NIPPON SHINYAKU CO., LTD.

The cover illustration is from *Shiritagari no Otsuki-sama* (“The Curious Moon”), a picture book published through the seventh Nippon Shinyaku Children’s Literary Awards contest.
For more information about the contest, please refer to page 31 of this report.

ANNUAL REPORT 2016

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Helping people lead healthier, happier lives

NIPPON SHINYAKU CO., LTD.

Helping people lead healthier, happier lives

In the nearly 100 years since its establishment in 1919, Nippon Shinyaku has committed itself, as an R&D-based producer of new medication, to a distinctive kind of drug discovery.
We have fulfilled the wishes of patients and medical professionals by listening to their voices, thereby developing and selling therapeutic medication aimed at diseases for which no effective treatment methodologies have been established.

Furthermore, since 1961, utilizing our technology and knowhow from the pharmaceuticals business, we have been branching out into the functional foods business, and today our functional foods are widely acclaimed and trusted.
In recent years we have proactively developed health food ingredients for the growing nutraceutical market—foods and food ingredients designed to maintain and improve health.
We strive toward being a company that plays a meaningful role in society, trusted and respected by the community as an essential part of the healthcare sector. To this end, Nippon Shinyaku will continue to provide society with not only pharmaceuticals but also functional food ingredients, thus fulfilling the idea that medicine and food share the same importance in maintaining good health.

What has supported the Company since it was established, and helped Nippon Shinyaku grow into what it is today, is none other than the determination of all employees to be involved hands-on in the production of innovative products for which there is a pressing necessity.
We will continue our quest to meet as yet unfulfilled medical needs, to put a smile on the faces of patients and their families, and to seek a better future for all.

Contents

Editorial Policy

Period Covered
Fiscal 2015 (April 1, 2015–March 31, 2016). Some sections of the report also discuss initiatives since April 2016.

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, 2016. 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.

The Path to Becoming a Corporation Essential to the Community

1940

First Japanese-made vermicide, Santonin

At a time when an unprecedented outbreak of roundworms was going on during the post-WWII years, the first domestic mass production of Santonin vermicide commenced after a long and arduous process, prior to which Japan had depended on imports from the U.S.S.R. This made a huge contribution to public health in Japan, and laid the groundwork for the beginning of Japanese exports of Santonin.

1934	Registered a patent for the production process of Santonin from mibuyomogi (*Artemisia maritima*)
1940	Launch of Santonin produced by Nippon Shinyaku
1944	Received 1st Agency for Technological Advancement Prize, and later in 1951, the Healthcare Culture Prize, both for Santonin research and production
1952	Began exporting Santonin

NIPPON SHINYAKU CO., LTD.

When the Company was established, there were very few R&D-based pharmaceutical companies, and most pharmaceutical products were imported. The company name Nippon Shinyaku (lit. “Japan New Medicine”) expresses our determination that Japan should be self-sufficient in its drug production.

1982 Completion of Central Research Laboratories (now Discovery Research Laboratories No. 1 Bldg.)

Major product launches by decade

1950s	Isomytal® bulk powder, a hypnotic and sedative Azunol® ointment for dermatological inflammatory disorders
1960s	Glycoran® tablets, an oral diabetes medication Eviprostat® tablets for benign prostatic hypertrophy
1970s	Cephadol® tablets for vertigo Bladderon® tablets for frequent urination
1980s	Gaslon N® tablets and fine granules, a mucosal-protective drug for gastritis/gastric ulcers
1990s	Selectol® tablets for hypertension and angina pectoris Hypen® tablets, a nonsteroidal anti-inflammatory drug Portolac® bulk powder for hyperammonemia
2000s	Azunol® gargle liquid 4% for pharyngitis and stomatitis Trisenox® injection for acute promyelocytic leukemia Cialis® for erectile dysfunction Adcirca® tablets for pulmonary arterial hypertension (PAH)
2010s	Vidaza® for injection for myelodysplastic syndrome Erizas® nasal powder for allergic rhinitis

Nippon Shinyaku will continue working to provide drugs that will bring hope to patients struggling with illness and their families.

Recent New Products

2013

Medication for supporting alcohol abstinence in patients with alcohol dependence, Regtect® tablets

Regtect® tablets, a new type of drug for aiding in the maintenance of alcohol abstinence, were approved in 2013 as the first new drug for this indication in about 30 years. It is thought that the drug suppresses the patient’s urge to drink by acting on the central nervous system.

2013

A treatment for dysmenorrhea developed to reduce estrogen dose, Lunabell® tablets ULD

With the goal of further reducing the frequency of adverse reactions associated with Lunabell® tablets LD for the indication of dysmenorrhea, we released Lunabell® tablets ULD, which have an even lower dose of estrogen (ethinyl estradiol), in 2013. It is a major product in the gynecological field for our company.

2014

Nippon Shinyaku’s leading urological drug, Zalutia® tablets

Zalutia® tablets are a once-daily tadalafil preparation for treating urinary disorders caused by benign prostatic hypertrophy. This phosphodiesterase type 5 inhibitor is one of our core products that is highly anticipated as a unique treatment with a new mode of action.

