

# ANNUAL REPORT 2015

Year ended March 31, 2015



## NIPPON SHINYAKU CO., LTD.

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The cover illustration is from *Pikkapika no Iwako-chan*, a picturebook published through the sixth Nippon Shinyaku Children's Literary Awards contest. For more information about the contest, please refer to page 29 of this report.

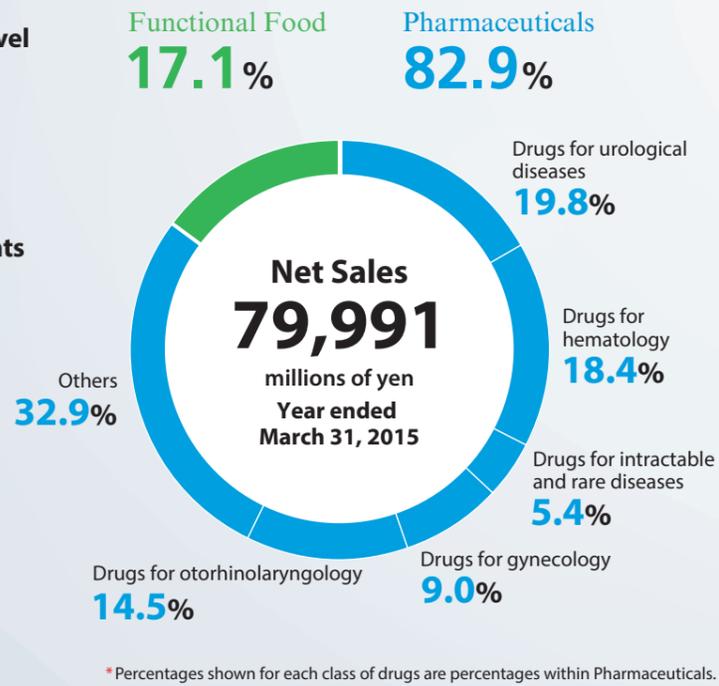


# Helping people lead healthier, happier lives

Nippon Shinyaku has provided products that help people lead healthier and happier lives through our pharmaceuticals business—part of our company since day one—and our functional food business, which operates under the belief that food is a form of medicine.

In the pharmaceuticals segment, we believe that our mission is to continually develop novel and unique medicines that benefit patients.

In the functional food segment, we leverage our expertise in pharmaceuticals to deliver proprietary functional food ingredients that are beneficial to society and that help people live healthier lives.



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## Pharmaceuticals

### Drugs for urological diseases



- Zalutia®
- Eviprostat®
- Bladderon®
- Estracyt®
- Cialis®

Benign prostatic hypertrophy (BPH) creates issues with degraded quality of life (QOL). Zalutia®, a drug for urinary disorders caused by BPH launched in April 2014, offers a new mechanism of action that ameliorates the dysuria of BPH and improves QOL.

### Drugs for hematology



- Vidaza®
- Cylocide®
- Trisenox®
- Amnolake®

Vidaza®, a myelodysplastic syndrome (MDS) treatment launched in March 2011, is permeating the market as the world's only drug that extends survival time for patients with MDS.

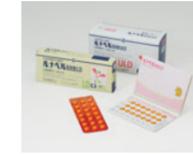
### Drugs for intractable and rare diseases



- Adcirca®
- Opsumit®
- Regtect®

Nippon Shinyaku provides drugs with differing mechanisms of action, including Adcirca®, a once-per-day oral formulation that exhibits the action of inhibiting phosphodiesterase-5 and Opsumit®, an endothelin receptor antagonist launched in June 2015, for the intractable disease pulmonary arterial hypertension.

### Drugs for primary domain\*



- Luabell® tablets LD
- Lunabell® tablets ULD

The Lunabell® combination tablet LD, which combines low-dosage estrogen and progesterone, has been approved for insurance coverage in Japan. The Lunabell® combination tablet ULD, which contains smaller dosage of estrogen, was also launched in September 2013 and is now widely used as a treatment for dysmenorrhea.

### Drugs for otorhinolaryngology



- Erizas®
- Baynas®
- Azunol® Gargle Liquid
- Cephadol®
- Livostin®

Erizas® Nasal Powder 200µg 28 metered spray, a dry powder-type spray treatment for allergic rhinitis, packages a 14-day supply of powder with a steroid active ingredient in a spray applicator.

### Others



- Onetram®
- Tramal®

Onetram® was launched in June 2015. Onetram® is a once-daily oral formulation that applies release technologies to tramadol hydrochloride, the active ingredient in Tramal®, a four-times daily formulation for cancer pain and chronic pain.

\* Drugs for primary domain refer to pharmaceuticals to be used for basic treatment in a variety of facilities and fields of medicine.

## Functional Food

### Health food ingredients



- Hyaluronic acid 3000
- Garcinia Powder J
- Mangosteen aqua
- Aronia TA
- NSCP aqua
- NS Amla extract powder

We leverage expertise in safety and quality control practices developed in our pharmaceuticals business to provide health food ingredients beneficial to maintaining and improving human health based on assured quality and evidence of efficacy.

### Preservatives



- Mikaku Fine Z
- Mikaku Fine BK
- Glycine GX-2
- Chefflead V
- R-88
- KC-20

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 extensive lineup can be used for just about any application in the food industry.

### Protein preparations and nutritional ingredients



- Milka MPI
- Lactocrystal
- PROGEL800
- Sodium Caseinate CW
- Enlacto HG
- Fitness S

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

### Spices and condiments



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

We utilize our extraction and manufacturing technologies developed in our pharmaceutical business to make spices, hot chili extracts, onion concentrate, as well as juice products from haskap and cantaloupe melon produced in Hokkaido.

### Others



- Suncircle H
- Nineace S

We provide products that disinfect and maintain hygienic standards of containers and equipment used in food processing plants.

## Editorial Policy

### • Period Covered

Fiscal 2014 (April 1, 2014–March 31, 2015). Some sections of the report also discuss initiatives since April 2015.

### • Companies Covered

Information in this report pertains to Nippon Shinyaku Co., Ltd. and its Japanese subsidiaries within the Nippon Shinyaku Group. However, some sections apply only to Nippon Shinyaku Co., Ltd.

\* Figures presented in this report are taken from Nippon Shinyaku's Financial Report for the year ended March 31, 2015. As figures have been rounded, totals may not exactly equal the sum of their composite statistics.

### 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.

## Consolidated Financial Highlights

### Summary of consolidated financial indicators

For the year	2011/3	2012/3	2013/3	2014/3	2015/3	2015/3
					millions of yen	thousands of U.S. dollars
Net sales	63,525	67,304	69,941	76,517	<b>79,991</b>	<b>666,591</b>
Pharmaceuticals	52,554	55,746	58,318	63,345	<b>66,340</b>	<b>552,833</b>
Drugs for urological diseases	13,741	13,189	12,334	12,609	<b>13,104</b>	<b>109,200</b>
Drugs for hematology	3,092	6,600	8,965	11,668	<b>12,224</b>	<b>101,866</b>
Drugs for intractable and rare diseases*1	—	—	—	3,014	<b>3,612</b>	<b>30,100</b>
Drugs for gynecology*1	—	—	—	5,645	<b>5,963</b>	<b>49,691</b>
Drugs for otorhinolaryngology*1	—	—	—	9,921	<b>9,638</b>	<b>80,316</b>
Functional food	10,970	11,558	11,622	13,172	<b>13,651</b>	<b>113,758</b>
Cost of sales	30,218	32,702	34,776	39,033	<b>41,226</b>	<b>343,550</b>
Gross income on sales	33,307	34,601	35,165	37,483	<b>38,764</b>	<b>323,033</b>
Selling, general and administrative expenses	28,151	28,588	28,263	29,445	<b>30,202</b>	<b>251,683</b>
Operating income	5,181	6,012	6,901	8,038	<b>8,562</b>	<b>71,350</b>
Net income	3,958	3,715	4,647	5,750	<b>5,882</b>	<b>49,016</b>
Depreciation and amortization	3,116	2,948	2,759	2,704	<b>2,665</b>	<b>22,208</b>
Capital investment	1,185	967	1,332	1,072	<b>1,239</b>	<b>10,325</b>
R&D expenses	8,967	9,414	9,049	9,530	<b>8,968</b>	<b>74,733</b>
End of the year					millions of yen	thousands of U.S. dollars
Total assets	102,737	106,304	113,730	118,188	<b>129,757</b>	<b>1,081,308</b>
Net assets	81,692	84,566	89,529	93,186	<b>101,207</b>	<b>843,391</b>
Financial information per share					yen	U.S. dollars
Book value per share	1,207.43	1,250.11	1,323.87	1,378.93	<b>1,498.88</b>	<b>12.49</b>
Earnings per share	58.62	55.04	68.87	85.25	<b>87.26</b>	<b>0.73</b>
Dividend per share	19	19	21	23	<b>25</b>	<b>0.21</b>
Principal financial indicators						%
Ratio of net worth	79.3	79.4	78.5	78.7	<b>77.8</b>	—
Return on equity	4.9	4.5	5.4	6.3	<b>6.1</b>	—
Pay-out ratio	32.4	34.5	30.5	27.0	<b>28.7</b>	—

\*1 The three domains of drugs for intractable and rare diseases, drugs for gynecology, and drugs for otorhinolaryngology are focus domains in the 5th Five-year Medium-term Management Plan that we launched in fiscal 2014, and for which we have provided disclosure from fiscal 2013

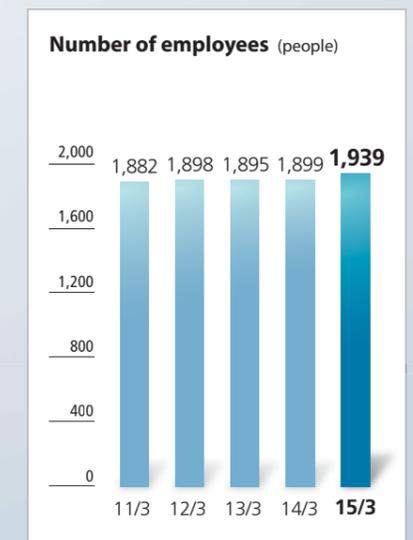
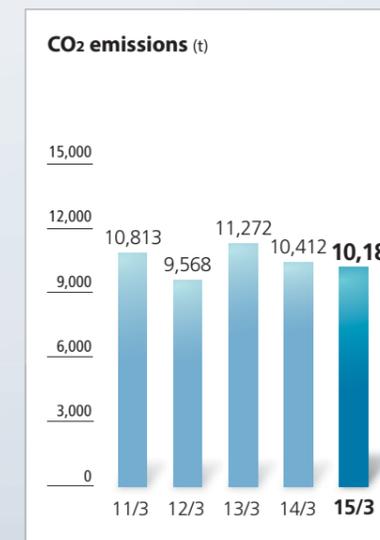
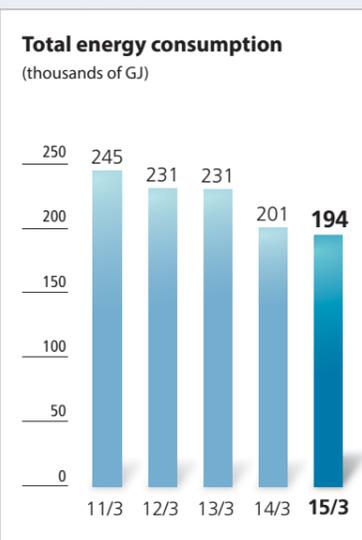
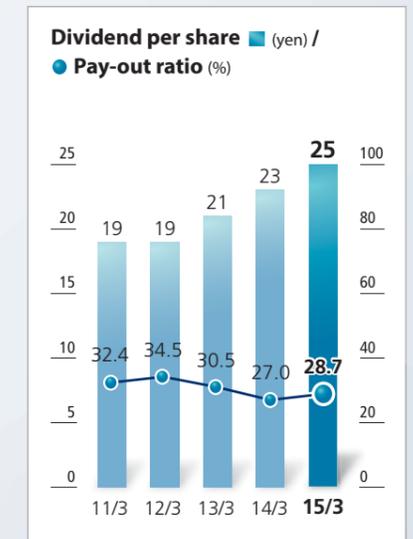
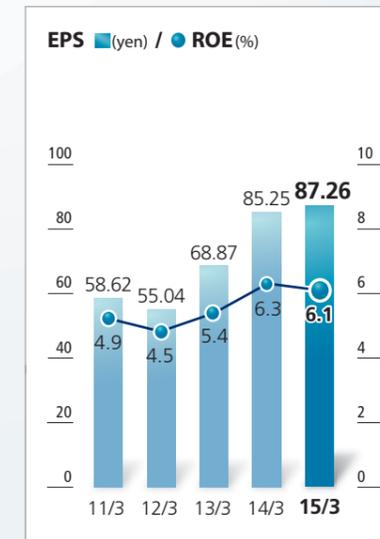
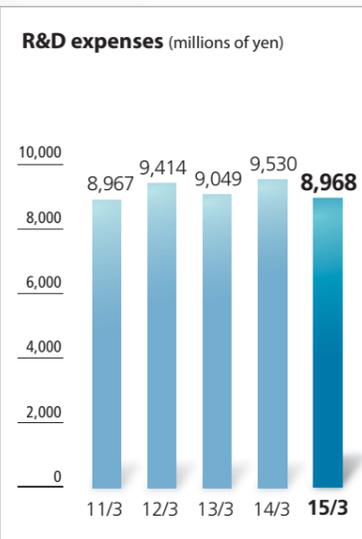
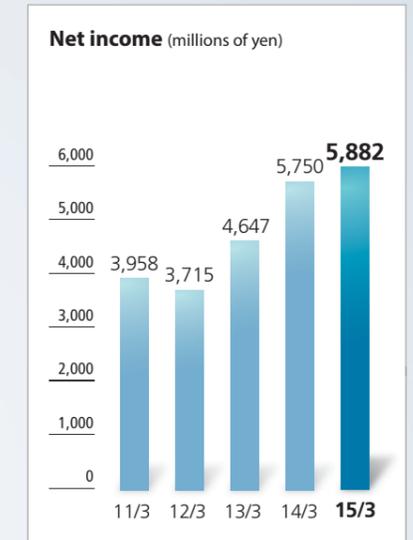
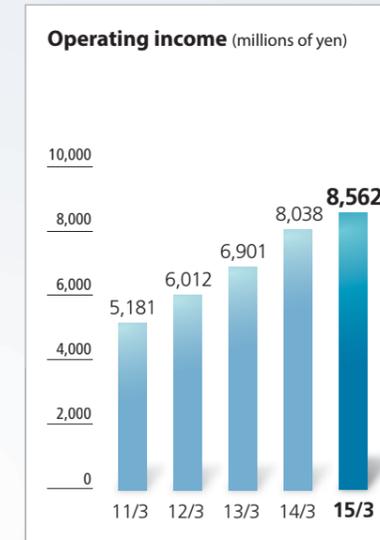
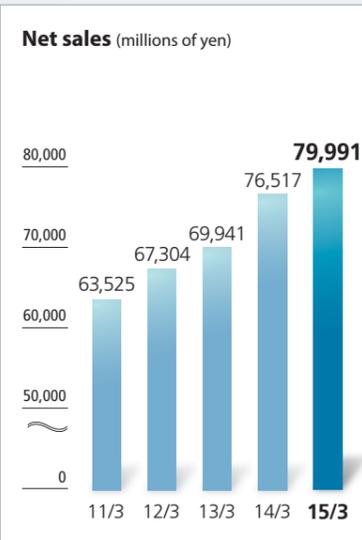
### ESG indices\*2 summary

	2011/3	2012/3	2013/3	2014/3	2015/3	
Total energy consumption (thousands of GJ)*3	245	231	231	201	<b>194</b>	—
CO2 emissions (t)*3	10,813	9,568	11,272	10,412	<b>10,183</b>	—
CO2 per unit of revenue (t/million yen)*3	0.171	0.143	0.162	0.136	<b>0.128</b>	—
Number of employees (people)	1,882	1,898	1,895	1,899	<b>1,939</b>	—

\*2 Indices related to environment, social, and corporate governance initiatives

\*3 Applies to main business locations (excluding our sales offices)

### Financial Highlights



# We Have Achieved Record Net Sales and Profits for the Second Year Straight



The Nippon Shinyaku Group's business environment during the year ended March 31, 2015 proved once again to be quite difficult for the pharmaceutical sector in general because of the ongoing emphasis on measures to limit medical costs, including the greater promotion of generics and NHI drug price revisions that took effect in April 2014, among other factors. Additionally, despite surging costs for imported raw materials in the functional food segment caused by the weak yen, consumers' inclination toward low priced products remains unchanged and competition in the market has grown more intense, resulting in challenging conditions.

Amid this environment, the Nippon Shinyaku Group proactively engaged in the sales and marketing of its innovative new drug products, achieving increased sales and profits for the second consecutive year. Our new product launches included Zalutia® for urinary disorders caused by benign prostatic hypertrophy, and Tramal® OD, a treatment for cancer pain and chronic pain. In terms of R&D, we received approval in Japan for Opsumit®, a treatment for pulmonary arterial hypertension, and Onetram®, an oral tramadol sustained release tablet. Meanwhile, outside of Japan, Actelion Pharmaceuticals Ltd., based in Switzerland and licensee of NS-304, applied for approval for pulmonary arterial hypertension in the United States and Europe, demonstrating our R&D pipeline made steady advances.

Shigenobu Maekawa  
President

## Helping People Lead Healthier, Happier Lives

### Business Philosophy

## Helping People Lead Healthier, Happier Lives

Our corporate slogan is to build a healthier future, so that people can live longer and enjoy more fruitful and more energetic lives.

## Business Results for the Year Ended March 31, 2015

### Posted Increased Net Sales, Operating Income, Ordinary Income and Net Income for the Third Consecutive Year

The Nippon Shinyaku Group recorded net sales of ¥79,991 million (up 4.5% year-on-year), operating income of ¥8,562 million (up 6.5% year-on-year), ordinary income of ¥8,928 million (up 3.8% year-on-year), and net income of ¥5,882 million (up 2.3% year-on-year). Net sales, operating income, ordinary income and net income each increased for the third consecutive year.

In the pharmaceuticals segment, sales of Tramal®, a treatment for cancer pain and chronic pain, Vidaza®, a remedy for myelodysplastic syndrome, and Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy newly launched in April 2014 and other drug products increased. As a result, net sales amounted to ¥66,340 million (up 4.7% year-on-year).

In the functional food segment, sales of health food ingredients declined, but sales of preservatives and nutritional ingredients increased. As a result, net sales in the segment were ¥13,651 million (up 3.6% year-on-year).

## Financial Position

### Assets, Debts, and Net Assets

For the year ended March 31, 2015, total assets increased by ¥11,568 million year-on-year to ¥129,757 million. Total liabilities increased by ¥3,548 million year-on-year to ¥28,550 million. Net assets increased by ¥8,020 million year-on-year to ¥101,207 million.

### Cash Flows

For the year ended March 31, 2015, cash and cash equivalents increased by ¥684 million year-on-year to ¥21,914 million. Net cash from operating activities amounted to ¥6,113 million, while net cash used in investing activities amounted to ¥3,718 million. Net cash expended for financing activities amounted to ¥1,773 million.

### 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 for 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.

### Code of Conduct

#### 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.

## Medium- and Long-Term Business Strategy

Both the pharmaceutical sector and functional food segment continue to face a challenging business environment marked by the ongoing emphasis on measures to limit medical costs as well as tougher competition in the market and consumers' unchanged inclination toward low prices. Given this environment, Nippon Shinyaku launched the 5th five-year Medium-term Management Plan that begins this fiscal year named "Aiming for New Growth – Pursuit of Originality –." This medium-term management plan lays out the scenarios for Nippon Shinyaku to realize new growth. We will clarify differences with competitors in all aspects of our work and by pursuing originality we establish a foundation and infrastructure for addressing the changing business environment.

### Pharmaceuticals Business Strategy

In the pharmaceuticals segment, we will target niche domains within the five main fields of focus (centered on urology, hematology and intractable/orphan diseases, as well as gynecology and otorhinolaryngology), concentrating management resources to expand our pipeline and increase market share.

As for R&D strategy, we will concentrate management resources within the main fields of focus that have unmet medical needs. We will also leverage outside resources to build on our novel drug development capabilities. At the same time, we will take a three-pronged approach to expanding our pipeline which includes in-house drug discovery, in-licensing and product life cycle management (PLCM).

In terms of marketing strategy, we will concentrate management resources in the main fields of focus to maximize pharmaceutical value and develop Zalutia®, Vidaza® and pulmonary arterial hypertension drugs into the next growth drivers of our business.



### Functional Food Business Strategy

In the functional food segment, we will provide original value-added products that are high quality and contribute to healthy longevity, active lifestyles, food safety and food waste reduction, as the functional food business of a pharmaceutical company. In turn, this will ensure we transform this business segment into a highly profitable one.

In terms of R&D strategy, we will focus management resources on the main focus areas of health food ingredients, preservatives, and nutritional ingredients, bringing to market functional foods that can be differentiated by high quality and high added-value.

As for marketing strategy, we will invest management resources in the main focus areas, while seeking to maximize product value and carry out marketing activities which avoid price competition.



### Human Resources Strategy

Recognizing that our people create originality, we will step up hiring and human resources development while also working diligently to enhance employee motivation.

## Corporate Social Responsibility Initiatives

### Executing Our Management Policy to Achieve Sustainable Growth Together with Society

The Nippon Shinyaku Group is committed to achieving our business philosophy of "Helping people lead healthier, happier lives." We will achieve sustainable growth together with society and fulfill our corporate social responsibility (CSR) through our management policy to supply unique and high-quality products, and earn the trust of society while developing each employee.

