥ 14,367	¥ 14,367	
Income taxes payable	2,115	2,115	
Total	¥ 16,482	¥ 16,482	

March 31, 2019	Thousands of U.S. Dollars		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	\$ 357,045	\$ 357,045	
Time deposits	8,891	8,891	
Notes and accounts receivables	424,747	424,747	
Marketable and investment securities	222,081	222,081	
Total	\$ 1,012,774	\$ 1,012,774	
Notes and accounts payables	\$ 134,324	\$ 134,324	
Income taxes payable	32,405	32,405	
Total	\$ 166,729	\$ 166,729	

#### 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, 2019 and 2018.

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

	Carrying Amount		
	Millions of Yen	Thousands of U.S. Dollars	
	2019	2018	2019
Investments in equity instruments that do not have a quoted market price in an active market	¥ 329	¥ 329	\$ 2,963

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

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	
Available-for-sale securities with contractual maturities				
Total	¥ 89,287	¥ 240	¥ 300	

March 31, 2018	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	¥ 27,510			
Time deposits	957			
Notes and accounts receivables	40,390			
Marketable and investment securities:				
Held-to-maturity securities	4,040	¥ 160		¥ 300
Available-for-sale securities with contractual maturities	400			
Total	¥ 73,298	¥ 160		¥ 300

March 31, 2019	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	\$ 357,045			
Time deposits	8,891			
Notes and accounts receivables	424,747			
Marketable and investment securities:				
Held-to-maturity securities	13,693	\$ 2,162	\$ 2,702	
Available-for-sale securities with contractual maturities				
Total	\$ 804,387	\$ 2,162	\$ 2,702	

## 11. OTHER COMPREHENSIVE INCOME (LOSS)

The components of other comprehensive income (loss) for the years ended March 31, 2019 and 2018, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2019	2018	2019
Unrealized gain (loss) on available-for-sale securities:			
Gains arising during the year	¥ (2,911)	¥ 3,215	\$ (26,225)
Amount before income tax effect	(2,911)	3,215	(26,225)
Income tax effect	882	(981)	7,945
Total	¥ (2,028)	¥ 2,234	\$ (18,270)
Deferred gain (loss) on derivatives under hedge accounting:			
Gains arising during the year		¥ 1	\$
Total	¥	¥	\$
Foreign currency translation adjustments:			
Adjustments arising during the year	¥ (4)	¥ (6)	\$ (36)
Total	¥ (4)	¥ (6)	\$ (36)
Defined retirement benefit plan (s):			
Adjustments arising during the year	¥ (2,009)	¥ (574)	\$ (18,099)
Reclassification adjustments to profit or loss	464	524	4,180
Amount before income tax effect	(1,545)	(49)	(13,918)
Income tax effect	471	15	4,243
Total	¥ (1,074)	¥ (34)	\$ (9,675)
Total other comprehensive income (loss)	¥ (3,107)	¥ 2,194	\$ (27,990)



## 12. NET INCOME PER SHARE

Reconciliation of the differences between basic and diluted net income per share ("EPS") for the years ended March 31, 2019 and 2018, 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, 2019- Basic EPS				
Net income available to common shareholders	¥16,302	67,354	¥242.04	\$2.18
For the year ended March 31, 2018- Basic EPS				
Net income available to common shareholders	¥12,953	67,355	¥192.31	

## 13. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 27, 2019, the Company's shareholders approved the following:

Payment of a year-end cash dividend of ¥41 (\$0.36) per share to holders of record at March 31, 2019, for a total of ¥2,761 million (\$24,873 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 decisionmaker 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				
	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

	Millions of Yen				
	2018				
	Reportable Segments			Reconciliations	Consolidated
	Pharmaceuticals	Functional Food	Total		
Sales:					
Sales to external customers	¥87,416	¥14,031	¥101,448		¥101,448
Total	¥87,416	¥14,031	¥101,448		¥101,448
Segment profit	¥16,351	¥728	¥17,079		¥17,079
Segment assets	88,285	10,914	99,200	¥58,991	158,192
Other:					
Depreciation	2,494	240	2,734	38	2,773
Increase in property, plant, and equipment and intangible assets	2,672	138	2,810		2,811

	Thousands of U.S. Dollars				
	2019				
	Reportable Segments			Reconciliations	Consolidated
	Pharmaceuticals	Functional Food	Total		
Sales:					
Sales to external customers	\$902,909	\$130,558	\$1,033,477		\$1,033,477
Total	\$902,909	\$130,558	\$1,033,477		\$1,033,477
Segment profit	\$177,288	\$8,693	\$185,981		\$185,981
Segment assets	844,792	98,009	942,801	\$577,576	1,520,387
Other:					
Depreciation	29,117	1,333	30,450	333	30,792
Increase in property, plant, and equipment and intangible assets	10,630	549	11,189		11,189

Note: Unallocated corporate assets included in "Reconciliations" for 2019 and 2018 are ¥64,111 million (\$577,576 thousand) and ¥58,991 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		
	2019		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	¥100,223	¥14,492	¥114,716

	Millions of Yen		
	2018		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	¥87,416	¥14,031	¥101,448

	Thousands of U.S. Dollars		
	2019		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	\$902,909	\$130,558	\$1,033,477

### 2. Information about Geographical Areas

#### (1) Sales

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

	Millions of Yen				
	2018				
	Europe			Other	Total
	Japan	Switzerland	Other		
	¥86,455	¥14,406	¥410	¥175	¥101,448

	Thousands of U.S. Dollars				
	2019				
	Europe			Other	Total
	Japan	Switzerland	Other		
	\$827,180	\$196,639	\$5,702	\$3,936	\$1,033,477

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 sheets as of March 31, 2019 and 2018.