In our CSR initiatives (see page 25), we endeavor to strike a balance between social contributions through our business activities, and social contributions outside of business. Our non-business activities include sponsorship of the Nippon Shinyaku Children's Literary Awards contest and the Shining Future for Children Fund. We send employees to teach workshops for elementary school students in the community, are involved in initiatives to preserve and maintain Kyoto culture, and arrange for our corporate baseball team to conduct baseball clinics for youth. We also run the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project, which creates heartwarming hospital art (see page 29).

Moving forward, we will continue our efforts to meet the expectations of stakeholders, and we welcome your continued feedback and support.



## Projected Business Results for the Year Ending March 31, 2016

### Increased Sales and Profits

In the pharmaceuticals segment next year, despite impacts from ongoing promotion of generics, we anticipate increased sales from further growth in our new drug product lineup, including Vidaza®, a remedy for myelodysplastic syndrome, Lunabell®, a treatment for dysmenorrhea, and Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy. We also expect an increase in sales from Opsumit®, a treatment for pulmonary arterial hypertension, and Onetram®, an oral tramadol sustained release tablet, launched in June 2015.

In the functional food segment, we forecast increased sales from our greater emphasis on new product development and launches as well as our strengthened initiatives toward priority products.

With the above in mind, we expect net sales of ¥90,000 million, operating income of ¥9,300 million, ordinary income of ¥9,500 million, and net income of ¥6,700 million.

### Dividends

#### Returning Profits to Shareholders

Under our strategy to maximize corporate value, Nippon Shinyaku strives to further strengthen its business foundations by bolstering R&D to expand the pipeline for product development, and retain sufficient earnings to enable it to maintain a corporate position to withstand increasingly competitive conditions. Our policy on reasonably returning profits to shareholders is to issue dividends linked to earnings and maintain a consolidated payout ratio of around 30%.

For the year ended March 31, 2015, we issued an annual cash dividend of ¥25 per share, comprising an interim dividend of ¥12 per share and year-end dividend of ¥13 per share. For the year ending March 31, 2016, we are projecting an annual cash dividend of ¥28 per share, comprising an interim dividend of ¥14 per share and year-end dividend of ¥14 per share.

  
 President

# Contributing to the Treatment of Pulmonary Arterial Hypertension

Nippon Shinyaku has set urology, hematology, and intractable and rare diseases as top-priority domains in our 5th Five-year Medium-term Management Plan, which commenced in fiscal 2014. We are now working to enhance our product lineup and maximize value in these domains. While the number of patients suffering from pulmonary arterial hypertension (PAH), considered an intractable and rare disease, has trended upward in recent years, treatment methods are advancing and a number of oral medicines have appeared. Nevertheless, the IP receptor agonist ((1) in table), which is seen as offering the highest level of treatment efficacy, does not yet exist as an agreeable oral dosage and remains dependent upon continuous intravenous administration. To resolve this issue, Nippon Shinyaku is working to develop a new orally available, long acting IP receptor agonist to meet the expectations of physicians and patients.

## Symptoms and incidence of PAH Patients increase to 10,000-20,000 in Japan

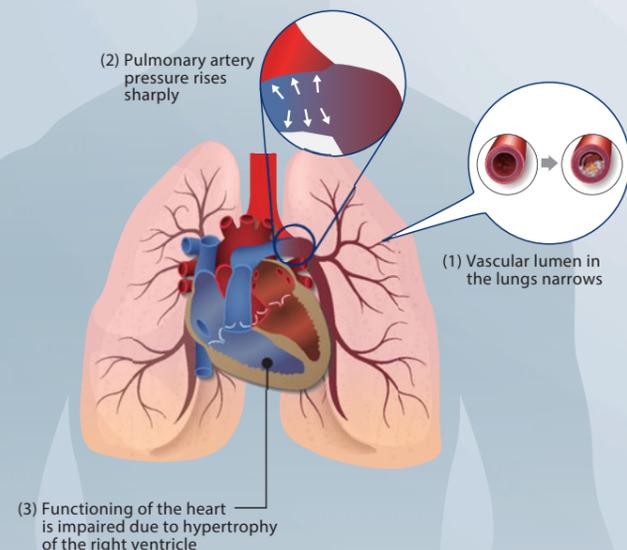
PAH is a rare disease in which blood pressure in the pulmonary artery, which sends blood from the heart to the lungs, becomes abnormally high due to some cause. While a mild case presents no particular subjective symptoms, the progression of the condition can present symptoms including breathing difficulty during physical activity, fatigue from even minimal exertion, and palpitations, making daily life increasingly difficult. The rise in pulmonary artery pressure places a burden on the heart and causes hypertrophy of the right ventricle, eventually triggering sudden death from right ventricular failure.

### The mechanism in onset of PAH

(1) Vascular lumen in the lungs narrows

(2) Blood pressure in the pulmonary artery becomes abnormally high

(3) Functioning of the lungs and heart is impaired



The incidence of PAH is said to be only several persons per million, but with recognition of the condition increasing among patients in recent years and treatment methods making progress, the number of patients is on the rise. The current number of PAH patients in Japan is estimated to be between 10,000 and 20,000.

## The expanding options for PAH treatment, and remaining issues

No effective drug existed to treat PAH for a long time, until the development of a method for continuous intravenous administration of prostacyclin (PGI<sub>2</sub>) as an IP receptor agonist significantly raised the efficacy of PAH treatment. PGI<sub>2</sub> is a type of the endogenous physiologically active substances known as prostaglandins. By binding to PGI<sub>2</sub> receptors, PGI<sub>2</sub> exhibits effects including vasodilation action and platelet aggregation inhibitory action. However, as PGI<sub>2</sub> is extremely unstable, maintaining its effect required continuous administration.

Subsequently, endothelin receptor antagonists (ERA) ((2) in table), phosphodiesterase type 5 inhibitors (PDE5i) ((3) in table), and other oral medicines have been applied clinically, significantly widening treatment options.

Even with a number of oral drugs for treating PAH available, however, continuous intravenous administration of PGI<sub>2</sub> remains the most effective treatment, and IP receptor agonists maintain a key role in PAH treatment. However, unlike ERA and PDE5i, PGI<sub>2</sub> is not yet available in an oral drug form with a highly satisfactory level of treatment.

## Development of the orally available, long acting IP receptor agonist selexipag

To address such unmet medical needs, Nippon Shinyaku is moving ahead with the development of NS-304 (selexipag), an orally available new IP receptor agonist. The chemical structure of selexipag differs from that of existing IP receptor agonists, and is characterized by high selectivity to IP receptor and

long-acting effect. A PII trial targeting PAH was first performed in Europe. Despite difficult conditions for confirmation of efficacy due to all trial subjects receiving ERA or PDE5i treatment, the trial yielded the statistically significant result that pulmonary vascular resistance (an indicator of difficulty for blood flow) declined with administration of selexipag, meeting the primary endpoint.

Building on this favorable outcome, our overseas licensee Actelion Pharmaceuticals Ltd. (Switzerland, Actelion below) conducted a global selexipag PIII trial, the GRIPHON study. This was the largest international joint study performed as a clinical trial targeting PAH, spanning 39 countries, 1,156 trial subjects, and up to 4.3 years of drug administration. Under strict testing conditions, the study admirably met its primary endpoint on efficacy, and the drug demonstrated good tolerability.\*

The study also performed analysis of key subgroups, including age, gender, WHO Functional Class, PAH etiology,

and background PAH therapy, observing the efficacy of selexipag in all analyses.

Application for approval of selexipag was submitted by Actelion in the U.S. and Europe in December 2014, and preparations for application are underway in Japan with Nippon Shinyaku and Actelion Pharmaceuticals Japan Ltd. conducting joint development. The launch of selexipag as a new treatment for PAH is being anticipated in Japan and overseas.

Nippon Shinyaku also looks forward to being able to propose treatment that is optimal for each individual patient through its line-up of medications with three different mechanisms of action, adding selexipag to macitentan and tadalafil shown in the table below.

\* An indication of the degree to which overt adverse effects (i.e., side effects) of a drug can be tolerated by a patient.

Table of PAH Treatments from Nippon Shinyaku

Treatment category	Generic name (Product name)	Mechanism of action
(1) IP receptor agonist (oral PGI <sub>2</sub> )	 <b>Selexipag</b> Japan: Preparation for application underway Overseas: Application submitted by Actelion	Exhibits vasodilation action, platelet aggregation inhibitory action, etc.
(2) Endothelin receptor antagonist (ERA)	 <b>Macitentan</b> (Opsumit®)	Expands blood vessels by suppressing the effect of endothelin, a substance that is produced in the body and exhibits a vasoconstrictor action.
(3) Phosphodiesterase type 5 inhibitor (PDE5i)	 <b>Tadalafil</b> (Adcirca®)	Expands blood vessels by strengthening the effect of nitrogen monoxide (NO), a vasodilator substance produced in the body.



**Market Conditions**

**Market conditions remain challenging**

Japan's prescription drug market shrank in size for the first time in eight years as a result of measures to curb medical expenses based on recent government policy. The market, which was valued at some ¥10.0165 trillion on a NHI price basis in fiscal 2013, declined by 0.6% to ¥9.9587 trillion in fiscal 2014. Under the NHI price system reform, prices of long-listed drugs\*1 for which generics have yet to reach a 60% share after five years from the initial listing\*2 have been reduced further every time NHI price revisions are made until the share reaches 60%. Moreover, the government has announced a policy measure to achieve an 80% or higher share for generics as early as possible by the end of fiscal 2020 to constrain medical costs, and the business environment in the domestic market is becoming increasingly severe.

At the same time, a trend has also developed of evaluating necessary drugs highly and strengthening drug discovery capability, as seen in the adoption of a SAKIGAKE Designation System and the loosening of designation criteria for orphan drugs for rare diseases.

\*1 Long-listed drug: An original drug for which the patent has expired and generic versions are available  
 \*2 Listing: Approved as a prescription drug covered by NHI

**Sales Conditions**

**Sales of new drug products have grown, resulting in increased revenues**

Nippon Shinyaku is shortening its R&D lead time in order to deliver new unique and high quality drug products to patients as soon as possible, and continues to bring new drug products to market. We are also committed to enhancing the value of

our existing pharmaceuticals by modifying drug formulations and applying for additional indications, so as to accommodate the needs of both patients and medical professionals alike.

Our pharmaceuticals business saw a decline in sales for existing core drugs due to the influence of generics and competitor drugs, but sales of new drug product lines increased robustly.

During the current fiscal year, sales rose for Vidaza®, a myelodysplastic syndrome treatment; Adcirca®, a treatment for pulmonary arterial hypertension; Tramal®, a treatment for cancer pain and chronic pain; and Regtect®, a drug for supporting alcohol abstinence in patients with alcohol dependence. Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy launched in April 2014, also contributed to sales. We further recorded sales from industrial property rights accompanying the partner-led overseas application for approval of our original product. As a result, net sales in the pharmaceuticals segment were ¥66,340 million, a year-on-year increase of 4.7%.

**Prospects for Fiscal 2015**

**Sales of new drug products expected to grow and result in increased revenues**

Although the environment surrounding the pharmaceutical industry is becoming more challenging, we are implementing strategies with a focus on our new drug product lineup based on strategic R&D management defined in our 5th Five-year Medium-term Management Plan.

In fiscal 2015, we will work toward the further market penetration of new product lines including Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy, for which dosing period restrictions\*3 were lifted in May 2015.

In March 2015, we obtained manufacture and marketing approval for Onetram® tablets 100mg (generic name: tramadol hydrochloride), an oral sustained release analgesic, which launched in June. We obtained manufacture and marketing approval for the pulmonary arterial hypertension remedy Opsumit® tablets 10mg (generic name: macitentan) in March 2015, launched this product and commenced co-promotion\*4 with Actelion Pharmaceuticals Japan Ltd. in June. We forecast a 41.6% year-on-year increase in net sales of these and other new product lines overall.

We also anticipate that growing our sales of new product lines will increase net sales in the pharmaceuticals segment by 14.7% year-on-year to ¥76,100 million.

In R&D, we are conducting PIII global joint trials of the non-Hodgkin's lymphoma treatment GA101 (generic name: obinutuzumab) targeting indolent and aggressive non-Hodgkin's lymphoma, and are making preparations for domestic application of the pulmonary hypertension treatment NS-304 (generic name: selexipag) for pulmonary arterial hypertension. (PII trials are underway for chronic thromboembolic pulmonary hypertension and arteriosclerosis obliterans.)

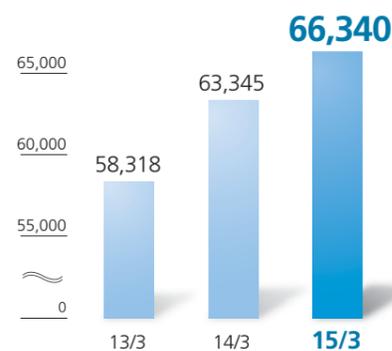
We are also moving ahead with PII trials for the antipruritic drug NS-141 and the nocturia treatment NS-986, with the aim of early and certain commercialization. We have completed an investigator-initiated early-stage and exploratory clinical trial for the Duchenne muscular dystrophy treatment NS-065/NCNP-01, the first Japanese-made nucleic acid drug\*5 to enter this stage, and are making preparations for a PII trial. In this manner, we will continue to bring unique drug products to market in order to boost our competitiveness and earning power, and maximize corporate value.

\*3 Dosing period restriction: A rule whereby new drugs can only be administered for a 14-day period for one prescription during the first year after their listing  
 \*4 Co-promotion: Provision of information by two cooperating companies  
 \*5 Nucleic acid drug: A collective name given to pharmaceuticals which contain linear nucleic acid or modified nucleic acid as the active ingredient and control the functions of a specific gene

**P**harmaceuticals

Nippon Shinyaku's core business is pharmaceuticals. This business mainly targets Japan's prescription drug market through development, manufacturing, and sales of therapeutic agents for intractable diseases that have yet to find an effective cure as well as for diseases where patients strongly require improved quality of life during treatment.

Net Sales (millions of yen)



## Business Segment

# Research & Development

### Nippon Shinyaku's R&D Vision

## Aiming to steadily and continually bring new drug products to market in specialty fields where we focus

As a basic strategy, we are focusing our R&D on the five priority domains of urology, hematology, intractable/rare diseases, gynecology, and otorhinolaryngology. Targeting these specialty fields, we aim to build our development pipeline around in-house drug discovery, licensing from other companies, and product life cycle management (PLCM) in order to steadily and continually bring new drug products to market.

### In-house Drug Discovery

With a focus on our core medical specialty of urological and hematological diseases, in-house drug discovery focuses on the development of highly competitive, unique and proprietary drugs. In addition, we are engaged in the development of drugs that address unmet medical needs – that is, medical needs for intractable/rare diseases or other illnesses for which effective therapies have not been established.

### In-licensing

We work actively to in-license both marketed products and development candidates in order to enhance a pipeline of products that promise synergies with our existing product lineup.

### Product Life Cycle Management

We examine new indications, new formulations, and other possibilities for our products on the market and under development, in order to maximize product value.

### Development of New Technology

## Focusing on the development of nucleic acid drugs

Nippon Shinyaku is actively engaged in the research of nucleic acid drugs at its Discovery Research Laboratories in Tsukuba. Nucleic acid drugs, which directly target disease-causing genes, show promise for their efficacy against intractable/rare diseases that are difficult to treat. By leveraging our advanced technology

and by promoting open innovation centered on cooperation with academia (universities and other academic research institutes), we aim to swiftly bring nucleic acid drug products to market.

### Development of the R&D Pipeline

## Progress being made on many development candidates

In April 2014, we launched Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy.

In December 2014, as a dosage form adding to Tramal® capsules 25mg and 50 mg, a four-times-daily drug for the treatment of cancer pain and chronic pain, we launched orally dissolving Tramal® OD tablets 25mg and 50 mg. In June 2015 we launched Onetram® tablets 100mg, a once-daily, oral tramadol sustained release tablet. Through the launch of these new products, we have widened available options for pain treatments.

In June 2015, we launched the endothelin receptor antagonist Opsumit® tablets 10mg, a pulmonary arterial hypertension drug. With this drug joining the Adcirca® tablets 20mg product already on the market, the further addition of the in-development NS-304 (generic name: selexipag) to the market will create a complete lineup of drugs that exhibit the three types of mechanism of action (endothelin receptor agonist, PDE5 inhibitor and IP receptor agonist) generally used in PAH therapy at present.

With regard to the status of applications, marketing approval application for Nippon Shinyaku's original drug selexipag was submitted in December 2014 to the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) by overseas licensing-out partner Actelion Pharmaceuticals Ltd.

Among products in the development stage, an early-stage and exploratory clinical trial has ended for the Duchenne muscular dystrophy treatment (code number: NS-065/NCNP-01) that is under joint development with the National Center of Neurology and Psychiatry (NCNP). Moreover, in April 2015, we launched PI trial of the endometriosis treatment NS-580. Developed by Nippon Shinyaku, this product is expected to yield analgesic effects by blocking the production of PGE<sub>2</sub>.



**Akira Matsuura**  
Director,  
General Manager,  
Research & Development  
Division

## Nippon Shinyaku is working to clarify our areas of priority and enhance our development pipeline

Nippon Shinyaku aims to clarify areas of priority in R&D, appropriately allocate management resources to the three pillars of in-house drug discovery, in-licensing, and PLCM, and steadily bring new products to market. A result of this approach has been the launch of orally dissolving Tramal® OD tablets in December 2014 and once-daily, oral tramadol sustained release tablet Onetram® tablets in June 2015. In addition, the development stage of many promising in-development products is making progress, as seen in the completion of an early-stage and exploratory clinical trial of the Duchenne muscular dystrophy drug NS-065/NCNP-01 and the start of a PI trial for the endometriosis drug NS-580.

Looking ahead, we will continue to actively engage in the development of new drugs, making use of new technologies such as nucleic acid drugs and focusing on illnesses for which therapies are not yet established. At the same time, we will make efforts to advance and expand our development pipeline so that we may bring pharmaceuticals as quickly as possible to the front lines of medicine that will delight patients who are awaiting new drugs.

### Pipeline: Domestic

As of June 15, 2015

Code No. (Generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase I	Phase II	Phase III	Application	Launch
<b>ACT-064992</b> (Macitentan)	Launch	Cardiovascular and metabolic system	Pulmonary arterial hypertension	Licensed-in from: Actelion Pharmaceuticals Ltd. (Switzerland)	Co-development: Actelion Pharmaceuticals Japan Ltd.					
A highly active, tissue-specific dual endothelin receptor antagonist that shows effect with one dose a day. Actelion conducted an international PIII trial, except in Japan, and obtained positive results. A joint PIII trial started in Japan in October 2012. Actelion Pharmaceuticals Japan applied for approval in Japan in May 2014, acquired manufacture and marketing approval in March 2015, and launched the product in June of the same year.										
<b>NS-24</b> (Tramadol hydrochloride)	Launch	Pain, inflammation, and allergies	Cancer pain Chronic pain	Licensed-in from: Paladin Labs Inc. (Canada)	Nippon Shinyaku					
Long-acting form of Tramadol hydrochloride, which has the same degree of efficacy and safety as Tramal® with one dose a day. Available in 17 countries around the world. PIII trial started in Japan in April 2012. Applied for approval in Japan in June 2014, acquired manufacture and marketing approval in March 2015, and launched in June of the same year.										
<b>NS-304</b> (Selexipag)	In preparation for application	Cardiovascular and metabolic system	Pulmonary arterial hypertension	Nippon Shinyaku	Co-development: Actelion Pharmaceuticals Japan Ltd.					
Orally-available, long-acting PGI <sub>2</sub> receptor agonist. Received orphan drug designation from the Ministry of Health, Labour and Welfare in September 2014, as a pulmonary arterial hypertension treatment. Efficacy evaluation of PII trial targeting pulmonary arterial hypertension, jointly conducted with Actelion Pharmaceuticals Japan Ltd., has been completed; currently in preparation for application in Japan.										
<b>GA101</b> (Obinutuzumab)	PIII	Hematologic malignancies	Indolent non-Hodgkin's lymphoma Aggressive non-Hodgkin's lymphoma	Licensed-in from: Chugai Pharmaceutical Co., Ltd.	Co-development: Chugai Pharmaceutical Co., Ltd.					
A humanized anti-CD20 monoclonal antibody which targets CD20 on B cells. Chugai Pharmaceutical Co., Ltd. began its development as a therapeutic for non-Hodgkin's lymphoma in Japan in October 2008. A joint development and marketing agreement was signed with Chugai Pharmaceutical Co., Ltd. in November 2012, and joint development is being conducted.										
<b>NS-304</b> (Selexipag)	PII	Cardiovascular and metabolic system	Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Co-development: Actelion Pharmaceuticals Japan Ltd.					
Orally-available, long-acting PGI <sub>2</sub> receptor agonist, currently in PII trial conducted together with Actelion Pharmaceuticals Japan Ltd.										
<b>NS-304</b> (Selexipag)	PII	Cardiovascular and metabolic system	Arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku					
Initiated PIIa trial in August 2013.										
<b>NS-141</b>	PII	Pain, inflammation, and allergies	Pruritus associated with cutaneous disease	Nippon Shinyaku	Nippon Shinyaku					
An external preparation with a new mechanism of action that has no antihistaminic activity. Has an effect on intractable pruritus that does not respond to existing treatments. Launched additional PIIa trial in September 2013 targeting itching caused by atopic dermatitis.										
<b>NS-986</b>	PII	Urology	Nocturia	Licensed-in from: Sumitomo Dainippon Pharma Co., Ltd.	Nippon Shinyaku					
Has a combination of antimuscarinic effect and ability to block sodium channels on afferent nerve fibers. Signed a licensing agreement with Sumitomo Dainippon Pharma Co., Ltd. in March 2013 for the exclusive development, manufacturing, and marketing of the product in Japan. PIIa trial (exploratory trial) began in December 2013 and ended in 2014.										
<b>NS-065/NCNP-01</b>	In preparation for PII	Other	Duchenne muscular dystrophy	Nippon Shinyaku	Nippon Shinyaku					
An antisense nucleic acid drug developed by Nippon Shinyaku. This is an injectable drug that induces the expression of dystrophin protein through the skipping of exon 53 of mutated dystrophin genes. Investigator-initiated early-stage and exploratory clinical trial ended in March 2015, and preparations for a PII trial are currently underway.										
<b>NS-580</b>	PI	Other	Endometriosis	Nippon Shinyaku	Nippon Shinyaku					
An orally available membrane-associated prostaglandin E synthase-1 (mPGES-1) inhibitor and endometriosis treatment free of hormone action, developed by Nippon Shinyaku. It is expected to exhibit an analgesic effect by blocking the production of PGE <sub>2</sub> . PI trial began in April 2015.										

### Pipeline: Overseas

Code No. (Generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase I	Phase II	Phase III	Application	Launch
<b>NS-304</b> (Selexipag)	Application	Cardiovascular and metabolic system	Pulmonary arterial hypertension	Nippon Shinyaku	Licensed-out to: Actelion Pharmaceuticals Ltd. (Switzerland)					
Application has been filed in US and Europe after our licensing-out partner Actelion Pharmaceuticals Ltd. (Switzerland) finished conducting a PIII trial worldwide (excluding Japan).										
<b>NM441</b> (Prulifloxacin)	PIII	Infectious diseases	Synthetic antibacterial	Nippon Shinyaku	Licensed-out to: Lee's Pharmaceutical Holdings Ltd. (Hong Kong)					
<b>NS-018</b>	PI/II	Hematologic malignancies	Myelofibrosis	Nippon Shinyaku	Nippon Shinyaku					
JAK2 tyrosine kinase inhibitor. Due to its high selectivity to activated JAK2, it is expected to be a treatment for myelofibrosis with increased efficacy and reduced side effects.										

## Business Segment

# Sales

### Core Measures

## Aiming to enhance our presence in core fields and become a pharmaceutical treatment partner

As part of our marketing strategy, the emphasis of marketing activities has been placed on our new lineup of drug products. Among these, new products such as the myelodysplastic syndrome treatment Vidaza® and the pulmonary arterial hypertension treatment Adcirca® are used by highly specialized physicians in specific fields of medicine. Our mission to ensure the proper usage of our drug products includes not only providing product information based on evidence, but also quickly capturing the ever-changing needs of patients and medical professionals, and timely delivering medical information that meets those needs.

In order to provide the information needed by medical practitioners in a timely manner, in fiscal 2013 we established an in-house MR qualification test program as part of our efforts to foster a corporate culture focused on daily knowledge acquisition and continual self improvement. In fiscal 2014 the success rate for the Basic course was 80%. The higher-ranked test takers progressed to Advanced and Specialist course certification tests. 17 persons passed the Advanced course, and 5 persons passed the more focused Specialist course.

Nippon Shinyaku aims to earn the trust of not only medical professionals but also of society, enhance our existential value and become the pharmaceutical treatment partner of choice for patients and medical professionals.

## Established a system that can respond promptly to the needs of medical professionals

In April 2015, the Marketing Division established promotion departments for the three domains in which it is making particular efforts, creating a framework for more strategic marketing of highly specialized products. Through this, we are combining marketing, academic, and logistics capabilities to formulate an action plan that incorporates marketing guidelines and product strategy into our marketing implementation. We clarify the

direction that each department should take and fuse the policies of each department into one, in order to execute precise action.

Main products handled by the newly established departments are: Zalutia® by Marketing & Development of Urology Department, Adcirca® and Opsumit® by Marketing & Development of Pulmonary Hypertension Department, and Vidaza® by Marketing & Development of Hematology Department. Pharmaceutical Information Department is in charge of Lunabell® and other primary product items. Through this arrangement, we are maximizing the value of our products by enhancing promotional campaigns targeting key opinion leaders (KOL)\*1 throughout Japan, formulating strategies for the future of the drugs, and executing specific action plans.

To ensure information on the proper use of our specialized drug products such as Vidaza® and Adcirca® is provided in an efficient manner, we have made changes to the structure of our marketing organization and added hospital sales offices. In MR activities, we will continue to strive for timely dissemination of information that matches the needs of medical experts as well as improve the quality and quantity of information provided.

\*1 Physicians with the power to influence other physicians in their treatment decisions and the prescription trend within their medical specialty

## Our commitment to compliance

We are constantly mindful of compliance and make efforts to ensure compliance is practiced appropriately so that each and every one of our employees is self aware as a member of the medical professional community that has peoples' lives in its hands. Every month we hold compliance training at all of our sales offices covering the Nippon Shinyaku Group Charter of Business Conduct, the Nippon Shinyaku Group Code of Practice, the Prescription Drug Promotion Code and the Fair Competition Code. Beginning in fiscal 2013, we have disclosed data on money we have provided to medical institutions in accordance with the Transparency guidelines for relationship between corporate activities and medical institutions established by the Japan Pharmaceutical Manufacturers Association. Furthermore, as measures against counterfeit pharmaceutical drug products, we work to educate medical professionals by exhibiting counterfeit erectile dysfunction (ED) drugs at events co-sponsored with the Japanese Society for Sexual Medicine.

## To achieve sustainable growth, Nippon Shinyaku is working to quickly maximize the potential of new products.

In fiscal 2014, the promotion of generic drug usage had a greater-than-expected impact on long-listed drugs. Amid this severe environment, in April 2014 we launched a promising new product in the urology domain: Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy. In this way, we achieve growth through marketing activities centered on the new products that we bring to market every year.

In fiscal 2015, the second year of our 5th Five-year Medium-term Management Plan, we will focus management resources on Zalutia® to effect a great jump forward and create a foundation for Opsumit®, a pulmonary arterial hypertension treatment that was launched in June. In fiscal 2015 we also established promotion departments for the three domains of urology, pulmonary hypertension and hematology, and are aiming to further grow new product lines through close cooperation between all divisions and practitioners on the front lines of medicine. With a commitment to exacting quality, we will engage in promoting proper product usage and strengthening our system for collection of information, and will continue to be a company trusted by patients and medical professionals alike.

**Shouzou Sano**  
Director,  
General Manager,  
Sales and Marketing  
Division

# Production

### Core Measures

## We boosted inventories of anti-cancer drugs and engaged in BCP\*2 at our Odawara Central Factory

Because our single greatest mission is to provide stable supplies of high quality active pharmaceutical ingredients and drug products, we have sourced raw materials from two separate suppliers, ensured the stable operation of production equipment, and pursued a rigorous approach to GMP\*3 controls. Anti-cancer drugs are a product with a particularly great impact on society. As in the previous year, in fiscal 2014 we again maintained target inventory levels and undertook the decentralization\*4 of inventory storage locations. In addition, we actively advanced BCP by performing regular building repair and production equipment maintenance at our Odawara Central Factory.

The new products launched in fiscal 2014 were supplied to the market without delay, and preparations are proceeding according to schedule for new products in fiscal 2015 as well. With the approval of Japan's accession to PIC/S\*5 in 2014 making PIC/S and GMP compliance a requirement, we will work to further raise our GMP level.

\*2 Business Continuity Plan  
\*3 Good Manufacturing Practice: Production management and quality management standards for pharmaceutical products  
\*4 A measure to reduce risk by splitting inventory between the Odawara Central Factory and East and West Logistic Centers  
\*5 A general abbreviation for Pharmaceutical Inspection Convention (PIC) and Pharmaceutical Inspection Co-operation Scheme (PIC/S)

## Leveraging our strength as a novel drug manufacturer to focus on the consignment manufacturing

At our Odawara Central Factory, we are leveraging the manufacturing technologies we have built up as a new drug manufacturer, as well as microparticle coating machinery that is among the largest in Japan, to actively develop a consignment manufacturing business spanning the formulation of investigational new drugs to commercial production.

In fiscal 2014, in addition to existing consignment products we began the manufacture of eight product items for five drugs. We

are also exploring formulation design for the consignment of orally disintegrating tablets as we continue to expand our consignment manufacturing business on the strength of our high technological capabilities and our reliability as a new drug manufacturer.

## Striving to advance quality assurance and safety management

Our Assurance Division is mainly in charge of product quality and safety management, which are both essential elements of any pharmaceuticals company.

In the area of product quality assurance, we comply with GQP\*6, perform audits of active pharmaceutical ingredients and formulations manufacturing locations in Japan and overseas, and check on GMP compliance status. We also respond promptly to quality-related claims by users. On the basis of these activities, we conduct management reviews (i.e., reviews of quality management activities) and undertake continuous improvements aimed at the construction of a better quality system.

In the area of safety management, we comply with GVP\*7, work under the cycle of collecting, evaluating, and implementing safety measures with respect to side effect-related data from medical institutions, and perform appropriate safety management. In fiscal 2014, in conjunction with manufacture and marketing approval for Onetram® tablets, we formulated a pharmaceutical risk management plan for tramadol hydrochloride products. In addition, we worked toward enhanced safety management through means such as appropriately responding to the package insert notification system under the Pharmaceuticals, Medical devices and Other Therapeutic Products Act that was enacted in November 2014.

In fiscal 2015, we will undertake the enhancement of integrated risk management from development to post-marketing, through means including review of pharmaceutical risk management planning, response to new drug approval applications, and support for the creation of Development Safety Update Report.

\*6 Good Quality Practice: Quality management standards for pharmaceutical products  
\*7 Good Vigilance Practice: Safety management standards for pharmaceutical products after marketing approval

## We are working to enhance our framework for stable supply of products and expand our consignment business.

Providing a stable supply of high quality drug products is our most important mission. Based on the 5th Five-year Medium-term Management Plan that began in fiscal 2014, we will provide a steady supply of products, will promote cost management at every stage of procurement, manufacture, and distribution, and will work to improve productivity. We will also perform consignment manufacturing spanning investigational new drug design and manufacture to commercial production, with the aim of expanding our consignment business. At the Odawara Central Factory, we plan to construct a highly active solid formulations building, launching production of our own products and consignment manufacturing of highly active formulations in fiscal 2018.

In fiscal 2014, we created a stable supply manual, enhanced the stable supply of products, and advanced cost management at all stages in addition to launching a company-wide project to reduce the cost of procured indirect materials. In our consignment business, we began the production of new consignment products.

In fiscal 2015, too, we will continue to enforce inventory management and further enhance our framework for the stable supply of products. At the same time, we will work to secure new consignment products, move forward on schedule with construction of our highly active solid formulations building, and expand our consignment business.

**Hitoshi Saito**  
Director,  
General Manager,  
Resource Procurement,  
Production & Assurance  
Division



**Market Conditions**

**Amid rising raw materials costs, consumers are increasingly conscious of thrift and of safety and security in food.**

In Japan's processed foods market, the price of imported raw materials soared due to the impact of the depreciation in the value of the yen, and the upward trend continues. Moreover, the increase in the rate of the consumption tax implemented in April 2014 has spurred consumer consciousness of thrift, so the processed food industry has received major blows from the increasing cost of raw materials and the declining volume of sales. Meanwhile, there have been issues with the use of expired raw materials, false place of origin labeling, and contamination, making consumers anxious about food. They are demanding unprecedented amounts of traceability-related data, including place of origin, and their awareness of food safety and security is becoming increasingly higher.

This challenging environment for the processed food industry has continued, but Nippon Shinyaku is moving forward to establish diverse product features, including quality, functionality, convenience, and health consciousness, and to develop markets based on new unconventional concepts.

**Sales Conditions**

**Revenue increased on the back of a rise in sales of preservatives, nutritional ingredients and soy proteins.**

We strengthened our initiatives aimed at flagship products (health food ingredients, preservatives, nutritional ingredients,

and soy proteins), and worked to expand sales channels. While sales of health food ingredients declined due to the impact of price competition, sales of preservatives increased under sales growth in shelf life-improving agents and glycine. Sales of nutritional ingredients held steady due to product price hikes and growing sales of milk proteins. In soy proteins, we significantly grew both sales volume and amount by setting clear targets and working to expand sales. Sales of the products rose 3.6% year-on-year to reach ¥13,651 million.

**Main Strategy**

**We will accurately assess conditions in society, and work to develop and expand sales of products that meet its needs.**

Nippon Shinyaku manufactures and markets products that include health food ingredients, preservatives, nutritional ingredients, protein preparations, seasonings and spices, and sterilizers and cleansers. A number of these products are used as raw materials in processed foods, health foods, and nutritional foods for seniors and medical or nursing care diets, while others are used for sanitation in food factories. Using a variety of techniques developed over many years in the pharmaceuticals business, these products are subject to strict quality control and have earned a strong reputation and trust within the food industry.

In terms of R&D, we are focused on developing functional food ingredients with high added value for the fields of health care and nutrition, in order to meet the growing health orientation of consumers and the needs of an aging society.

In terms of sales, we have identified health food ingredients, preservatives, nutritional ingredients, and soy proteins as our flagship products, and will work to expand sales of these through the setting of clear targets. In health food ingredients, we will focus on expanding sales of mangosteen extract, hyaluronic acid, the new product aronia extract, and garcinia extract, for which labeling of efficacy may become possible under the food with function claims labeling system. In preservatives, we have launched and are working to expand sales channels for Mikaku Fine Z, a product that incorporates our proprietary formulation

technology, and R-88, a new product for use in boiled rice. With regard to nutritional ingredients, we are expanding sales channels of milk proteins not only in the medical and nursing care fields, but also in the fields of sports nutrition for athletes and health foods for active seniors. In protein preparations, our focus is on expanding sales of soy proteins.

In the area of quality assurance, we are reinforcing our product risk management to satisfy consumers' increasing demands for safe and secure foods. We are strengthening our quality assurance system through means such as inspections of suppliers' factories in Japan and overseas, and are working to provide accurate and prompt information on products.

In terms of production, we maintain ongoing positive relationships with our suppliers, and are working with our subsidiary Tajima Shokuhin Kogyo Co., Ltd. to provide a stable supply of high quality products.

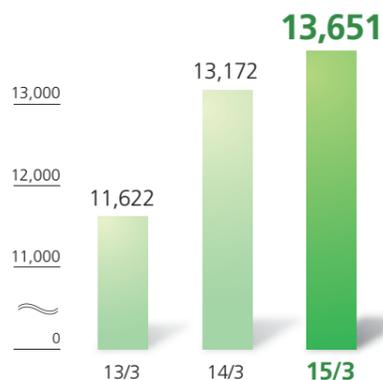
**Prospects for Fiscal 2015**

**In addition to expanding sales of core products, bringing new products to market, and addressing the food with function claims labeling system, we will also move forward with our business of exporting products to overseas markets.**

For the next fiscal year, we forecast sales of ¥13,920 million, a 2.0% increase year-on-year. Although difficult market conditions are expected to persist in the food industry, we will strive to expand sales of our flagship products and bring new products to market under a policy of providing original functional food ingredients that contribute to healthy longevity, active lifestyles, food safety, and food waste reduction. In particular, we will expand our health care business with a focus on initiatives to address the food with function claims labeling system. In addition, we will look beyond the domestic market and pursue our business of exports to markets in Asia, where economic development and population growth are rapid.

Nippon Shinyaku launched its functional food business in 1961 with the belief that "medicine and food have the same origin." As the functional food business division of a pharmaceutical company, we help people lead healthier, happier lives in terms of diet by developing and providing high quality, highly original functional food materials that put safety and security first.

Net Sales (millions of yen)



**We will forge ahead with the pursuit of high quality and high added value with the aim of new growth.**

As the functional foods business of a pharmaceutical company, we provide high-quality and high-value-added functional food materials in the fields of health care, nutrition, and processed foods.

Recent years have seen a growing emphasis on self-medication, or the management of one's own health, from the perspectives of prevention of diseases and pre-disease conditions. Amid this trend, in April 2015 Japan launched the food with function claims labeling system to aid consumers in making product choices based on correct information. This system enables products to claim functional benefits after clearing specific criteria for functionality and safety. Taking this system as more than a mere business opportunity, we are seriously studying how our products can meet consumer needs and generate satisfaction, and will take action accordingly.

In addition, we will go beyond the provision of food ingredients to expand our business into the development and marketing of final products that can directly convey our passion for foods to customers, as we aim for new growth in our functional foods business.



**Kenro Kobayashi**  
Director,  
General Manager,  
Functional Food  
Division

# Assuring Transparency in Management and Fulfilling Accountability

## Corporate Governance and Internal Control

### Our Approach to Corporate Governance

At Nippon Shinyaku, we recognize that it is a critical management priority to fulfill our accountability to all stakeholders, by securing the transparency of management in order to raise our corporate value through social contributions. This makes it essential for our corporate governance to function effectively, and we are committed to further expanding the framework for internal control, compliance, and risk management.

### Framework for Corporate Governance

Nippon Shinyaku employs a system of auditors, with the general meeting of shareholders, Board of Directors, and Board of Auditors serving as internal bodies.

Two external directors have been elected since fiscal 2013 to further strengthen the supervisory function related to the execution of duties by directors and to further boost transparency and objectivity in management. The Board of Directors is comprised of nine directors, including these two external directors, and convenes in principle once a month. The Board of Directors makes decisions and reports on important matters related to management. Each director is responsible for executing separate areas of work in order to efficiently manage the Company.

The Board of Auditors is comprised of four auditors including two outside auditors. These auditors attend meetings of the Board of Directors and other important meetings, in addition to reviewing documents and periodically meeting with the President. They also work closely with the Internal Audit Department, a dedicated auditing department directly under the President, to provide an effective framework for audits.

### Internal Control System

The internal control system is stipulated under the Companies Act and prescribes the fundamental policies of the Board of Directors, while establishing a framework to ensure the proper execution of the business. Through internal control, we strive to ensure regulatory compliance and raise the effectiveness and efficiency of our business. Moreover, we comply with the internal control reporting applied from fiscal 2008 in accordance with the Financial Instruments and Exchange Act, operate under a framework we have developed for assuring proper financial reporting, and, through the Internal Audit Department positioned directly under the President, evaluate the state of internal controls for financial reporting.

In addition, we have Compliance Operating Rules in place to secure the proper execution of business activities and employee duties, and have assigned a dedicated department to encourage compliance, while having a system in place for internal reporting. At the same time, we have assigned a dedicated department for risk management, to variously manage risks that could have a critical impact on the management of the Company.

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.

To verify that these frameworks are operating properly, the Internal Audit Department works with the Board of Auditors and accounting auditor to also audit the effectiveness of internal controls, compliance efforts, and risk management.

## Compliance

### Framework for Compliance

The Nippon Shinyaku Group implements Compliance Operating

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

### Compliance Initiatives

Group-wide compliance initiatives are planned, formulated and implemented by the dedicated department, with input from the compliance council.

In fiscal 2014, the President and compliance officer issued messages to employees in April and October 2014 to stress the need for compliance, and we implemented the training and education activities outlined below.

#### Compliance Training in Fiscal 2014

Type of Training	Description
Departmental compliance training (monthly)	Conducted 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 (April, October)	Training that focuses on teaching compliance to newly promoted managers.
Direct training (October to December)	Training conducted at Head Office, Business Offices, and all Group companies. The theme for fiscal 2014 was "Power Harassment and Reporting, Contact, and Consultation."
Training on the Charter of Business Conduct for new employees	Request to enhance understanding of and compliance with the Charter of Business Conduct.

#### Education Initiatives

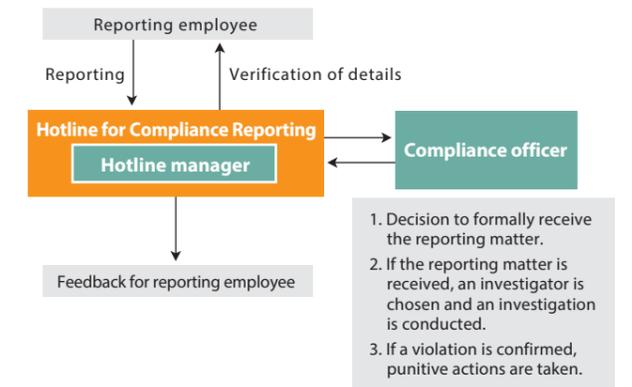
- Conducted e-learning education for compliance for employees in the 2nd year of employment.
- Prepared a compliance education poster with a slogan and design applied by employees, and put up posters in each department.
- Created compliance cards combined with safety contact cards and distributed these to all employees.

### 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. The hotline can be reached through a dedicated phone number or e-mail address, and guidelines are 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 in fact. Employees are briefed on the hotline in training, and all employees receive a card that lists the hotline contact information, so that they are familiar with the system.



## Risk Management

### Initiatives for Risk Management

The Nippon Shinyaku Group has Basic Risk Management Rules in place that direct the Company to identify underlying risks surrounding the company and specify departments that are responsible for each risk. The Group also designates measures to prevent risks and crises as well as species countermeasures for when these situations arise.

Every year, based on the results of past activities and of risk awareness surveys, we hold discussions among department heads and the Directors in charge of divisions, and work on selected risks of high importance.

In fiscal 2014, we selected "information management" and "harassment" as risks of high importance for the Group as a whole, and undertook improvement of awareness and strengthening of our management framework.