#### (3) Information about Major Customers

	2019		
	Sales		Related Segment Name
Name of Customers	Millions of Yen	Thousands of U.S. Dollars	
Actelion Pharmaceuticals Ltd.	¥21,827	\$196,639	Pharmaceuticals
Alfresa Corporation	17,511	157,756	Pharmaceuticals
Suzuken Co., Ltd.	17,309	155,936	Pharmaceuticals
MEDICEO CORPORATION	16,980	152,972	Pharmaceuticals

	2018	
	Sales	
Name of Customers	Millions of Yen	Related Segment Name
MEDICEO CORPORATION	¥16,461	Pharmaceuticals
Suzuken Co., Ltd.	15,896	Pharmaceuticals
Alfresa Corporation	15,763	Pharmaceuticals
Actelion Pharmaceuticals Ltd.	14,406	Pharmaceuticals





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INDEPENDENT AUDITOR'S REPORT

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

We have audited the accompanying consolidated balance sheet of Nippon Shinyaku Co., Ltd. (the "Company") and its consolidated subsidiaries as of March 31, 2019, and the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these 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 misstatements, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements 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 entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its consolidated subsidiaries as of March 31, 2019, and the consolidated results of their operations and their 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.

Deloitte Touche Tohmatsu LLC

June 27, 2019

Member of  
Deloitte Touche Tohmatsu Limited

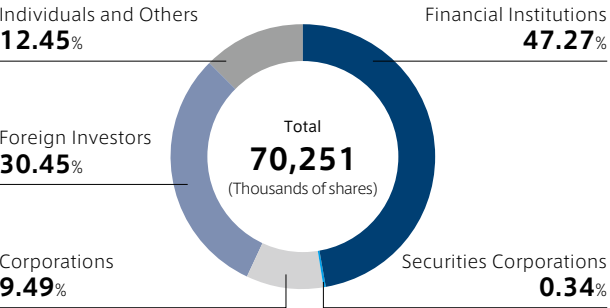
Corporate Data

Corporate Name	Nippon Shinyaku Co., Ltd.	Representative Director	Shigenobu Maekawa, President
Founded	November 20, 1911	Independent and Certified Public Accountants	Deloitte Touche Tohmatsu
Date of Incorporation	October 1, 1919		Shijokarasuma FT Square
Head Office	14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan		20, Naginataboko-cho, Karasuma-higashiiru, Shijo-dori, Shimogyo-ku, Kyoto 600-8008, Japan
	Phone: +81-75-321-1111		
	Facsimile: +81-75-321-0678	Issued and Outstanding Number of Shares	70,251,484
	http://www.nippon-shinyaku.co.jp/english/	Number of Shareholders	4,673
Paid-in Capital	¥5.2 billion (Listed on the First Section of the Tokyo Stock Exchange)	Share Registrar	Mitsubishi UFJ Trust and Banking Corporation
			6-3, Fushimimachi 3-chome, Chuo-ku, Osaka 541-0044, Japan

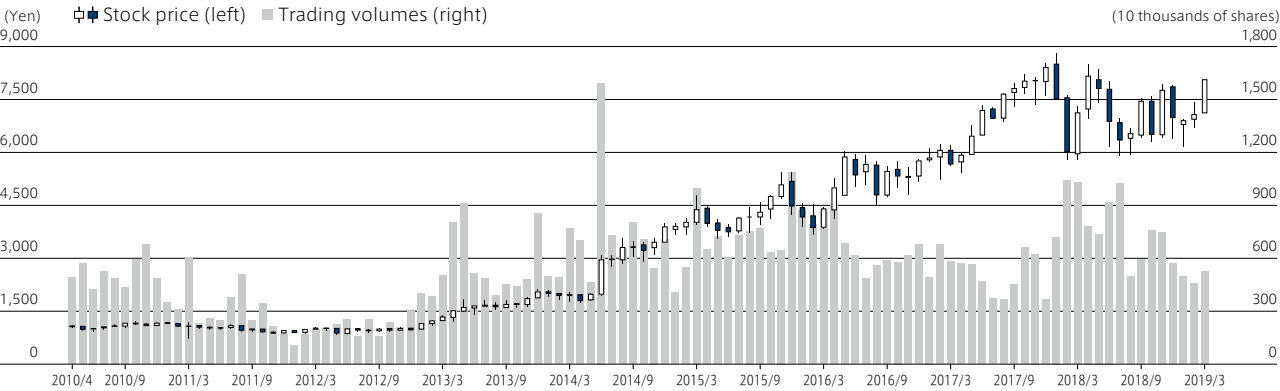
Major Shareholders

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.
STATE STREET BANK AND TRUST COMPANY 505001
THE CHASE MANHATTAN BANK, N. A. LONDON SPECIAL ACCOUNT NO. 1
Nippon Life Insurance Company
JPMC OPPENHEIMER JASDEC LENDING ACCOUNT
Japan Trustee Services Bank, Ltd. (Trust account 9)

Distribution of Shares Issued



Stock Price and Trading Volumes



Network As of April 1, 2019

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 Logistics Center, West Logistics 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