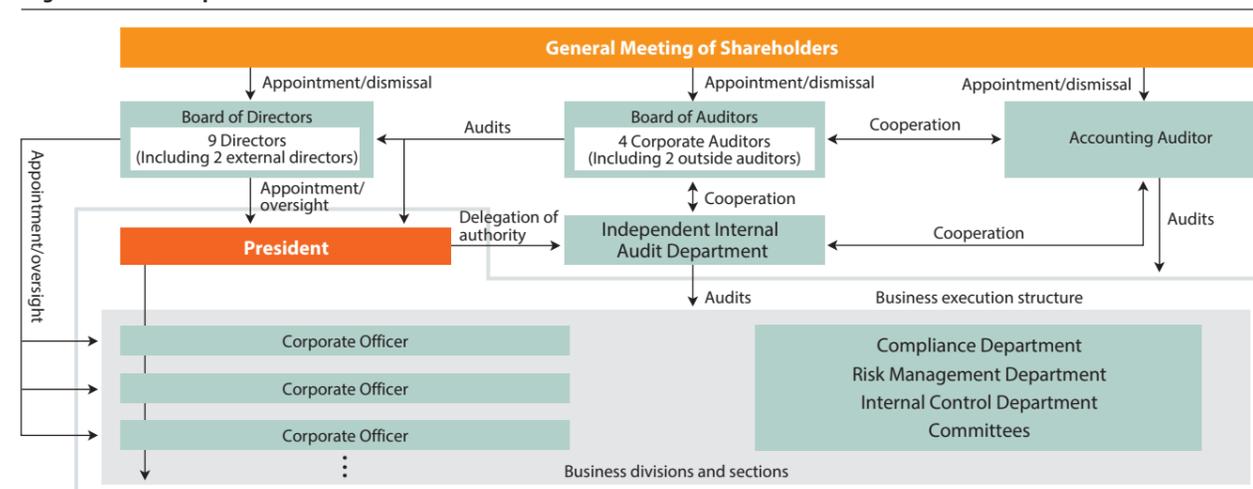
With regard to information management, we worked to strengthen the proper management of documents and electronic data by enforcing compliance with the operation manuals for confidential information and the electronic data operations and management rules created by each department. In addition, through a company-wide message board and compliance training, we raised awareness concerning computer virus and cyber terrorism countermeasures, as well as measures to prevent leaks of confidential information.

With regard to harassment, we have created a booklet on prevention of harassment that is distributed to all employees. We also worked to raise consciousness concerning harassment prevention in our compliance training and other trainings.

In fiscal 2015, we again selected "information management" and "harassment" as risks of high importance that we are working to address, and further added "disasters".

We also greatly reworked the content and targets of our risk awareness survey, expanding its scope from management positions to all employees. This has allowed us to understand how each and every employee sees risks, and to assess the state of employees' awareness.

#### Organization for Corporate Governance



## Framework for Risk Management

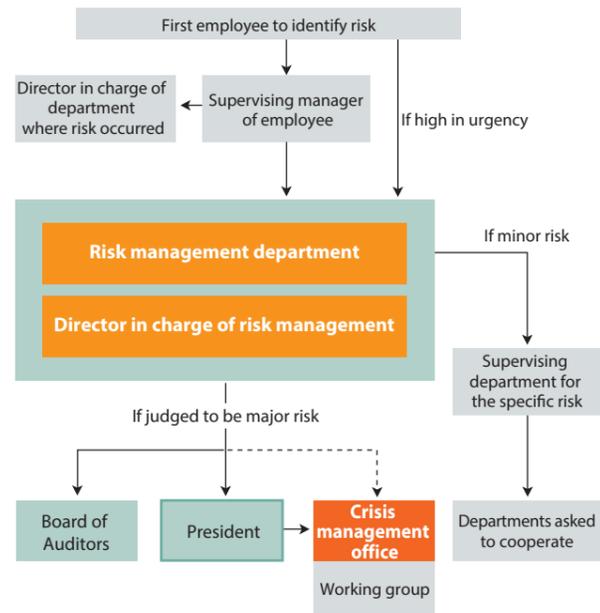
The Nippon Shinyaku Group has a contact system and response procedures in place if a risk or crisis arises, under Basic Risk Management Rules.

The initial discoverer of a risk notifies the supervising manager, who in turn notifies the risk management department and the director in charge of the department where the risk occurred. The risk management department reports to the director in charge of risk management, and the director judges the degree of impact on business activities from the risk. If the risk is determined to have a minor impact, the supervising department for the particular risk is instructed to respond and take action.

However, if the risk is determined to have a major impact signifying a crisis, the situation is immediately reported to the President and a temporary crisis management office is assembled headed by the Company's directors.

The temporary crisis management office assembles a working group that confirms the background to the risk, its current state, and the status of damage, after which it works to contain and deal with the incident or accident.

### Path of Risk Notification (as of April 1, 2015)



## Initiatives for Information Security

In today's rapidly shifting business conditions, the information risks that affect corporations are continually changing, while the spread of new and convenient information technologies is also giving rise to new risks. To secure and maintain information security, corporations are expected to continually implement measures under a security policy.

Nippon Shinyaku implements a basic policy and rules to guide our initiatives for information security. We operate an information security management system (ISMS) committee that implements specific rules for information security, guided by the basic policy and rules.

Under such a policy and framework, we disclose information to the public in a timely, appropriate and fair manner as well as responsibly protect and manage personal information and customer information obtained through our business activities. We are also advancing technological measures tailored to progress in IT and changes in society in order to protect the Nippon Shinyaku Group's information assets from physical and technological risks. At the same time, as a countermeasure against human risks, we have revised various company rules and educate our employees on the importance of information security and following the rules.

In fiscal 2014 we focused our activities on computer viruses, cyber terrorism, and the corruption, disappearance, fabrication, and leak of electronic data, and engaged in employee education, awareness-raising, and disclosure of information.

Amid frequently-occurring leaks of personal information in recent years, the government has enacted a national identification number system (Act on the Use of Numbers to Identify a Specific Individual in the Administrative Procedure) to which companies will begin conforming from January 2016. As this will involve the handling of personal information inside and outside of the company, we have launched an internal project to review information management under the system. We are also conducting education on the national identification number system and personal information management within our internal training for employees.

We are currently reassessing Nippon Shinyaku's IT environment and are undertaking ongoing review and investigation to address any vulnerable areas.

Going forward, we will continue to reinforce our information security system while placing emphasis on the prevention of leakages of confidential information.

## Respect for and Protection of Intellectual Property Rights

In recognizing the importance of intellectual properties, the Nippon Shinyaku Group's Patent Strategy Committee formulates global patent application strategies as well as examines and determines measures to address various issues associated with intellectual properties created during various stages, from early R&D to post-marketing. To ensure the freedom of our business activities, 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 risk through the examination of rights and other means.

## Board of Directors, Corporate Officers and Corporate Auditors



Front row, from left: Matsuura, Tanaka, Maekawa, Yura, Saito  
Back row, from left: Sugiura, Kobayashi, Sano, Sakata

### President

Shigenobu Maekawa

### Managing Director

Tsugio Tanaka

(General Manager, Business Management)

### Directors

Yoshiro Yura

(General Manager, Administration Div.)

Akira Matsuura

(General Manager, Research & Development Div.)

Hitoshi Saito

(General Manager, Resource Procurement, Production & Assurance Div.)

Kenro Kobayashi

(General Manager, Functional Food Div.)

Shouzou Sano

(General Manager, Sales and Marketing Div.)

Yukio Sugiura

(External Director)

Hitoshi Sakata

(External Director)

### Corporate Auditors

Kenji Kameyama

(Standing Corporate Auditor)

Tomoyuki Oota

(Standing Corporate Auditor)

Yasuo Tanabe

(Outside Auditor)

Kazuhiro Imai

(Outside Auditor)

### Corporate Officers

Taro Sakurai

(General Manager, Finance & Accounting Dept.)

Kiyotaka Konno

(General Manager, Clinical Development Div.)

Hideya Mukai

(General Manager, Discovery Research Labs.)

Seiichiro Morimura

(General Manager, Business Development Div.)



From left: Imai, Kameyama, Oota, Tanabe

Takashi Takaya

(General Manager, Sales and Marketing Planning Div.)

Takanori Edamitsu

(General Manager, Corporate Planning Dept.)

Yuji Kamiyoshi

(General Manager, Nishinohon Div.)

Masato Matsuoka

(General Manager, R&D Administration Div.)

As of June 26, 2015

## Comments from External Directors

The constant search for and development of excellent new in-house products and the fostering of a research and development pipeline that will lead to the next generation of products are crucial activities in new drug discovery. From an independent perspective, I capitalize on my expert knowledge and insight as a pharmacologist and make utmost efforts to oversee and check Nippon Shinyaku's research and development, management, and profitability. Amid my constant efforts to support innovative pharmaceutical development, in fiscal 2014 an investigator-initiated early-stage and exploratory clinical trial for a therapeutic agent for Duchenne muscular dystrophy (NS-065/NCNP-01) was completed, and preparations for a phase II trial were begun, amid expectations for the appearance of a nucleic acid drug. These achievements created a great sense of progress during the year.

Looking ahead, I aim to actively engage in interaction with young researchers and to improve our international competitiveness while considering further ways to contribute to society.



Yukio Sugiura

I have heard that the environment surrounding pharmaceutical companies is becoming increasingly severe under the expansion of generic drugs and a NHI drug price scheme that promotes new drug creation. I recognize that at such a time of change, we External Directors are being asked to make every effort to enhance corporate governance, and to engage in thinking on the same footing as corporate officers in order to contribute to the revitalization of business and the improvement of corporate value. Toward that end, I have deepened my understanding of the company's business by participating in Board of Directors' briefings, training report meetings, individual department briefings, and so on.

I feel that the Board of Directors in fiscal 2014 displayed change in a good sense, such as in more active discussions and upgraded meeting materials. From here on out, I hope to further enhance my knowledge and support the development of sound management.

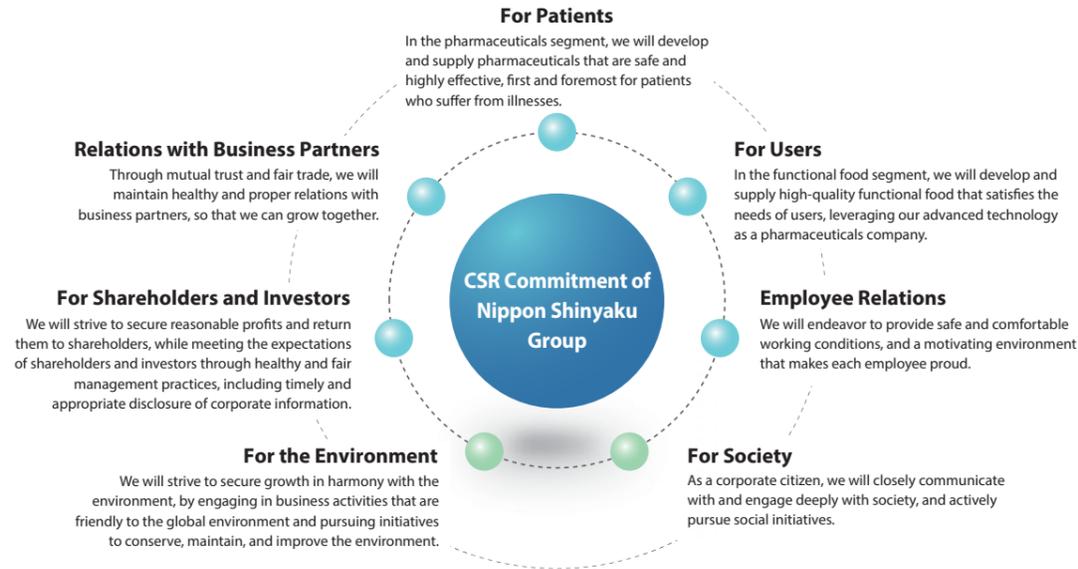


Hitoshi Sakata

# CSR Management

## Our Approach to Corporate Social Responsibility

The Nippon Shinyaku Group places great importance on meeting the expectations of diverse stakeholders who are connected with our business activities, in order to meet our corporate social responsibility (CSR). To realize this approach, we have established codes of conduct for each group of stakeholders.

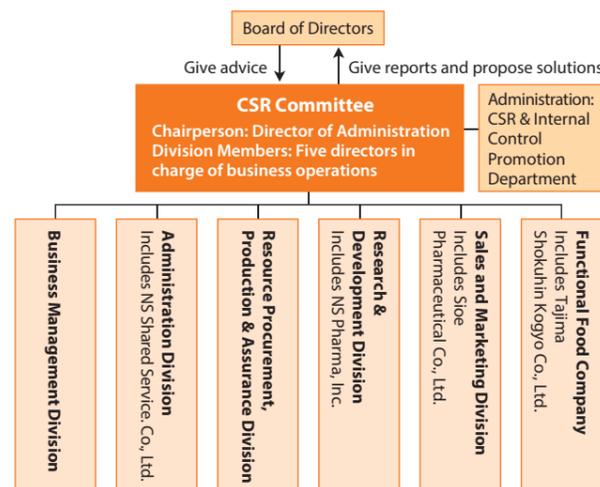


## Framework for CSR

The Nippon Shinyaku Group operates a CSR Committee that lays out the direction of CSR initiatives and works to confirm that corporate activities meet social standards and expectations, in seeking to expand the Group-wide implementation of CSR initiatives under the basic CSR policy.

The committee engages in inter-departmental discussions regarding the direction of CSR initiatives and important related matters raised by business divisions, and reports to the Board of Directors and proposes solutions as the need arises.

### Framework for Corporate Social Responsibility (as of April 1, 2015)



## Policy Regarding Dialogue with Stakeholders

Nippon Shinyaku promotes CSR and we consider it important to listen to and engage in dialogue with all stakeholders —patients, business partners, users, shareholders, investors, and employees. Requests and feedback that we receive through dialogue help to shape our corporate activities, in aiming to fulfill our responsibilities to stakeholders and earn their confidence.

We believe that meeting the expectations of all stakeholders as the Nippon Shinyaku Group overall will enable us to grow as a corporation and in turn contribute to the sustainable growth of society.

## Creation of Charter of Business Conduct

The Nippon Shinyaku Group aims to continue expanding its pharmaceutical and functional food businesses following its philosophy of "helping people lead healthier, happier lives," while striving to be a company with a meaningful existence in healthcare.

For this reason, we believe it is of the utmost importance for each and every employee to implement our management policies of supplying unique and high-quality products, earning the trust of society, and developing each employee in our business activities.

In addition, we understand that in order to earn the trust of our stakeholders, we are expected to strive to achieve regulatory compliance and adhere to internal rules, as well as conduct fair and honest business activities according to high ethical standards.

As such, the Nippon Shinyaku Group has developed the Charter

of Business Conduct to serve as basic standards to put into practice within our business activities.

### Nippon Shinyaku Group Charter of Business Conduct (revised in July 2011)

I	We will act with high ethical standards and in accordance with our business philosophy and management policy while always being conscious of our social responsibilities. We will also achieve regulatory compliance and adhere to internal rules in fostering a relationship of trust with society.
II	We, as employees of a company that deals with products that affect life, will strive to enhance our qualifications and quality of our work and act creatively.
III	We will maintain a safe and comfortable work environment by respecting each individual's rights and personality.
IV	We will promote business activities that are environmentally friendly, and will aim to maintain and improve the global environment.
V	We will build a trusting relationship with our stakeholders through timely and adequate communication of company information.
VI	We will implement unfettered competition that is fair and transparent by maintaining a healthy and adequate relationship with the politicians, governments, and business partners.
VII	We fully recognize the values of our corporate assets including information asset, and will manage these appropriately.
VIII	We will not comply with inappropriate or unlawful requests from antisocial forces or organizations who threaten the safety and order of civil society.
IX	As a member of society, we will take a proactive approach in social contribution activities.
X	We will comply with international rules and local regulations, as well as respect local culture and customs in our global business activities.

## Respect for Human Rights

The Nippon Shinyaku Group respects human rights and the personalities of individuals. We believe that a company can grow only

## Further building relationships of trust with society

In order for a company to earn the trust of society and develop sustainably, it is vital that corporate management address the three perspectives of economy, society, and the environment.

With our business philosophy of "Helping people lead healthier, happier lives" at the core of our activities, the Nippon Shinyaku Group contributes to society by providing urinary system drugs matched to the needs of an aging society, functional foods for the maintenance of health, and therapies to aid patients with intractable diseases such as hematologic malignancies and pulmonary hypertension. We also partake in social contribution activities that include the Nippon Shinyaku Children's Literary Awards, promote the "Maruenu Supplement" project that provides support to working women, and, as a part of our environmental conservation initiatives, make efforts to preserve biodiversity through actions including the protection and nurturing of endangered plant species.

From here on out, we will continue working toward our goal of a "Company with a meaningful existence in healthcare," will hold to high ethical standards, and will engage in a variety of CSR activities as we work even harder to enhance our relationships of trust with society.

after the individuals' independence and creativity are fully leveraged. We view harassment in particular as a major problem that harms respect for the individual. The Nippon Shinyaku Group has established and enforced the Harassment Prevention Rules in order to prevent harassment in any form and maintain a positive workplace environment. We are also working to prevent harassment through compliance training and other means.

## Ethical Considerations for R&D

Nippon Shinyaku has established a framework to ensure that human rights and animal welfare are rightly considered in each stage of the development of new drugs.

Basic research that predicts the safety and efficacy of medicines in humans follows internal rules established according to the ethical guidelines issued by the Japanese government (including the Ethical Guidelines for Medical and Health Research Involving Human Subjects) to give ethical consideration to the providers of human specimens, such as cells, tissue, and blood. Our research ethics committee, comprising insiders and external parties, carefully and fairly reviews the research and publicly discloses information related to these reviews.

Clinical trials to verify the efficacy and safety of medicines in humans are carried out with a strong emphasis on the human rights of patients who participate in these trials, and protecting their personal information as well as securing their safety and welfare. We adhere to legislation such as the Pharmaceutical Affairs Law and standards such as GCP<sup>\*1</sup> and strive to conduct high quality clinical trials by reviewing the ethical and scientific validity of the clinical trial through our internal review committee.

Research using animals to confirm the safety and efficacy of medicines follows internal rules that are compliant with regulations and guidelines on animal welfare. We make sure all animal testing gives proper consideration to the 3R principles<sup>\*2</sup> through the operations of a committee for animal testing.

\*1 GCP: Good Clinical Practice

\*2 The 3R principles refer to "replacement" for considering alternatives to animal testing, "reduction" to minimize the use of animals, and "refinement" to reduce the agony or discomfort animals suffer



**Yoshiro Yura**  
Director,  
General Manager,  
Administration  
Division

# CSR Activities Report

## Standing Alongside Patients and Medical Professionals



### In Pursuit of a Future Only Nippon Shinyaku Can Achieve

With a focus on patients with intractable conditions for which there is no effective treatment and on diseases where there is a strong desire to improve quality of life, Nippon Shinyaku is passionately committed to making unique medicines. Our job goes beyond supplying medicines and includes providing information on the medicines we market, educating patients, and finding ways to eradicate counterfeit drugs that cause serious health consequences. Our highest mission is to continue our many efforts to ensure the safety of our patients.

#### Providing Information

##### Educating Consumers about Ailments through Our Website

At Nippon Shinyaku, we distribute information helpful for resolving health concerns through our company website.

On our "Support Site for Alcohol Dependence" (<http://alcoholic-navi.jp/>), we provide a range of information about treatment for alcohol dependence that includes messages from medical specialists, abstinence success stories, and healthcare cost data. The site also hosts a Q&A section in response to common questions and misunderstandings.

On our "ED Care Support" website (<http://www.ed-care-support.jp/>), we introduce medical institutions where individuals can receive consultation on erectile dysfunction (ED). We also post information aimed at dispelling misunderstandings about the condition, to relieve any psychological resistance to seeking out help.

In fiscal 2015, we plan to launch "Pulmonary Arterial Hypertension Treatment Support," a new site for patients of this condition and their families. The site aims to relieve the anxiety and concerns of patients regarding treatment, daily life, and medical costs. We believe that the site will be an aid for patients and their families in constructively dealing with pulmonary arterial hypertension treatment.

##### Providing Information about Nippon Shinyaku's Medicines

As pharmaceutical products have been described as "chemicals with directions attached," they are only effective when used properly based on accurate information. Consequently, Nippon Shinyaku has Drug Consultants who receive inquiries from physicians and pharmacists, and reply with advice on the proper usage of our products. In addition, we respond to a broad range of inquiries from patients and the general public with accurate, easily understood information.

Although the quantity of inquiries has been increasing year by year, introducing a CTI system\*1 has allowed us to continue to provide prompt, accurate responses. Our system allows us to quickly convey valuable patients' and medical professionals' opinions and comments to the relevant department. It also helps us to reflect this information in our reports to Ministry of Health, Labour and Welfare authorities and in our new drug formulations.

For those seeking reference material, the Nippon Shinyaku

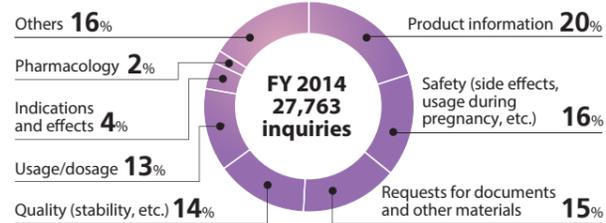
corporate website carries information for medical professionals and patients. Medical professionals can find pharmaceutical information including drug information sheets\*2, interview forms, package inserts, and updated usage warnings. Patients and general readers can find a pharmaceuticals guide and information aimed at improving wellness.

We also contributed to a variety of media, such as our educational advertisements on ED in newspapers and in the magazine *President*. These contributions inform readers of accurate information on illnesses and up to date research developments in pharmaceutical treatments.

\*1 Computer Telephony Integration system: A system linking telephones and computers that routes calls to customer service representatives and provides information management and analysis functionality

\*2 Explanation sheets (in Japanese, English, and other languages) intended for patients

#### Common Inquiries



#### Quality Assurance and Supply Stability

##### Reliability Assurance from the R&D Stage to Post-Marketing

Under the leadership of the Assurance Division, Nippon Shinyaku strives to unflinchingly 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 sales approval. Our Assurance Division audits these documents at the appropriate stage to assure the accuracy of non-clinical test data and the reliability of clinical trials.

After receiving manufacture and marketing approval, we assure the quality of the product being manufactured and sold, affirm its safety, and work to manage and maintain manufacture and marketing approval and marketing authorization.

#### Pharmaceutical Products Reliability Assurance

R&D stage		
Nonclinical tests		Clinical trials
Test data reliability assurance based on GLP*3 and reliability criteria		Clinical trial reliability assurance based on GCP
Post-manufacture and marketing		
Manufacturing	Marketing	Maintenance and management of approval and authorization
Post-manufacture and marketing quality assurance based on GMP and GQP	Post-manufacture and marketing safety management based on GVP	Maintenance and management of manufacture and marketing approval and marketing authorization

\*3 GLP: Good Laboratory Practice

#### Close Collaboration between Three Management Chiefs

To become a marketing authorization holder a company must obtain official government approval to manufacture and market new drugs. This system requires that marketing authorization holders shall appoint "three chiefs": a marketing supervisor-general, a quality assurance manager, and a post-manufacturing-and-sales safety management supervisor. The marketing supervisor-general oversees the other two chiefs and is the official ultimately responsible for products brought to market.

At Nippon Shinyaku, we follow these stipulations and appoint the three officials as a team of leaders that meets regularly to share information and ensure close, collaborative operations between all relevant departments.

Nippon Shinyaku's Quality Assurance Division works to ensure the highest quality products. In close cooperation with domestic and overseas bulk substance and product manufacturing plants, audits of manufacturing facilities are performed regularly, or more often if necessary, to check the status of compliance with GMP and other compliance targets. Our Safety Management Division collects information on product side effects, etc. from a wide variety of sources, including domestic and overseas medical institutions, medical professionals, partner companies, patients, patient families, medical journals, and reports from academic associations. We analyze and evaluate this information, determine necessary response measures, issue reports to regulatory agencies, and supply feedback to patients and medical professionals.

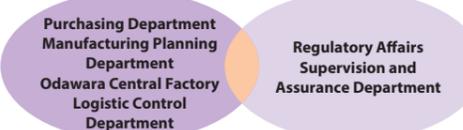
#### Framework for Supplying Products

We implement a framework to secure the rapid and stable supply of high quality pharmaceuticals through the use of sophisticated supply chain management (SCM), covering 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 sourcing ingredients from more than one supplier to ensure stable procurement.

#### Framework for Supplying Products

SCM  
Supply Chain Management



#### Stable Supply of Product

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. Under a vision to be a factory that is competitive in terms of cost and quality, we have implemented the management method BSC\*4 and are establishing strategy from a many-sided perspective that incorporates financials, customers, business processes, human resources, innovation, and more. We set KPIs\*5 to manage our progress toward achievement of this strategy and vision.

Also, we have adopted a Business Continuity Plan (BCP) in the event of any disasters, so that disruptions to the supply of products to patients may be avoided. In addition, we have diversified our storage locations for product inventory and are working with various partner companies to bolster our mutual support frameworks. In fiscal 2014, with our continued focus on avoiding shortage risk, we have increased the inventory on hand of anti-cancer drugs and other products with great importance in society.

\*4 Balanced Scorecard: A method for comprehensively measuring how a company's strategy has been executed

\*5 Key Performance Indicators: Particularly important indicators among the business process monitoring indicators set in BSC to achieve corporate goals

#### Responding to Patient Needs

Nippon Shinyaku makes product modifications and quality improvements based on feedback received from patients and medical professionals. Examples of this include the development of products that are both easy to swallow and convenient to use.

For example, we are developing and providing medicines with less bitter aftertastes for patients who experience unpleasant tastes and orally dissolving medicines without any need for water for patients who have difficulty swallowing tablets.

#### Measures Against Counterfeit Drugs

Counterfeit medicines can have serious health consequences and have grown into a major worldwide issue. Private import over the Internet especially presents an increasing threat.

Nippon Shinyaku recognizes that improved counterfeiting awareness represents a means to eliminate counterfeit drugs and an important aspect of its corporate social responsibility to ensure patient safety. To combat the counterfeiting of ED medicines, we are partnering with three companies involved in the manufacture and distribution of ED treatments to jointly hold press seminars for media-related parties, and are working to raise awareness of the issue through exhibits of counterfeit drugs at academic society meetings.

Additionally, through our Anti-Counterfeiting Committee, we verify and scrutinize information concerning counterfeits of our products to enact appropriate countermeasures, cooperate with our licensor and industry organizations, and provide information to government and other related parties.

# CSR Activities Report

## In Partnership with Employees

### Building Rewarding, Comfortable Workplaces

Individual growth is the soil of corporate growth. Based on this belief, we have created an array of education and training programs aimed at providing each of our employees with opportunities for growth. Another focus of ours is on fostering a corporate culture where individual human rights are respected, developing systems to ensure the health and safety of employees, promoting a work-life balance, encouraging active participation by women in the workplace, and creating environments where people can work without worry.

#### Creating Productive, Employee-Friendly Workplaces

As part of work-life balance promotion efforts that we describe as "Achieving a virtuous cycle that harmonizes fulfilling work (Motivation) with a rewarding lifestyle (Daily sense of fulfillment)," Nippon Shinyaku conducts the "Good Job Initiative."

We envision the goal of the Good Job Initiative as: working productively, resting regularly, and leading a fruitful lifestyle that increases one's satisfaction and zest for life.

Our policies for effecting this include identifying overloads, wastefulness, and inconsistencies, while advancing productivity and equality through incorporating appropriate rotation of duties. This prevents work from being disproportionately assigned only to certain individuals.

In fiscal 2012, we introduced a staggered working hours system that lets employees change starting and ending hours of work according to individuals' childcare, nursing care, and work circumstances.

In fiscal 2013 we further enhanced the leave acquisition system, and established measures including company-wide clock-out days, President's Message communications, and biweekly communication of information on our initiatives for Good Job.

In fiscal 2014, we implemented the Work Style Review Initiative,

which aims to further improve work styles by examining the current work styles of every employee through the setting of focused working hours and the use of self-inspection tools.

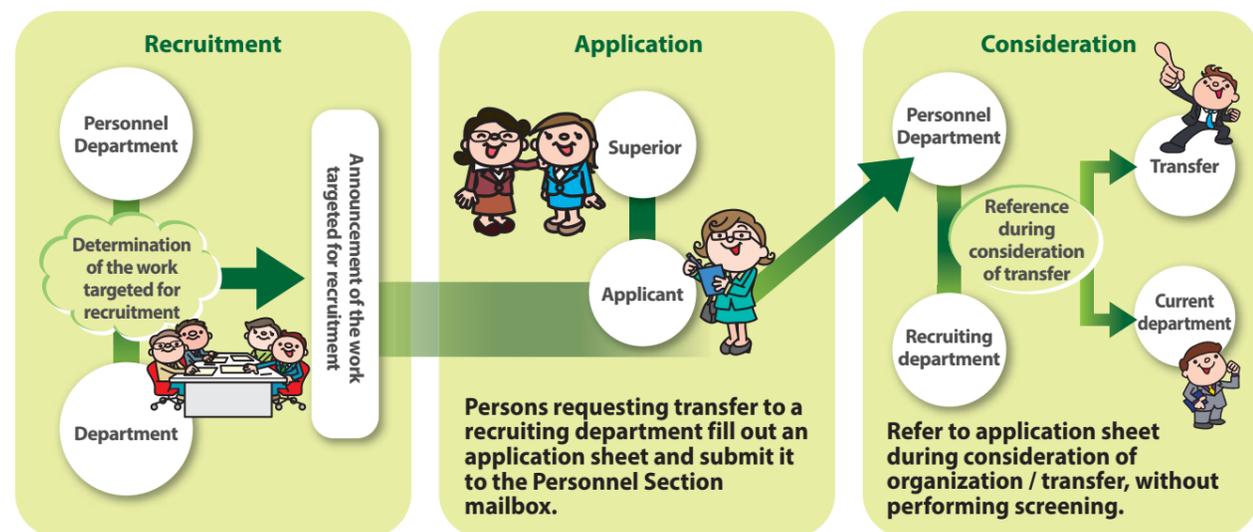
In fiscal 2015, we will continue to enhance our initiatives in this area.

#### Career Support System: "Growth for Each and Every Employee"

In fiscal 2014, we reformed our CAST (Career Approach SysTem) in-house employee recruitment system. We eliminated recruitment guidelines and application requirements in principle, creating a system that matches motivated applicants with departments that are recruiting.

In addition to this, Nippon Shinyaku has established a Career Support Academy called CASA. This system is structured on the twin aspects of education and training for each level of employees, and elite education and training for core personnel. Support is also available for employees seeking to attain higher level degrees such as a doctorate or MBA. Our intention is to recognize the increased corporate value that comes from enhancements in the abilities of our employees, as well as to create a challenging and active organizational environment.

### Procedures from recruitment to personnel transfers under CAST



### 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 focused on expanding employment and creating new job opportunities based on the principle of inclusion. Consequently, in collaboration with a special-needs support school since fiscal 2007, we have carried out a dual system of study while working\*. This system includes features such as involving a number of consultants for disabled workers. The consultants are stationed in the workplace to help promote an environment where disabled workers will be able to productively work side by side with non-disabled workers. This is one example of how we are working to create comfortable work environments.



Envelope stuffing and mailing work for annual report      Linen work (laundrying)

\* 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 (i.e., reemployment system) allowing continued work until age 65. This system takes in workers again even 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. At present, about 30 persons are active under the system in a variety of departments.

### Occupational Health and Safety

Nippon Shinyaku is committed to securing employee health and safety, and complying with Industrial Safety and Health Law in order to create comfortable working conditions. We are committed to pursuing unified initiatives for health and safety.

We conduct risk assessment and risk prediction activities to identify potential risks and hazards in our workplaces and establish measures to prevent them. The research laboratories also put an emphasis on conducting risk assessments for chemical substances, which is another effort towards preventing occupational accidents.



Occupational safety poster

### Mental Health Care

Nippon Shinyaku effectively promotes the four types of care noted in the guidelines for mental health care released by the Ministry of Health, Labour and Welfare in 2000. With the goal of undertaking prevention, early detection, early response, treatment, and prevention of recurrence with regard to mental disorders, in fiscal 2003 we implemented the EAP (Employee Assistance Program) of an external organization and are engaged in ongoing and planned mental health care.

## TOPICS

### Promoting Women in the Workplace

Nippon Shinyaku launched the "Maruenu Supplement" project in June 2011 to support women wanting to take a step up in their careers.

While efforts to promote increased activity by women have ramped up in recent years, Nippon Shinyaku has acted early to position such efforts as 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 2014, Nippon Shinyaku endorsed the promotion of "Positive Action" that is the gist of the "Actively promote diversity and support further activity by women" goal implemented by the Ministry of Health, Labour and Welfare, and issued our own Positive Action Declaration. In addition, we communicated messages from Directors regarding the promotion of activity by women, made clear to employees that the action is a company-wide initiative, and conducted networking events for all female managers to foster more career advancement consciousness and self-awareness as role models.

In fiscal 2015, too, we will actively engage in the promotion of further activity by women.



Scene at a networking event for female managers

# CSR Activities Report

## Joining with Society and Local Communities



### Acting as a Member of Society to Bring About a Better World

In addition to supplying high-quality drugs as a pharmaceuticals manufacturer, our other role is contributing to the development of communities as a member of society. We are working hard to educate patients, support organizations carrying out activities that benefit the public, sponsor and host sporting and cultural events, and carry out cultural preservation activities in our hometown of Kyoto.

We have also instituted the Nippon Shinyaku Children's Literary Awards with the hope that we can nurture the spirited growth and future dreams of the children who will inherit our world.

#### Disease Education Activities

A significant number of women endure menstrual cramps, with relatively few of them aware that endometriosis or other disorders are possible causes. Nippon Shinyaku promotes a public education campaign symbolized by yellow ribbons in order to disseminate accurate information on menstrual cramps and endometriosis. We also host seminars on menstrual pains primarily during Women's Health Week between March 1 and 8, and provide educational materials and other information to women troubled by this medical condition on our website called Talking About Menstrual Cramps (<http://seiritsu.jp/>).

As another example of activities involving education about diseases, we held a seminar on the topic of menstrual cramps, with participation by citizens, at The 29th General Assembly of the Japan Medical Congress in April 2015.



Our "Talking About Menstrual Cramps" website

#### The Nippon Shinyaku Children's Literary Awards

Nippon Shinyaku wants to nurture the spirited growth and future dreams of the children who will inherit our world. With this hope in mind, we created the Nippon Shinyaku Children's Literary Awards to commemorate our 90th anniversary in 2009. The Nippon Shinyaku Children's Literary Awards work with the support of the Japan Juvenile Writers Association to call for works of art as either stories or illustrations. A winning submission is selected in each category and both works of art are made into picture books. Approximately 30,000 of these books are then distributed nation-wide to places like medical institutions and public libraries, as well as education boards in Kyoto (the site of our head offices) and Odawara (the site of our Central Factory). Also, visitors to our website (<http://kodomo-bungaku.jp/>) are

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

At the Nippon Shinyaku Children's Literary Awards ceremony for the winners held in October 2014, we held a workshop at which we invited local children to decorate white stones with drawings of the heroine of *Pikkapika no Iwako-chan*, a picture book created in the sixth Awards.

Furthermore, through our Shining Future for Children Fund, we collect donations from employees to support the Japan Committee – Vaccines for the World's Children, which strives to protect children in developing countries from infectious disease.



Picture book *Pikkapika no Iwako-chan*



Group photograph from the Awards Ceremony

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

Since 2013, we have visited a number of locations throughout Japan for the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project. Led by

illustrator Seitaro Kuroda, this project centered on locals banding together to create wall art.

We launched the initiative at the Onotown Public General Hospital in Fukushima Prefecture in March 2013. We have subsequently carried it out in regions around the country, including at The Second Emergency Medical Clinic in Kitakyushu City in April 2014 and at Hiroshima University Hospital in August 2014. At Hiroshima University Hospital, children from the pediatric ward and children from the Tanpopo Nursery inside the hospital made crayon drawings of fish, seals, and other creatures, with encouragement from Mr. Kuroda.

We will continue to implement Nippon Shinyaku & Seitaro Kuroda Smiles Art Project and visit local hospitals and other facilities to strengthen the bond among doctors, patients, the elderly, children, students, and all people in society, and put a smile on their faces by making art together.



Group photo with participants at Hiroshima University Hospital

#### Initiatives to Preserve Biodiversity

Nippon Shinyaku's Yamashina Botanical Research Institute was founded in 1934 as the Yamashina Pilot Farm and is an important part of our R&D efforts. The facility stores and cultivates nearly 3,000 varieties of medicinal and therapeutic plants gathered from across the globe. One of the products from the Institute, mibuyomogi, was used as an ingredient in our Santonin vermicide and greatly contributed to the growth of Nippon Shinyaku. Also among the plants preserved and cultivated at the Institute are tree tumbo (*Welwitschia mirabilis*) and many other species that are facing global extinction, including 140 original species appearing in the Japanese Pharmacopoeia as natural remedies. The Institute values horticultural research from the standpoint of preserving our natural biodiversity. It takes part in initiatives to protect rare plants in its home area of Kyoto, and is actively involved in activities to protect and cultivate the hollyhock that decorates the famed Aoi Matsuri ("Hollyhock Festival").

Additionally, the Institute maintains close contact with experts from universities and botanical gardens across Japan and also holds discussions on environmental issues as well as the protection and cultivation of species facing extinction through seminars and other means.

The Institute hosts tours by appointment, with about 1,400 persons visiting the facilities in fiscal 2014. The Institute also organized a tour of its facilities and held an indigo dyeing event during summer break for local elementary students.



Yamashina Botanical Research Institute

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

For more than half a century Nippon Shinyaku has annually produced washcloths and calendars with pictures made using Katazome, a traditional stencil dyeing technique unique to Kyoto. These works feature Kyoto's seasonal scenery, customs and historical events. Also, four times a year, we publish an independent quarterly magazine called *Kyo*. This publication showcases the profound appeal of Kyoto from a number of perspectives — it carries in-depth articles introducing the wonders of Kyoto, from proud cultural assets like its shrines and temples, to its cuisine and famous local products.



Calendar and the quarterly magazine *Kyo*

A washcloth featuring a "Kyoto pine" motif

#### Supporting Education through Sports

The Nippon Shinyaku amateur baseball team provides practical coaching guidance to elementary and senior high school students to promote sports in the local community. In November 2014, the Kyoto High School Baseball Federation winter training was held at Wakasa Stadium Kyoto. There we provided coaching for about 350 team members and managers from 75 high school teams in Kyoto Prefecture. In January 2015, we held our 5th Youth Baseball Workshop for 21 teams and about 250 youngsters from Kyoto Prefecture. Organized by the Kyoto Baseball Association and co-sponsored by the Kyoto City Amateur Sports Association, the workshop contributed to enhancing the skill levels of elementary school and high school players.

In the same month, we collaborated with the Odawara Sports Association to hold the 7th Odawara Youth Baseball Clinic for 6 teams and about 90 players from youth baseball clubs in the city of Odawara, Kanagawa Prefecture, where our Odawara Central Factory is located.

We also provided baseball coaching for university students and other activities. Through these we are working to improve youths' baseball skills and physical strength, while increasing our interaction with local communities.



The 5th Kyoto Youth Baseball Workshop



# CSR Activities Report

## Environmental Conservation Activities

### To Be a Company That Is Kind to the Environment

In order to pass on nature's bounty to future generations, Nippon Shinyaku is fully aware that its pursuits are closely tied with nature and recognizes the importance of practicing business activities that are in harmony with the environment. Drawing upon this concept, in 1998 we established the Nippon Shinyaku Basic Environmental Policy, our guidelines for environmental preservation activities. We set voluntary targets in accordance with these guidelines and work to reduce our impact on the environment.

#### Nippon Shinyaku Basic Environmental Policy

**As a corporate citizen and to help people lead healthier and happier lives, Nippon Shinyaku will work to enrich society by establishing a policy for sustainable conservation of the environment, and settings goals for the entire company to pursue.**

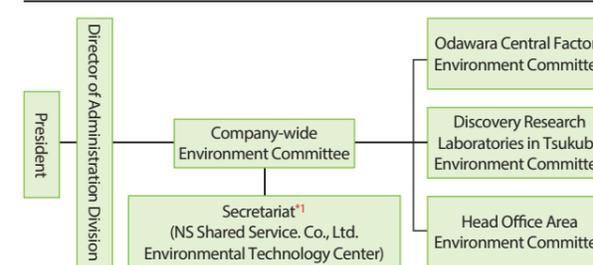
1. We will establish and operate an internal organization responsible for environmental issues, for the collective pursuit of environmental conservation initiatives. We will also expand our self-management for the sustainable pursuit of environmental conservation initiatives.
2. We will comply with environmental regulations and prepare internal rules and manuals to enhance our environmental conservation initiatives.
3. We will predict and assess environmental impacts starting from the planning and development phases, to reduce environmental impacts at all phases in the product life cycle.
4. We will enhance our efforts in the areas of resource and energy conservation, waste reduction, recycling, chemical substances management, and green procurement.
5. We will train and educate all employees to recognize the importance of environmental conservation and act in a responsible manner.
6. We will actively communicate with local communities and share information, in an effort to enhance the quality of our environmental conservation initiatives.

#### Environmental Management System

Nippon Shinyaku formulated the Nippon Shinyaku Basic Environmental Policy as the guideline for our environmental conservation activities. The Company-wide Environment Committee, chaired by the director of Administration Division, was established to

put this policy into practice and deliberates on the direction of environmental preservation activities and targets. In fiscal 2014, we launched the 4th Nippon Shinyaku Environmental Targets Plan (from fiscal 2014 to fiscal 2016), under which we engage in activities while checking our progress in achieving its targets.

#### Environmental Management Structure



<sup>1</sup>The Secretariat (Royal Co., Ltd. Environmental Technology Center) changed its name to NS Shared Service Co., Ltd. Environmental Technology Center in April 2015

#### Putting Environmental Management System Certification into Action

At our Odawara Central Factory production site, Nippon Shinyaku acquired ISO14001 international environmental management certification in August 2004 as a mechanism for promoting continuous environmental improvements, and is engaged in ongoing environmental management activities. At the head office area, our site for research and development, we acquired KES Environmental Management System Standard Step 2 (hereinafter KES Step 2) certification in June 2012 and are engaged in environmental management activities.

#### Results in Year 1 of the 4th Nippon Shinyaku Environmental Targets Plan (FY2014-2016)

Nippon Shinyaku has drawn up a Basic Environmental Policy to serve as a set of guidelines for its environmental conservation activities. Voluntary environmental targets have been established to help guide the entire company toward reducing environmental impacts and making contributions to society. In fiscal 2014, we began initiatives under the 4th Nippon Shinyaku Environmental Targets Plan (from

fiscal 2014 to fiscal 2016). We have made overall steady progress in the first fiscal year of the plan, including the achievement of reductions of 15.7% in total energy consumption and 3.7% in CO<sub>2</sub> emissions compared with fiscal 1990. We will continue engaging in environmental preservation activities to achieve our voluntary environmental targets.

Objective	Targets	Results in FY 2014
Promotion of energy conservation and global warming countermeasures	<ul style="list-style-type: none"> <li>Reduce total energy consumption (GJ) in FY 2016 to below 1990 levels<sup>*2</sup></li> <li>Medium- to long-term target: The target for reducing CO<sub>2</sub> emissions shall be the same as that of the Japan Pharmaceutical Manufacturers Association.</li> </ul>	<ul style="list-style-type: none"> <li>Total energy consumption<sup>*3</sup> in FY 2014 was 15.7% lower than in FY 1990.</li> <li>CO<sub>2</sub> emissions<sup>*4</sup> were 3.7% lower than in FY 1990.</li> </ul>
Reduction of Waste	<ul style="list-style-type: none"> <li>Actively pursue the 3Rs (Reduce, Reuse, Recycle) and work to increase our usage ratio of recycled materials.</li> <li>Reduce the final amount of landfilled waste in FY 2016 by more than 65% of FY 2005 levels.</li> <li>Keep the final landfill waste ratio below 1% in FY 2016.</li> </ul>	<ul style="list-style-type: none"> <li>In FY 2014, we promoted the 3Rs. Final amount of landfilled waste was reduced to 2 tons, 86% lower than in FY 2005, achieving a final landfill waste ratio of 0.4%.</li> </ul>
Promote Proper Management of Chemical Substances	<ul style="list-style-type: none"> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>Dichloromethane handled in FY 2014 increased 84% (185%) over FY 2013 (FY 2012); acetonitrile increased 15% (29%).</li> </ul>
Promote an Environmental Management System (EMS)	<ul style="list-style-type: none"> <li>Effectively improve the results of our environmental performance by maintaining certifications for environmental management systems (ISO14001 and KES Step 2).</li> </ul>	<ul style="list-style-type: none"> <li>We maintained certification and registration processes for ISO14001 and KES Step 2.</li> </ul>
Environmentally Conscious Product Upgrades and Materials Procurement	<ul style="list-style-type: none"> <li>Reduce product packaging materials as part of pharmaceutical and food product package simplification efforts.</li> <li>Promote green purchasing and procurement practices.</li> </ul>	<ul style="list-style-type: none"> <li>We reviewed standards for pharmaceutical packaging materials (aluminum, paper, etc.) and reduced our usage.</li> <li>Green purchasing ratio: 90%</li> </ul>
Communication with Society and Local Neighbors	<ul style="list-style-type: none"> <li>Actively participate in activities to give back to the areas where we do business.</li> <li>Appropriately disclose information (through our corporate website and Annual Report) to society and to the local areas of our business offices.</li> </ul>	<ul style="list-style-type: none"> <li>We participated in regional volunteer cleanup activities.</li> <li>We issued the Nippon Shinyaku Report 2014 and updated our website.</li> </ul>

<sup>\*2</sup>Total energy consumption, which is not dependent on CO<sub>2</sub> emission coefficient and directly reflects energy-saving efforts, was chosen as the indicator for the three-year period

<sup>\*3</sup>Among total energy consumption of 235,594 GJ, the total energy consumption that targets the business locations to which fiscal 1990 emissions are applicable (i.e., our main business locations apart from our sales offices, etc.)

<sup>\*4</sup>This figure is for the business locations to which the fiscal 1990 emission amounts are applicable (i.e., our main business locations apart from our sales offices, etc.); total emissions were 12,839 tons. Calculations are made using the CO<sub>2</sub> real emission coefficients from the Ministry of Economy, Trade and Industry.

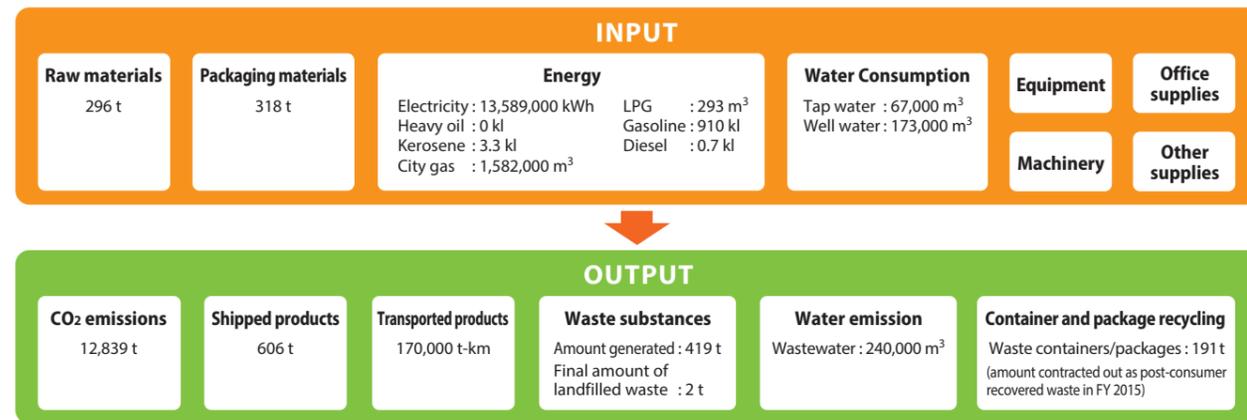
# CSR Activities Report

## Material Balance in Our Business Activities

Material balance refers to the amounts of input, in terms of resources and energy used in our business activities, and output, in terms of the environmental impact of manufactured and marketed products, waste substances, greenhouse gas emissions, wastewater, etc. Understanding the material balance offers a way to gain an

overall picture of Nippon Shinyaku's effect on the environment.

Nippon Shinyaku uses the material balance information in its efforts to decrease the amounts of resource and energy inputs as well as environmentally detrimental outputs from its business activities.



## Environmental Accounting

Nippon Shinyaku carries out environmental accounting, based on Company criteria, aimed at efficiently and effectively promoting our environmental preservation efforts. As part of this environmental accounting, we quantitatively assess environmental conservation costs and environmental conservation benefits. The costs are categorized according to the connections between

business activities and environmental impacts, and the benefits are the result of efforts to lessen our burden on the environment. The environmental conservation benefits are stated as year-on-year increases or decreases in environmental impact items in the material balance calculations.

\* Statistical methodology: refer to the Ministry of the Environment's Environmental Accounting Guidelines, 2005 ver.

### Environmental Conservation Costs

(thousands of yen)

Costs	Investments	Expenses	Primary Initiatives
Costs within our business areas	12,459	180,515	
Pollution prevention costs	11,319	45,703	Maintenance management of wastewater processing facilities
Global environmental conservation costs	1,140	71,034	Energy conservation activities
Resource recycling costs	0	63,778	Proper waste disposal efforts
Upstream and downstream costs	0	9,811	Contract costs for post-consumer container/packaging recovery efforts <sup>*5</sup>
Management activity costs	0	86,577	EMS maintenance and operation, green space conservation, environment-related personnel expenses
R&D costs	0	0	-
Social activity costs	0	2,623	Donations and funding for groups involved with our Elementary School lectures and environmental preservation initiatives
Environmental remediation costs	0	0	-
<b>Total</b>	<b>12,459</b>	<b>279,526</b>	

(excluding our sales offices)

### Environmental Conservation Benefits

Benefit verification	Units	FY 2013 Results	FY 2014 Results	Amount of Increase/Reduction	Rate of Increase/Reduction
CO <sub>2</sub> emissions	Tons	13,136	12,839	(297)	(2.3%)
Electricity usage	Thousand kWh	13,589	13,589	0	0.0%
Oil, kerosene usage	kl	4	3	(1)	(25.0%)
City gas, LPG usage	Thousand m <sup>3</sup>	1,726	1,582	(151)	(7.4%)
Gasoline, diesel usage	kl	928	910	(18)	(1.9%)
Water consumption (main business locations)	Thousand m <sup>3</sup>	245	240	(5)	(2.0%)
Waste substances generated (main business locations)	Tons	367	419	52	14.0%
Final amount of landfilled waste (main business locations)	Tons	1	2	1	100.0%

<sup>\*5</sup> Nippon Shinyaku pays commission fees based on the amount of product containers and packaging generated in accordance with the Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging. The amount of payments in fiscal 2014 amounted to 6,379,000 yen.

## Promotion of energy conservation and global warming countermeasures

<b>Targets</b>	Constrain total energy consumption in fiscal 2016 to the level of fiscal 1990 or lower.
<b>Results</b>	Total energy consumption <sup>*6</sup> in fiscal 2014 was 194,229 GJ, a 15.7% reduction from fiscal 1990 (230,432 GJ).

### Energy Conservation Efforts

Nippon Shinyaku is continuously endeavoring to conserve energy and reduce emissions of CO<sub>2</sub>. These efforts include switching boilers and air conditioning equipment to energy efficient models when they reach the end of their life span, and reassessing how and when the equipment is operated.

In fiscal 2014, in addition to company-wide efforts to conserve electricity and energy, we replaced a portion of lighting fixtures in the head office area with high-efficiency types, and began full-scale operation of the high-efficiency electric refrigerator installed in the Research Laboratories in fiscal 2013.

As a result, total energy consumption<sup>\*6</sup> in fiscal 2014 was 194,229 GJ, which was 6,316 GJ (3.1%) lower than in fiscal 2013 (200,545 GJ), or 36,203 GJ (15.7%) lower than in the base fiscal year of 1990 (230,432 GJ).

In addition, CO<sub>2</sub> emissions<sup>\*7</sup> were 10,183 tons, or 229 tons (2.2%) less than in fiscal 2013 (10,412 tons) and 386 tons (3.7%) lower than in the base fiscal year of 1990 (10,569 tons).

<sup>\*6</sup> Among total energy consumption of 235,594GJ, the total energy consumption that covers the business locations to which fiscal 1990 emissions are applicable (i.e., our main business locations apart from our sales offices, etc.)

<sup>\*7</sup> This figure is for the business locations to which the fiscal 1990 emission amounts are applicable (i.e., our main business locations apart from our sales offices, etc.); total emissions were 12,839 tons. Calculations are made using the CO<sub>2</sub> real emissions coefficients from the Ministry of Economy, Trade and Industry

### Introducing Environmental Friendly Vehicles in Our Sales Fleet

Our policy is to use low emissions models (with 4 star ratings for 75% emissions reduction based on 2005 criteria) for our fleet of sales force vehicles, and since fiscal 2008 we have been gradually phasing in high gas mileage, low CO<sub>2</sub> hybrid models. As of the end of fiscal 2014, 97.8% of the 714 vehicles used by our sales force were low emissions vehicles.

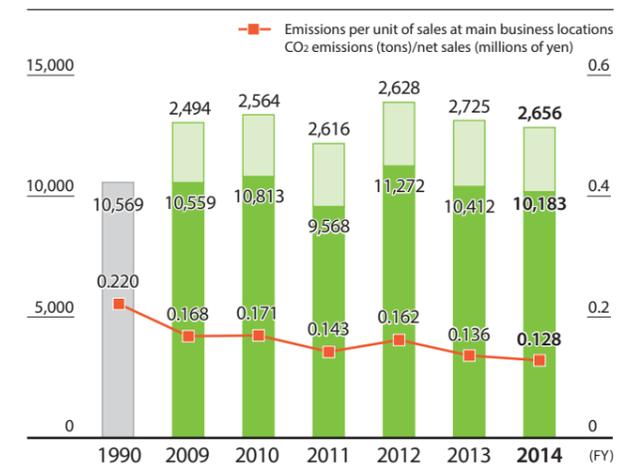
In addition, we stepped up our environmental preservation activities by promoting use of public transport in Tokyo. At the same time, we are promoting awareness of eco-driving throughout the Company.



Sales force hybrid vehicle

### CO<sub>2</sub> Emissions

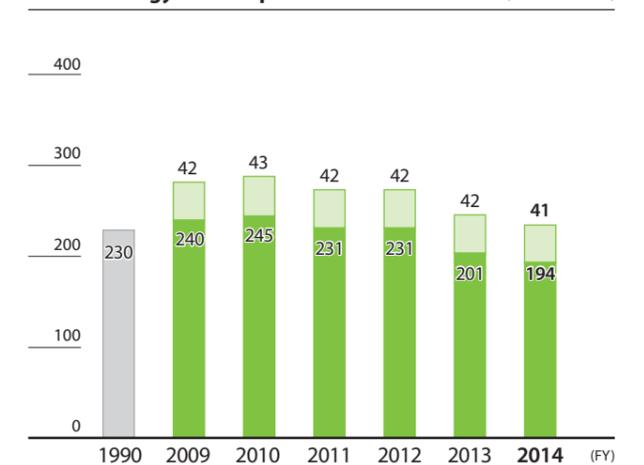
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Legend: Sales offices, etc. (light green); Main business locations: Head Offices, Odawara Central Factory, Chitose Synthesis Plant & Functional Food Plant (until FY2012), Discovery Research Laboratories in Tsukuba (dark green).

### Overall Energy Consumption

(thousands of GJ)



Legend: Sales offices, etc. (light green); Main business locations: Head Offices, Odawara Central Factory, Chitose Synthesis Plant & Functional Food Plant (until FY2012), Discovery Research Laboratories in Tsukuba (dark green).

# CSR Activities Report

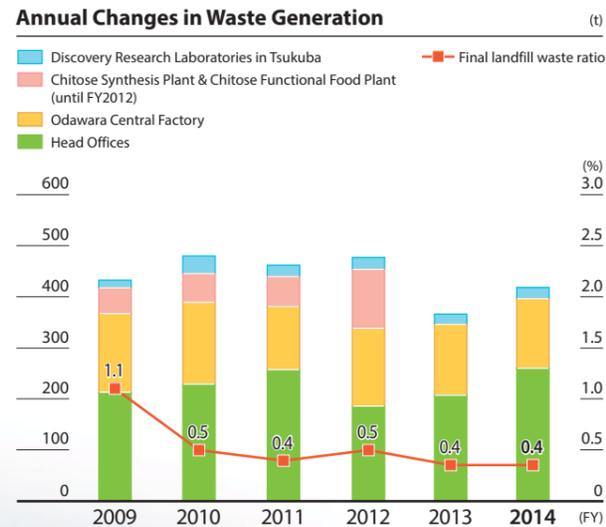
## Reducing Volume of Waste

<b>Targets</b>	Work to raise the resource recycling rate through active promotion of the 3Rs (Reduce, Reuse, Recycle). <ul style="list-style-type: none"> <li>• Reduce the final amount of landfill waste in fiscal 2016 by 65% or more compared with fiscal 2005.</li> <li>• Reduce the final landfill waste ratio in fiscal 2016 to 1.0% or lower.</li> </ul>
<b>Results</b>	<ul style="list-style-type: none"> <li>• We reduced our final amount of landfill waste in fiscal 2014 by 86% compared with fiscal 2005, achieving the target.</li> <li>• Our final landfill waste ratio in fiscal 2014 was 0.4%, achieving a ratio of 1.0% or lower for five years straight.</li> </ul>

### Results of Initiatives

There was no major change in fiscal 2014 in the amounts of waste generated at our Odawara Central Factory and Discovery Research Laboratories in Tsukuba. However, at the Head Offices, a large volume of confidential documents and metals from fixed assets was generated from disassembly of the production building and the accompanying sorting of unneeded items. Accordingly, the amount of waste generated in fiscal 2014 was 419 tons, an increase of 52 tons from fiscal 2013. Our final amount of landfill waste increased by 1 ton to 2 tons, meeting our target for waste with an 86% reduction from the 14.6 tons output in fiscal 2005. Our final landfill waste ratio of 0.4% met our target of a 1.0% or lower for the fifth year straight.

Also, in accord with the PCB Special Measures Act, we are stringently following storage protocol for PCB waste in the head office area and the Odawara Central Factory.



## Proper Management of Chemical Substances

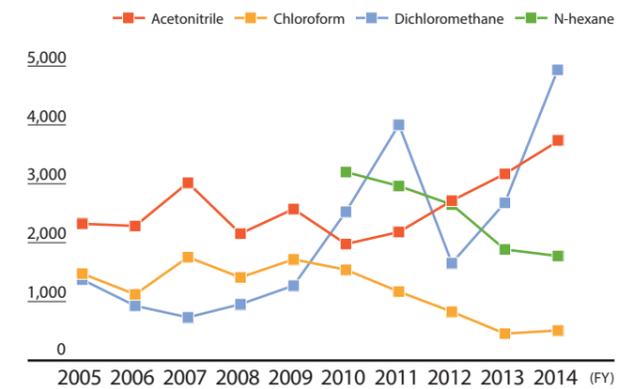
<b>Targets</b>	Continually reduce emissions into the natural environment by promoting appropriate management of chemical substances, including chemical substances designated under the PRTR System.
<b>Results</b>	The amounts of dichloromethane and acetonitrile we handled in fiscal 2014 increased by 84% and 15% compared with fiscal 2013 (185% and 29% compared with fiscal 2012), respectively.

### Results of Initiatives

We submit reports to the legal authorities on business sites that handle more than 1 ton of Class 1 designated chemical substances per year based on the PRTR system under the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof.

In recent years, the amounts of dichloromethane and acetonitrile that we handle are on an upward trend. The amount of dichloromethane handled in fiscal 2014 increased by 84% from fiscal 2013 (185% from fiscal 2012) due to increased frequency of manufacturing compounds that require dichloromethane, while the amount of acetonitrile handled increased 15% over the same period (29% from fiscal 2012) due to an increase in quality assessment items for HPLC analyses accompanying progress in research and development.

### Usage Amounts of Class 1 Designated Chemical Substances under the PRTR System (kg)



### Measures for Chemical Hazards and Biohazards

Nippon Shinyaku endeavors to properly handle new chemical substances, genetically modified organisms, and pathogens used in the research and development of pharmaceuticals, in order to prevent environmental pollution, occupational accidents, and harmful health effects.

Chemical experiments that present environmental or safety concerns are conducted in chemical hazard compliant facilities, following risk assessments based on the activities of the Nippon Shinyaku Environment Committee, Chemical Substance Management Committee, and Occupational Health and Safety Committee. In fiscal 2014 we upgraded our IT systems for chemical substances management and worked to enhance related internal education.

Research materials that are genetically modified or are considered pathogenic are handled carefully by biohazard compliant facilities after a pre-screening carried out by our Biosafety Committee and other organs.

In the event an accident occurs during these experiments or research, we have also put a system in place to quickly notify the regulatory authorities and relevant persons in-house.



Odawara Central Factory

# Financial Section

Operating Results P37

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Consolidated Financial Statements P39

Consolidated Balance Sheet

Consolidated Statement of Income

Consolidated Statement of Comprehensive Income

Consolidated Statement of Changes in Equity

Consolidated Statement of Cash Flows

## Operating Results

### 1. Fundamental Policy Regarding Profit Sharing

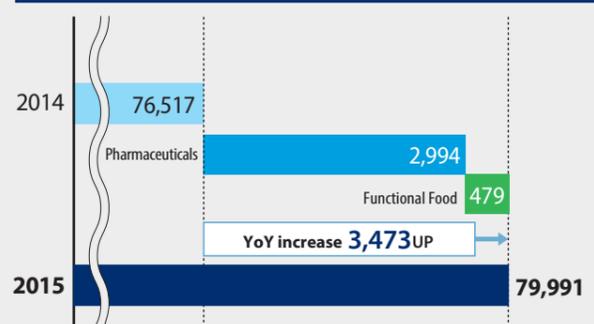
Under our strategy to maximize corporate value, we strive to strengthen our business foundations by bolstering R&D to expand the pipeline for product development, and retaining sufficient earnings to enable us to maintain a corporate position to withstand increasingly competitive conditions.

Our policy on returning profits to shareholders is to issue dividends linked to earnings and maintain a consolidated payout ratio of around 30%. In some cases, we may exclude extraordinary gains and/or losses when calculating the payout ratio.

For the year ended March 31, 2015, we issued an annual cash dividend of ¥25 per share, comprising an interim dividend of ¥12 per share and year-end dividend of ¥13 per share.

For the year ending March 31, 2016, we are projecting an annual dividend of ¥28 per share, comprising an interim dividend of ¥14 per share and year-end dividend of ¥14 per share.

Sales Breakdown (millions of yen)



## 2. Financial Condition

Increases in inventory assets, notes and accounts receivables, and cash and deposits compared to the previous fiscal year end caused current assets to rise by ¥5,738 million. Fixed assets increased by ¥5,829 million due to an increase in investment securities, despite a decrease in tangible and intangible fixed assets compared to the previous fiscal year end. As a result, total assets increased by ¥11,568 million compared to the previous fiscal year end to ¥129,757 million.

Current liabilities increased by ¥2,513 million compared to the previous fiscal year end, due in part to increases in notes and accounts payables-trade and income taxes payable. Liabilities for retirement benefits decreased while deferred tax liabilities increased, resulting in a net ¥1,034 million increase in long-term liabilities. As a result, total liabilities increased by ¥3,548 million compared to the previous fiscal year end to ¥28,550 million.

Equity increased by ¥3,879 million compared to the previous fiscal year end to ¥92,429 million. Accumulated other comprehensive income increased by ¥4,136 million to ¥8,569 million. As a result, net assets increased by ¥8,020 million to ¥101,207 million.

The equity ratio was 77.8%.

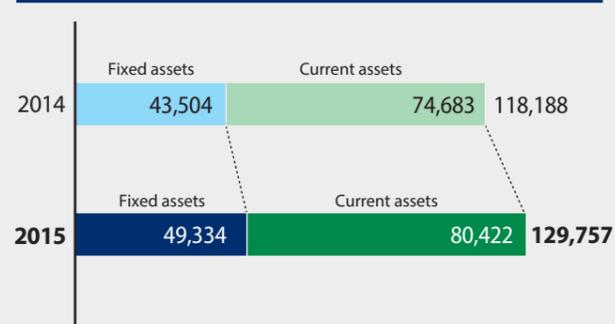
Net cash provided by operating activities amounted to ¥6,113 million. The main cash inflows were income before income taxes of ¥8,928 million, depreciation costs of ¥2,665 million, and an increase in trade payables of ¥1,019 million, while the main outflows were an increase in inventory assets of ¥3,925 million and income tax, etc. paid of ¥2,087 million.

Net cash used in investing activities amounted to ¥3,718 million. The main cash outflows were expenditures of ¥1,156 million for tangible fixed assets and ¥1,070 million for the acquisition of license rights.

Net cash used in financing activities amounted to ¥1,773 million, primarily comprising cash payment of dividends.

As a result, cash and cash equivalents as of March 31, 2015 increased by ¥684 million compared to the previous fiscal year end, to ¥21,914 million.

Consolidated Balance Sheet (Assets) (millions of yen)



## 3. Summary of Consolidated Business Results

### (1) Pharmaceuticals

In the pharmaceuticals segment, sales declined for products including Gaslon N®, a remedy for gastric ulcers and gastritis, and Hypen®, a non-steroidal analgesic and anti-inflammatory agent, while sales increased for Tramal®, a cancer pain and chronic pain treatment, and Vidaza®, a remedy for myelodysplastic syndrome. Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy newly launched in April 2014, also contributed to sales, and we recorded income from industrial property rights accompanying the partner-led overseas application for approval of our original product. As a result, net sales were ¥66,340 million, a year-on-year increase of 4.7%.

### (2) Functional Food

In the functional food segment, sales of health food ingredients decreased while sales of preservatives, nutritional ingredients, and protein preparations all increased. As a result, net sales increased 3.6% year-on-year to ¥13,651 million.

## Business Risks

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 current fiscal year.

### 1. Regulatory Control Risks

The core pharmaceuticals and functional food businesses of the Nippon Shinyaku Group are strictly regulated under the Pharmaceuticals, Medical Devices and Other Therapeutic Products Act and Food Sanitation Act. In the event that regulatory changes require the Group to recall or cease the sale of products, it could impact our business results.

In addition, there are intellectual property theft risks and product liability risks that in some cases could impact our business results.

### 2. 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 licensing of new pharmaceuticals is not high. If R&D is abandoned because drugs are found not to be effective or there are safety issues, we will not be able to recover the capital that we invested, and in some instances this could affect the financial position or business results of the Nippon Shinyaku Group.

### 3. 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 our business results.

### 4. Drug Price Revision Risks

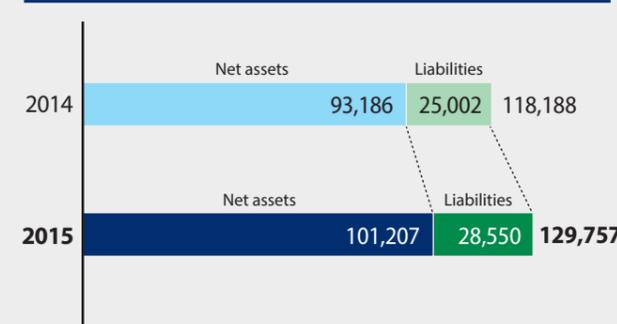
The selling price of drugs used for medical care is set based on drug price standards under the national health insurance system. Drug price standards are generally revised downward every two years. Depending on extent of the price decrease, it could impact the business results of the Nippon Shinyaku Group.

### 5. Manufacturing and Procurement Risks

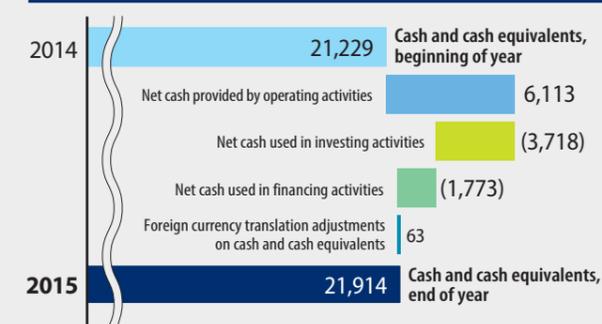
The Nippon Shinyaku Group is improving its production efficiency by concentrating its manufacturing facilities. At the same time, if operations at manufacturing facilities cease due to a natural disaster or other circumstance, it could interrupt the supply of products and impact our business results.

In addition, we procure certain products and important ingredients from specific suppliers. If the supply is interrupted, it could impact our business results.

Consolidated Balance Sheet (Liabilities/Net Assets) (millions of yen)



Consolidated Statement of Cash Flows (millions of yen)



## Consolidated Balance Sheet

 Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
 March 31, 2015

ASSETS	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2015	2014	2015
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents (Note 10)	¥ 21,914	¥ 21,229	\$ 182,616
Time deposits (Note 10)	227	267	1,891
Marketable securities (Notes 3 and 10)	500		4,166
Notes and accounts receivables (Note 10):			
Trade notes	274	328	2,283
Trade accounts	34,736	33,808	289,466
Other	147	280	1,225
<b>Total notes and accounts receivables</b>	35,158	34,417	292,983
Inventories (Note 4)	19,658	15,733	163,816
Deferred tax assets (Note 9)	1,698	1,678	14,150
Other current assets	1,265	1,357	10,541
<b>Total current assets</b>	80,422	74,683	670,183
<b>PROPERTY, PLANT, AND EQUIPMENT:</b>			
Land	7,449	7,433	62,075
Buildings and structures	23,645	23,742	197,041
Machinery, equipment, and vehicles	11,006	10,615	91,716
Tools, furniture, and fixtures	8,814	8,784	73,450
Construction in progress	74	104	616
<b>Total</b>	50,990	50,680	424,916
Accumulated depreciation	(35,596)	(35,009)	(296,633)
<b>Net property, plant, and equipment</b>	15,393	15,670	128,275
<b>INVESTMENTS AND OTHER ASSETS:</b>			
Investment securities (Notes 3 and 10)	22,078	16,063	183,983
Long-term prepaid expenses	8,287	7,981	69,058
Deferred tax assets (Note 9)	57	60	475
Other assets	3,518	3,729	29,316
<b>Total investments and other assets</b>	33,941	27,834	282,841
<b>TOTAL</b>	¥ 129,757	¥ 118,188	\$ 1,081,308

See notes to consolidated financial statements.

LIABILITIES AND EQUITY	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2015	2014	2015
<b>CURRENT LIABILITIES:</b>			
Notes and accounts payables (Note 10):			
Trade notes	¥ 1,792	¥ 1,772	\$ 14,933
Trade accounts	5,326	4,326	44,383
Other	2,904	2,784	24,200
<b>Total notes and accounts payables</b>	10,022	8,883	83,516
Income taxes payable (Note 10)	2,161	1,537	18,008
Accrued expenses	3,759	3,739	31,325
Deposits from customers	284	279	2,366
Other current liabilities	1,542	816	12,850
<b>Total current liabilities</b>	17,770	15,257	148,083
<b>LONG-TERM LIABILITIES:</b>			
Liability for retirement benefits (Note 5)	7,997	8,857	66,641
Deferred tax liabilities (Note 9)	2,286	510	19,050
Other long-term liabilities	495	376	4,125
<b>Total long-term liabilities</b>	10,779	9,744	89,825
<b>EQUITY</b> (Notes 6 and 13):			
Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares	5,174	5,174	43,116
Capital surplus	4,445	4,445	37,041
Retained earnings	85,137	81,105	709,475
Treasury stock – at cost, 2,868,940 shares in 2015 and 2,820,656 shares in 2014	(2,327)	(2,175)	(19,391)
Accumulated other comprehensive income:			
Unrealized gain on available-for-sale securities	9,600	5,841	80,000
Deferred gain (loss) on derivatives under hedge accounting	(11)	1	(91)
Foreign currency translation adjustments	17	(4)	141
Defined retirement benefit plans	(1,037)	(1,406)	(8,641)
<b>Total</b>	100,998	92,982	841,650
<b>Minority interests</b>	208	204	1,733
<b>Total equity</b>	101,207	93,186	843,391
<b>TOTAL</b>	¥ 129,757	¥ 118,188	\$ 1,081,308



## Consolidated Statement of Cash Flows

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Year Ended March 31, 2015

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2015	2014	2015
<b>OPERATING ACTIVITIES:</b>			
Income before income taxes and minority interests	¥ 8,928	¥ 8,598	\$ 74,400
Adjustments for:			
Income taxes – paid	(2,087)	(2,854)	(17,391)
Depreciation and amortization	2,665	2,704	22,208
Changes in assets and liabilities:			
Decrease (increase) in trade notes and trade accounts receivables	(873)	129	(7,275)
Increase in inventories	(3,925)	(2,466)	(32,708)
Decrease (increase) in other current assets	92	(117)	766
Increase in trade notes and trade accounts payables	1,019	1,071	8,491
(Decrease) increase in other current liabilities	465	(43)	3,875
Decrease in liability for retirement benefits	(547)	(759)	(4,558)
Other – net	375	(245)	3,125
<b>Total adjustments</b>	<b>(2,814)</b>	<b>(2,582)</b>	<b>(23,450)</b>
<b>Net cash provided by operating activities</b>	<b>6,113</b>	<b>6,015</b>	<b>50,941</b>
<b>INVESTING ACTIVITIES:</b>			
Capital expenditures	(1,156)	(1,121)	(9,633)
Purchases of investment securities	(1,000)	(904)	(8,333)
Purchases of software	(109)	(142)	(908)
Acquisition of license rights	(1,070)	(1,243)	(8,916)
Other – net	(381)	54	(3,175)
<b>Net cash used in investing activities</b>	<b>(3,718)</b>	<b>(3,357)</b>	<b>(30,983)</b>
<b>FINANCING ACTIVITIES:</b>			
Cash dividends paid	(1,618)	(1,484)	(13,483)
Increase in treasury stock	(152)	(82)	(1,266)
Other – net	(2)	(39)	(16)
<b>Net cash used in financing activities</b>	<b>(1,773)</b>	<b>(1,606)</b>	<b>(14,775)</b>
<b>FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS</b>			
	63	133	525
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>684</b>	<b>1,185</b>	<b>5,700</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	<b>21,229</b>	<b>20,044</b>	<b>176,908</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>¥ 21,914</b>	<b>¥ 21,229</b>	<b>\$ 182,616</b>

See 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 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 2014 consolidated financial statements to conform to the classifications used in 2015.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Nippon Shinyaku Co., Ltd. (the "Company"), is incorporated and operates. Japanese yen figures less than a million yen are rounded down to the nearest million yen, except for per share data. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥120 to \$1, the approximate rate of exchange at March 31, 2015. U.S. dollar figures less than a thousand dollars are rounded down to the nearest thousand dollars, except for per share data. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## a. Consolidation

The consolidated financial statements as of March 31, 2015 and 2014, include the accounts of the Company and its significant two domestic and one overseas subsidiaries (together, the "Companies"). Consolidation of the remaining subsidiary would not have a material effect on the accompanying consolidated financial statements.

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.

Investment in one unconsolidated subsidiary is stated at cost. If the equity method of accounting had been applied to the investment in this company, the effect on the accompanying consolidated financial statements would not be material.

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 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 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 is principally computed by the declining-balance method while the straight-line method is applied to buildings acquired after April 1, 1998. The range of useful lives is principally from 10 to 50 years for buildings and structures, from eight to 10 years for machinery, equipment, and vehicles, and from four to six 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 defined contribution pension plan for employees. Certain consolidated subsidiaries have unfunded retirement benefit plans.

Effective April 1, 2000, the Company adopted a new accounting standard for retirement benefits and accounted 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 straight-line basis. Actuarial gains and losses are amortized on a straight-line basis over 15 years within the average remaining service period. Past service costs are amortized on a straight-line basis over 15 years within the average remaining service period.

In May 2012, the Accounting Standards Board of Japan (the ASBJ) issued ASBJ Statement No. 26, "Accounting Standard for Retirement Benefits" and ASBJ Guidance No. 25, "Guidance on Accounting Standard for Retirement Benefits," which replaced the accounting standard for retirement benefits that had been issued by the Business Accounting Council in 1998 with an effective date of April 1, 2000, and the other related practical guidance, and were followed by partial amendments from time to time through 2009.

- (a) Under the revised accounting standard, 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 any resulting deficit or surplus is recognized as a liability (liability for retirement benefits) or asset (asset for retirement benefits).
- (b) The revised accounting standard does not change how to recognize actuarial gains and losses and past service costs in profit or loss. Those amounts are recognized in profit or loss over a certain period no longer than the expected average remaining service period of the employees. However, actuarial gains and losses and past service costs that arose in the current period and have not yet been recognized in profit or loss are included in other comprehensive income and actuarial gains and losses and past service costs that were recognized in other comprehensive income in prior periods and then recognized in profit or loss in the current period, are treated as reclassification adjustments (see Note 11).
- (c) The revised accounting standard also made certain amendments relating to the method of attributing expected benefit to periods, the discount rate and expected future salary increases.

This accounting standard and the guidance for (a) and (b) above are effective for the end of annual periods beginning on or after April 1, 2013, and for (c) above are effective for the beginning of annual periods beginning on or after April 1, 2014, or for the beginning of annual periods beginning on or after April 1, 2015, subject to certain disclosure in March 2015, all with earlier application being permitted from the beginning of annual periods beginning on or after April 1, 2013. However, no retrospective application of this

accounting standard to consolidated financial statements in prior periods is required.

The Company applied the revised accounting standard and guidance for retirement benefits for (a) and (b) above, effective March 31, 2014, and for (c) above, effective April 1, 2014.

With respect to (c) above, the Company changed the method of attributing the expected benefit to periods from a straight-line basis to a benefit formula basis, the method of determining the discount rate from using the period which approximates the expected average remaining service period to using a single weighted-average discount rate reflecting the estimated timing and amount of benefit payment and the method of estimating expected future salary increases from salary increases "expected to be certain" to salary increases "expected," and recorded the effect of (c) above as of April 1, 2014, in retained earnings. As a result, liability for retirement benefits as of April 1, 2014, increased by ¥360 million (\$3,000 thousand), and retained earnings as of April 1, 2014, decreased by ¥232 million (\$1,933 thousand). The effect on profit and loss in the current period is minor.

#### h. Asset Retirement Obligations

In March 2008, the ASBJ issued the accounting standard for asset retirement obligations, ASBJ Statement No. 18, "Accounting Standard for Asset Retirement Obligations," and ASBJ Guidance No. 21, "Guidance on Accounting Standard for Asset Retirement Obligations." Under this accounting standard, an asset retirement obligation is defined as a legal obligation imposed either by law or contract that results from the acquisition, construction, development, and the normal operation of a tangible fixed asset and is associated with the retirement of such tangible fixed asset. The asset retirement obligation is recognized as the sum of the discounted cash flows required for the future asset retirement and is recorded in the period in which the obligation is incurred if a reasonable estimate can be made. If a reasonable estimate of the asset retirement obligation cannot be made in the period the asset retirement obligation is incurred, the liability should be recognized when a reasonable estimate of asset retirement obligation can be made. Upon initial recognition of a liability for an asset retirement obligation, an asset retirement cost is capitalized by increasing the carrying amount of the related fixed asset by the amount of the liability. The asset retirement cost is subsequently allocated to expense through depreciation over the remaining useful life of the asset. Over time, the liability is accreted to its present value each period. Any subsequent revisions to the timing or the amount of the original estimate of undiscounted cash flows are reflected as an adjustment to the carrying amount of the liability and the capitalized amount of the related asset retirement cost.

#### i. Allowance for Doubtful Accounts

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

#### j. Leases

In March 2007, the ASBJ issued ASBJ Statement No. 13, "Accounting Standard for Lease Transactions," which revised the previous accounting standard for lease transactions issued. The revised accounting standard for lease transactions was effective for fiscal years beginning on or after April 1, 2008.

Under the previous accounting standard, finance leases that were deemed to transfer ownership of the leased property to the lessee were capitalized. However, other finance leases were permitted to be accounted for as operating lease transactions if certain "as if capitalized" information was disclosed in the notes to the lessee's financial statements. The revised accounting standard requires that all finance lease transactions be capitalized by recognizing lease assets and lease obligations in the balance sheet. In addition, the accounting standard permits leases that existed at the transition date and do not transfer ownership of the leased property to the lessee to continue to be accounted for as operating lease transactions.

#### k. Bonuses to Directors and Audit and Supervisory Board Members

Bonuses to directors and Audit and Supervisory Board members are accrued at the end of the year to which such bonuses are attributable.

#### l. Income Taxes

The provision for income taxes is computed based on the pretax income included in the consolidated statement of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted income tax rates to the temporary differences.

#### m. Foreign Currency Transactions

All short- and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statement of income to the extent that they are not hedged by forward exchange contracts.

#### n. Foreign Currency Financial Statements

The balance sheet accounts and revenue and expense accounts of the overseas consolidated subsidiary are translated into Japanese yen at the current exchange rates as of the balance sheet date except for equity, which is translated at historical rates. Differences arising from such translation are shown as "Foreign currency translation adjustments" under accumulated other comprehensive income in a separate component of equity.

#### o. Derivative Financial Instruments

The Company uses foreign currency forward contracts as a means of hedging exposure to foreign currency risks related to the procurement of merchandise from overseas

suppliers. The Company does not enter into derivatives for trading or speculative purposes. Derivative financial instruments and foreign currency transactions are classified and accounted for as follows: a) all derivatives are recognized as either assets or liabilities and measured at fair value, and gains or losses on derivative transactions are recognized in the consolidated statement of income and b) for derivatives used for hedging purposes, if such derivatives qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are deferred until maturity of the hedged transactions. The foreign currency forward contracts are utilized to hedge foreign currency exposures in procurement of raw materials from overseas suppliers. Trade payables denominated in foreign currencies are translated at the contracted rates if the forward contracts qualify for hedge accounting.

#### p. Per Share Information

Basic net income per share (EPS) is computed by dividing net income available to common shareholders by the weighted-average number of common shares outstanding for the period.

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

#### q. Accounting Changes and Error Corrections

In December 2009, the ASBJ issued 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 under this standard and guidance are 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 financial statements are restated.

#### r. New Accounting Pronouncements

Accounting Standards for Business Combinations and Consolidated Financial Statements - In September 2013, the ASBJ issued revised ASBJ Statement No. 21, "Accounting Standard for Business Combinations," revised ASBJ Guidance No. 10, "Guidance on Accounting Standards for Business Combinations and Business

Divestitures," and revised ASBJ Statement No. 22, "Accounting Standard for Consolidated Financial Statements." Major accounting changes are as follows:

**(a) Transactions with noncontrolling interest**

A parent's ownership interest in a subsidiary might change if the parent purchases or sells ownership interests in its subsidiary. The carrying amount of minority interest is adjusted to reflect the change in the parent's ownership interest in its subsidiary while the parent retains its controlling interest in its subsidiary. Under the current accounting standard, any difference between the fair value of the consideration received or paid and the amount by which the minority interest is adjusted is accounted for as an adjustment of goodwill or as profit or loss in the consolidated statement of income. Under the revised accounting standard, such difference shall be accounted for as capital surplus as long as the parent retains control over its subsidiary.

**(b) Presentation of the consolidated balance sheet**

In the consolidated balance sheet, "minority interest" under the current accounting standard will be changed to "noncontrolling interest" under the revised accounting standard.

**(c) Presentation of the consolidated statement of income**

In the consolidated statement of income, "income before minority interest" under the current accounting standard will be changed to "net income" under the revised accounting standard, and "net income" under the current accounting standard will be changed to "net income attributable to owners of the parent" under the revised accounting standard.

**(d) Provisional accounting treatments for a business combination**

If the initial accounting for a business combination is incomplete by the end of the reporting period in which the business combination occurs, an acquirer shall report in its financial statements provisional amounts for the items for which the accounting is incomplete. Under the current accounting standard guidance, the impact of adjustments to provisional amounts recorded in a business combination on profit or loss is recognized as profit or loss in the year in which the measurement is completed. Under the revised accounting standard guidance, during the measurement period, which shall not exceed one year from the acquisition, the acquirer shall retrospectively adjust the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date and that would have affected the measurement of the amounts recognized as of that date. Such adjustments shall be recognized as if the accounting for the business combination had been completed at the acquisition date.

**(e) Acquisition-related costs**

Acquisition-related costs are costs, such as advisory fees or professional fees, which an acquirer incurs to effect a

business combination. Under the current accounting standard, the acquirer accounts for acquisition-related costs by including them in the acquisition costs of the investment. Under the revised accounting standard, acquisition-related costs shall be accounted for as expenses in the periods in which the costs are incurred.

The above accounting standards and guidance for (a) transactions with noncontrolling interest, (b) presentation of the consolidated balance sheet, (c) presentation of the consolidated statement of income, and (e) acquisition-related costs are effective for the beginning of annual periods beginning on or after April 1, 2015. Earlier application is permitted from the beginning of annual periods beginning on or after April 1, 2014, except for (b) presentation of the consolidated balance sheet and (c) presentation of the consolidated statement of income. In the case of earlier application, all accounting standards and guidance above, except for (b) presentation of the consolidated balance sheet and (c) presentation of the consolidated statement of income, should be applied simultaneously.

Either retrospective or prospective application of the revised accounting standards and guidance for (a) transactions with noncontrolling interest and (e) acquisition-related costs is permitted. In retrospective application of the revised standards and guidance, the accumulated effects of retrospective adjustments for all (a) transactions with noncontrolling interest and (e) acquisition-related costs which occurred in the past shall be reflected as adjustments to the beginning balance of capital surplus and retained earnings for the year of the first-time application. In prospective application, the new standards and guidance shall be applied prospectively from the beginning of the year of the first-time application.

The revised accounting standards and guidance for (b) presentation of the consolidated balance sheet and (c) presentation of the consolidated statement of income shall be applied to all periods presented in financial statements containing the first-time application of the revised standards and guidance.

The revised standards and guidance for (d) provisional accounting treatments for a business combination are effective for a business combination which occurs on or after the beginning of annual periods beginning on or after April 1, 2015. Earlier application is permitted for a business combination which occurs on or after the beginning of annual periods beginning on or after April 1, 2014.

The Company expects to apply the revised accounting standards and guidance for (a), (b), (c) and (e) above from April 1, 2015, and for (d) above for a business combination which will occur on or after April 1, 2015, and is in the process of measuring the effects of applying the revised accounting standards and guidance in future applicable periods.

### 3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2015 and 2014, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Current:			
Government and corporate bonds	¥ 500		\$ 4,166
Total	¥ 500		\$ 4,166
Noncurrent:			
Equity securities	¥ 22,078	¥ 16,063	\$ 183,983
Total	¥ 22,078	¥ 16,063	\$ 183,983

The costs and aggregate fair values of marketable and investment securities at March 31, 2015 and 2014, were as follows:

	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
March 31, 2015				
Securities classified as:				
Available-for-sale:				
Equity securities	¥ 7,958	¥ 13,786		¥ 21,745
Held-to-maturity	500			499

	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
March 31, 2014				
Securities classified as:				
Available-for-sale:				
Equity securities	¥ 6,958	¥ 8,772		¥ 15,730

	Thousands of U.S. Dollars			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
March 31, 2015				
Securities classified as:				
Available-for-sale:				
Equity securities	\$ 66,316	\$ 114,883		\$ 181,208
Held-to-maturity	4,166			4,158

### 4. INVENTORIES

Inventories at March 31, 2015 and 2014, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Finished products and merchandise	¥ 12,936	¥ 9,983	\$ 107,800
Work in process	2,058	1,643	17,150
Raw materials	4,663	4,106	38,858
Total	¥ 19,658	¥ 15,733	\$ 163,816

### 5. RETIREMENT BENEFITS

1. Defined Benefit Pension Plan

(1) The changes in defined benefit obligation for the years ended March 31, 2015 and 2014, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Balance at beginning of year (as previously reported)	¥ 25,769	¥ 26,554	\$ 214,741
Cumulative effect of accounting change	360		3,000
Balance at beginning of year (as restated)	26,129	26,554	217,741
Current service cost	936	872	7,800
Interest cost	378	526	3,150
Actuarial (gains) losses	1,290	(850)	10,750
Benefits paid	(1,145)	(1,333)	(9,541)
Balance at end of year	¥ 27,589	¥ 25,769	\$ 229,908

(2) The changes in plan assets for the years ended March 31, 2015 and 2014, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Balance at beginning of year	¥ 16,911	¥ 15,140	\$ 140,925
Expected return on plan assets	673	602	5,608
Actuarial gains	1,404	537	11,700
Contributions from the employer	1,408	1,627	11,733
Benefits paid	(808)	(997)	(6,733)
Others	1	1	8
Balance at end of year	¥ 19,592	¥ 16,911	\$ 163,266

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

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Funded defined benefit obligation	¥ 24,928	¥ 19,824	\$ 207,733
Plan assets	(19,592)	(16,911)	(163,266)
	5,336	2,912	44,466
Unfunded defined benefit obligation	2,661	5,944	22,175
Net liability arising from defined benefit obligation	¥ 7,997	¥ 8,857	\$ 66,641
Liability for retirement benefits	¥ 7,997	¥ 8,857	\$ 66,641
Net liability arising from defined benefit obligation	¥ 7,997	¥ 8,857	\$ 66,641

(4) The components of net periodic benefit costs for the years ended March 31, 2015 and 2014, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Service cost	¥ 936	¥ 872	\$ 7,800
Interest cost	378	526	3,150
Expected return on plan assets	(673)	(602)	(5,608)
Amortization of prior service cost	45	45	375
Recognized actuarial losses	512	363	4,266
Others	5	22	41
Net periodic benefit costs	¥ 1,204	¥ 1,226	\$ 10,033

(5) Other comprehensive income on defined retirement benefit plans for the years ended March 31, 2015 and 2014

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Prior service cost	¥ (45)		\$ (375)
Actuarial gains	(627)		(5,225)
Total	¥ (672)		\$ (5,600)

(6) Accumulated other comprehensive income on defined retirement benefit plans as of March 31, 2015 and 2014

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Unrecognized prior service cost	¥ 156	¥ 201	\$ 1,300
Unrecognized actuarial losses	1,369	1,996	11,408
Total	¥ 1,525	¥ 2,198	\$ 12,708

(7) Plan assets

a. Components of plan assets

Plan assets as of March 31, 2015 and 2014, consisted of the following:

	2015		2014	
	2015	2014	2015	2014
Domestic bonds	20.6%	23.1%		
Home shares	20.4	16.3		
Foreign bonds	14.1	13.8		
Foreign shares	16.4	13.6		
General accounts	25.3	29.9		
Others	3.2	3.3		
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 which are expected currently and in the future from the various components of the plan assets.

(8) Assumptions used for the years ended March 31, 2015 and 2014, are set forth as follows:

	2015	2014
Discount rate	0.2–1.3%	2.0%
Expected rate of return on plan assets	4.0%	4.0%

2. Defined Contribution Pension Plan

Premiums for defined contribution pension plan were ¥48 million (\$400 thousand) and ¥46 million for the years ended March 31, 2015 and 2014, 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 dividend upon resolution at the shareholders meeting. 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 (noncash 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 ¥8,968 million (\$74,733 thousand) and ¥9,530 million for the years ended March 31, 2015 and 2014, respectively.

## 8. LEASES

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

Total rental expenses for the years ended March 31, 2015 and 2014, were ¥1,257 million (\$10,475 thousand) and ¥1,240 million, respectively.

Future minimum payments under noncancelable operating leases were as follows:

	Operating Leases	
	2015	2014
	Millions of Yen	Thousands of U.S. Dollars
Due within one year	¥ 4	\$ 33
Due after one year	8	66
Total	¥ 12	\$ 100

## 9. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes, which, in the aggregate, resulted in normal effective statutory tax rates of approximately 35.5% and 38.0% for the years ended March 31, 2015 and 2014 respectively. The overseas subsidiary is subject to the income tax of the country in which it operates.

The tax effects of significant temporary differences that resulted in deferred tax assets and liabilities at March 31, 2015 and 2014, are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Deferred tax assets:			
Retirement benefits	¥ 2,559	¥ 3,191	\$ 21,325
Accrued expenses	1,023	1,084	8,525
Property, plant, and equipment	51	59	425
Other	1,406	1,380	11,716
Less valuation allowance	(325)	(367)	(2,708)
Deferred tax assets	4,715	5,349	39,291
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	4,185	2,930	34,875
Deferred gains on sales of property	1,035	1,155	8,625
Other	23	35	191
Deferred tax liabilities	5,245	4,120	43,708
Net deferred tax assets (liabilities) ¥	(529)	¥ 1,228	\$ (4,408)

A reconciliation between the normal effective statutory tax rates and the actual effective tax rates reflected in the accompanying consolidated statements of income for the years ended March 31, 2015 and 2014, are as follows:

	2015	2014
Normal effective statutory tax rate	35.5%	38.0%
Expenses not deductible for income tax purposes	1.6	2.4
Income not taxable for income tax purposes	(1.1)	(1.0)
Tax credits for research and development costs	(6.7)	(7.1)
Effect of tax rate reduction	3.7	1.0
Flat rate municipal tax	0.7	0.7
Other – net	0.3	(1.0)
Actual effective tax rate	34.0%	33.0%

New tax reform laws enacted in 2015 in Japan changed the normal effective statutory tax rate for the fiscal year beginning on or after April 1, 2015, to approximately 33% and for the fiscal year beginning on or after April 1, 2016, to approximately 32%. The effect of these changes was to decrease deferred tax liabilities, net of deferred tax assets, by ¥46 million (\$383 thousand), in the consolidated balance sheet as of March 31, 2015, and to increase income taxes-deferred in the consolidated statement of income for the year then ended by ¥333 million (\$2,775 thousand).

**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 used, not 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 certificate of deposits, 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 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 early. 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 exchange risk and interest rate risk)**

Foreign currency trade payables are exposed to fluctuations in foreign currency exchange rates. Such foreign 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, 2015	Millions of Yen		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	¥ 21,914	¥ 21,914	
Time deposits	227	227	
Notes and accounts receivables	35,010	35,010	
Marketable and investment securities	22,245	22,245	
<b>Total</b>	<b>¥ 79,397</b>	<b>¥ 79,397</b>	

Notes and accounts payables	¥ 10,022	¥ 10,022	
Income taxes payable	2,161	2,161	
<b>Total</b>	<b>¥ 12,184</b>	<b>¥ 12,184</b>	

March 31, 2014	Millions of Yen		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	¥ 21,229	¥ 21,229	
Time deposits	267	267	
Notes and accounts receivables	34,137	34,137	
Investment securities	15,730	15,730	
<b>Total</b>	<b>¥ 71,364</b>	<b>¥ 71,364</b>	

Notes and accounts payables	¥ 8,883	¥ 8,883	
Income taxes payable	1,537	1,537	
<b>Total</b>	<b>¥ 10,421</b>	<b>¥ 10,421</b>	

March 31, 2015	Thousands of U.S. Dollars		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	\$ 182,616	\$ 182,616	
Time deposits	1,891	1,891	
Notes and accounts receivables	291,750	291,750	
Marketable and investment securities	185,375	185,375	
<b>Total</b>	<b>\$ 661,641</b>	<b>\$ 661,641</b>	

Notes and accounts payables	\$ 83,516	\$ 83,516	
Income taxes payable	18,008	18,008	
<b>Total</b>	<b>\$ 101,533</b>	<b>\$ 101,533</b>	

**Cash and cash equivalents, time deposits, notes and accounts receivables**

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

**Marketable and investment securities**

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

**Notes and accounts payables and income taxes payable**

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

**Derivatives**

Fair value information for derivatives is omitted from disclosure because fair values and unrealized gains were immaterial for the years ended March 31, 2015 and 2014.

**(b) Financial instruments whose fair value cannot be reliably determined**

	Carrying Amount		
	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Investments in equity instruments that do not have a quoted market price in an active market	¥ 332	¥ 332	\$ 2,766

**(5) Maturity analysis of financial assets and securities with contractual maturities**

March 31, 2015	Due in One Year or Less	
	Millions of Yen	Thousands of U.S. Dollars
Cash and cash equivalents	¥ 21,914	\$ 182,616
Time deposits	227	1,891
Marketable securities	500	4,166
Notes and accounts receivables	35,010	291,750
<b>Total</b>	<b>¥ 57,652</b>	<b>\$ 480,433</b>

**11. OTHER COMPREHENSIVE INCOME**

The components of other comprehensive income for the years ended March 31, 2015 and 2014, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2015	2014	2015
Unrealized gain on available-for-sale securities:			
Gains arising during the year	¥ 5,014	¥ 1,285	\$ 41,783
Amount before income tax effect	5,014	1,285	41,783
Income tax effect	(1,255)	(433)	(10,458)
<b>Total</b>	<b>¥ 3,758</b>	<b>¥ 852</b>	<b>\$ 31,316</b>
Deferred loss on derivatives under hedge accounting:			
Loss arising during the year	¥ (20)	¥ (4)	\$ (166)
Income tax effect	7	1	58
<b>Total</b>	<b>¥ (13)</b>	<b>¥ (3)</b>	<b>\$ (108)</b>
Foreign currency translation adjustments:			
Adjustments arising during the year	¥ 22	¥ 25	\$ 183
<b>Total</b>	<b>¥ 22</b>	<b>¥ 25</b>	<b>\$ 183</b>
Defined retirement benefit plans: Adjustments arising during the year	¥ 114		\$ 950
Reclassification adjustments to profit	557		4,641
Amount before income tax effect	672		5,600
Income tax effect	(303)		(2,525)
<b>Total</b>	<b>¥ 369</b>		<b>\$ 3,075</b>
<b>Total other comprehensive income</b>	<b>¥ 4,136</b>	<b>¥ 874</b>	<b>\$ 34,466</b>

**12. NET INCOME PER SHARE**

Net EPS for the years ended March 31, 2015 and 2014, were as follows:

	Millions of Yen	Thousands of Shares	Yen	Dollars
	Net Income	Weighted-Average Shares	EPS	
For the year ended March 31, 2015 - Basic EPS				
Net income available to common shareholders	¥ 5,882	67,405	¥ 87.26	\$ 0.73
For the year ended March 31, 2014 - Basic EPS				
Net income available to common shareholders	¥ 5,750	67,455	¥ 85.25	

Diluted net EPS is not disclosed because there are no dilutive securities outstanding.

**13. SUBSEQUENT EVENTS**

At the general shareholders' meeting held on June 26, 2015, the Company's shareholders approved the following:

Payment of a year-end cash dividend of ¥13 (\$0.11) per share to holders of record at March 31, 2015, for a total of ¥875 million (\$7,291 thousand).

**14. SEGMENT INFORMATION**

Under ASBJ revised ASBJ Statement No. 17, "Accounting Standard for Segment Information Disclosures," and issued 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 such information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments.

**1. Description of reportable segments**

The Companies' reportable segments are those for which separate financial information is available and regular evaluation by the Company's management is being performed in order to decide how resources are allocated among the Companies. Therefore, the Companies' reportable segments consist of the 'Pharmaceuticals' industry and 'Functional Food' industry. 'Pharmaceuticals' industry consists of the manufacturing and sale of drugs for urological diseases, inflammation and allergy, hematologic malignancies, cardiovascular and metabolic diseases, gastrointestinal disorders, and other diseases. '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, assets, 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, assets, and other items is as follows:**

	Millions of Yen				
	2015				
	Reportable Segment				
	Pharmaceuticals	Functional Food	Total	Reconciliations	Consolidated
Sales:					
Sales to external customers	¥ 66,340	¥ 13,651	¥ 79,991		¥ 79,991
Intersegment sales or transfers					
Total	66,340	13,651	79,991		79,991
Segment profit	8,255	307	8,562		8,562
Segment assets	74,380	10,777	85,158	¥ 44,598	129,757
Other:					
Depreciation	2,505	132	2,638	27	2,665
Increase in property, plant, and equipment and intangible assets	1,151	88	1,239		1,239

	Millions of Yen				
	2014				
	Reportable Segment				
	Pharmaceuticals	Functional Food	Total	Reconciliations	Consolidated
Sales:					
Sales to external customers	¥ 63,345	¥ 13,172	¥ 76,517		¥ 76,517
Intersegment sales or transfers					
Total	63,345	13,172	76,517		76,517
Segment profit	7,899	139	8,038		8,038
Segment assets	71,191	9,327	80,518	¥ 37,670	118,188
Other:					
Depreciation	2,546	128	2,675	28	2,704
Increase in property, plant, and equipment and intangible assets	1,016	56	1,072		1,072

	Thousands of U.S. Dollars				
	2015				
	Reportable Segment				
	Pharmaceuticals	Functional Food	Total	Reconciliations	Consolidated
Sales:					
Sales to external customers	\$ 552,833	\$ 113,758	\$ 666,591		\$ 666,591
Intersegment sales or transfers					
Total	552,833	113,758	666,591		666,591
Segment profit	68,791	2,558	71,350		71,350
Segment assets	619,833	89,808	709,650	\$ 371,650	1,081,308
Other:					
Depreciation	20,875	1,100	21,983	225	22,208
Increase in property, plant, and equipment and intangible assets	9,591	733	10,325		10,325

Notes: Unallocated corporate assets included under "Reconciliations" for 2015 and 2014 are ¥44,598 million (\$371,650 thousand) and ¥37,670 million, respectively, and consist 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		
	2015		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	¥ 66,340	¥ 13,651	¥ 79,991

	Thousands of U.S. Dollars		
	2015		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	\$ 552,833	\$ 113,758	\$ 666,591

**3. Information about major customers**

Name of Customers	2015			Related Segment Name
	Sales			
	Millions of Yen	Thousands of U.S. Dollars		
MEDICEO CORPORATION	¥ 15,510	\$ 129,250		Pharmaceuticals
Alfresa Corporation	13,616	113,466		Pharmaceuticals
Suzuken Co., Ltd.	12,821	106,841		Pharmaceuticals
Toho Pharmaceutical Co., Ltd.	8,237	68,641		Pharmaceuticals

**2. Information about geographical area****(1) Sales**

Information about geographical area is omitted, as sales to external customers located in Japan accounted for more than 90% of net sales presented in the consolidated statement of income for the year ended March 31, 2015.

**(2) Property, plant, and equipment**

Information about geographical area is omitted, as property, plant, and equipment located in Japan accounted for more than 90% of property, plant, and equipment presented in the consolidated balance sheet as of March 31, 2015.



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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, 2015, 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, 2015, 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 26, 2015

Member of  
 Deloitte Touche Tohmatsu Limited

**Corporate Data/Investor Information**

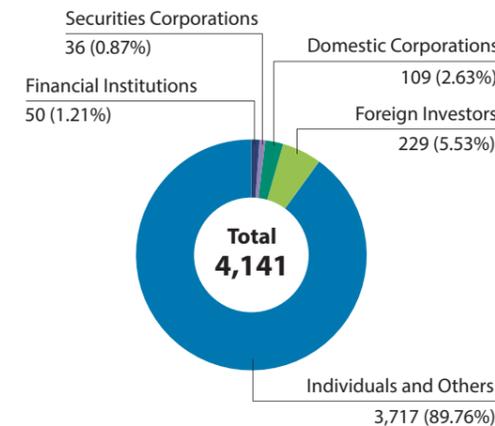
As of March 31, 2015

**Corporate Data**

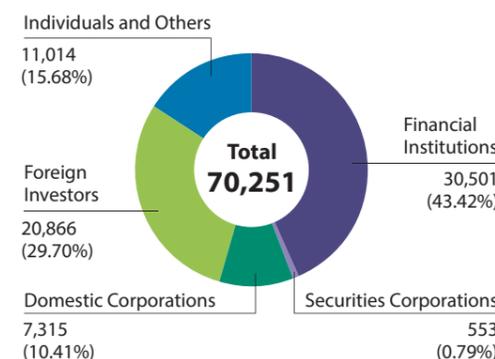
<p><b>Corporate Name</b> Nippon Shinyaku Co., Ltd.</p> <p><b>Founded</b> November 20, 1911</p> <p><b>Date of Incorporation</b> October 1, 1919</p> <p><b>Paid-in Capital</b> ¥5,174 million</p> <p><b>Representative Director</b> Shigenobu Maekawa President</p> <p><b>Employees</b> 1,939</p>	<p><b>Head Office</b> 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan Phone: +81-75-321-1111 Facsimile: +81-75-321-0678 URL: <a href="http://www.nippon-shinyaku.co.jp/english/">http://www.nippon-shinyaku.co.jp/english/</a></p> <p><b>Independent and Certified Public Accountants</b> Deloitte Touche Tohmatsu Shijokarasuma FT Square 20, Naginataboko-cho, Karasuma-higashiiru, Shijo-dori Shimogyo-ku, Kyoto 600-8008, Japan</p> <p><b>Share Register</b> Mitsubishi UFJ Trust and Banking Corporation 6-3, Fushimimachi 3-chome, Chuo-ku, Osaka 541-8502, Japan</p>	<p><b>Issued and Outstanding Number of Shares</b> 70,251,484</p> <p><b>Number of Shareholders</b> 4,141</p> <p><b>Major Shareholders</b> Meiji Yasuda Life Insurance Company The Master Trust Bank of Japan, Ltd. (Trust account) GOLDMAN, SACHS &amp; CO. REG The Bank of Tokyo-Mitsubishi UFJ, Ltd. The Bank of Kyoto, Ltd. Japan Trustee Services Bank, Ltd. (Trust account) Nippon Life Insurance Company PERSHING-DIV. OF DLJ SECS. CORP. Nippon Shinyaku Employees' Stockholding Tokio Marine &amp; Nichido Fire Insurance Co., Ltd.</p>
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**Investor Information**

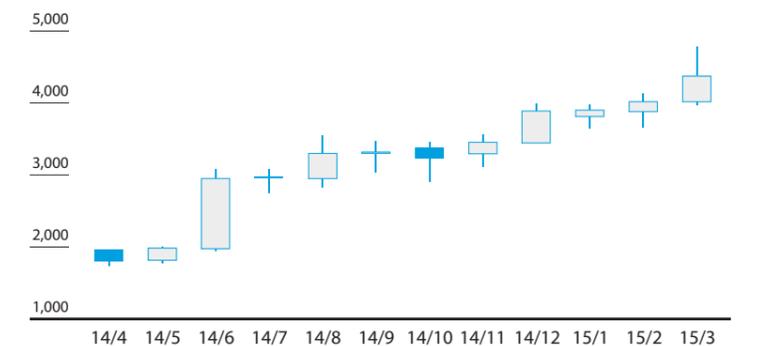
**Distribution of Shareholders**



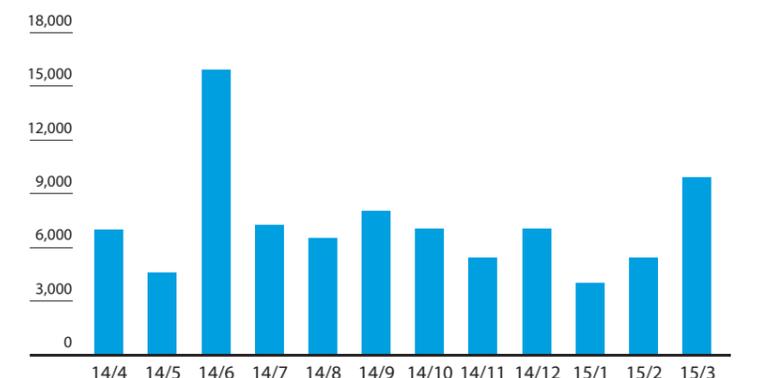
**Distribution of Shares Issued** (Thousands of shares)



**Stock Price**



**Trading Volumes**



## Service Network

### Offices in Japan

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#### Tajima Shokuhin Kogyo Co., Ltd.

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#### NS Pharma, Inc.

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### Overseas Offices/Subsidiaries



Beijing Representative Office



London Office



NS Pharma, Inc.