2015

A novel ERA that will serve as a primary drug in the treatment of PAH, Opsumit® tablets

Opsumit® tablets, a novel endothelin receptor antagonist originally discovered and synthesized by Actelion, have been demonstrated as clinically efficacious and safe in a placebo-controlled, double-blind trial with a treatment period of more than two years that was conducted by Actelion outside Japan (SERAPHIN study). They were approved in the U.S. and Europe in 2013, with approval in other countries following, and in Japan in 2015. Opsumit® tablets are co-promoted in Japan in collaboration with Actelion Pharmaceuticals Japan Ltd.

2015

Drugs contributing to a better quality of life in patients suffering from cancer pain and chronic pain, Tramal® OD tablets, Tramal® injection and Onetram® tablets

We offer three tramadol hydrochloride formulations: Tramal® OD tablets, Tramal® injection, and Onetram® tablets. Tramal® OD tablets are taken four times daily, and Onetram® tablets are taken once daily. Onetram® tablets were approved for the indications of cancer pain and chronic pain in 2015.

Corporate Data

As of March 31, 2016

Corporate Name
Nippon Shinyaku Co., Ltd.

Founded
November 20, 1911

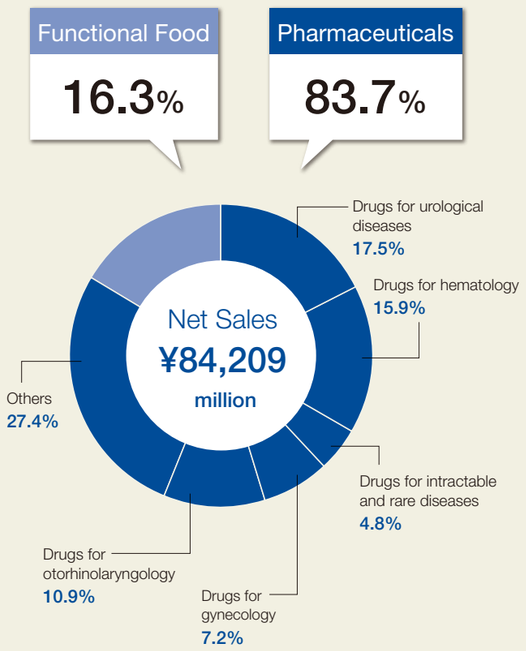
Date of Incorporation
October 1, 1919

Head Office
14, Nishinosho-Monguchi-cho, Kisshoin,
Minami-ku, Kyoto 601-8550, Japan
Phone: +81-75-321-1111
Facsimile: +81-75-321-0678
http://www.nippon-shinyaku.co.jp/english/

Paid-in Capital
¥5,174 million

Representative Director
Shigenobu Maekawa, President

Employees
1,950



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 gynecology

- Lunabell® 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 a smaller dosage of estrogen, was also launched in September 2013 and is now widely used as a treatment for dysmenorrhea.

Drugs for hematology

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

Vidaza®, a myelodysplastic syndrome (MDS) treatment, is permeating the market as the world's only drug that extends survival time for patients with MDS, and serves to reduce the frequency of blood transfusions and raise patient QOL.

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.

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.

Others

- Onetram®
- Tramal® OD

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

Functional Food

Health food ingredients

- Hyaluronic Acid 3000
- Garcinia Powder J
- Mangosteen Aqua
- Aronia TA
- NSCP Aqua

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.

Spices and condiments

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

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

Preservatives

- Mikaku Fine Z
- Mikaku Fine BK
- Glycine GX-2
- Cheflead 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.

Others

- Suncircle H
- Nineace S

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

Protein preparations and nutritional ingredients

- Milka MPI
- Lactocrystal
- PROGEL800
- 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.

We strive toward being a company that plays a meaningful role in society as an essential member of the healthcare sector.

Posted increased net sales, ordinary income and net income for the fourth consecutive year

Net sales for the Nippon Shinyaku Group in the current period were ¥84.209 billion (up 5.3% year-on-year). In terms of profit, operating income was ¥8.549 billion (down 0.2%), attributable to the posting of revenue from industrial property rights accompanying the partner-led European approval of one of our original products being delayed to the next period. Ordinary income was ¥8.952 billion (up 0.3%), while net income attributable to owners of the parent was ¥6.340 billion (up 7.8%). Net sales, ordinary income, and net income each increased for the fourth consecutive year.

In the pharmaceuticals segment, sales of long-listed drugs decreased, but increases were noted for new product suites including Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy, and Vidaza®, a drug for myelodysplastic syndrome, and all in all, sales increased by 6.3% year-on-year to ¥70.489 billion. The revenue from industrial property rights accompanying the partner-led U.S. approval of selexipag (code number: NS-304), our original pulmonary arterial hypertension (PAH) remedy, also contributed to revenue growth. In the functional food segment, increases were noted in sales of protein preparations and health food ingredients, bringing sales to ¥13.720 billion, a year-on-year increase of 0.5%.

Selexipag, licensed out to the Swiss company Actelion Pharmaceuticals Ltd., was granted marketing authorization in the U.S. in December 2015, and went onto the U.S. market in January 2016. The drug was approved in Europe in May 2016, and entered the German market in June. In Japan, the new drug application as a treatment for PAH was submitted in January 2016. NS-065, the first Japanese-made nucleic acid drug to treat Duchenne muscular dystrophy, entered a Phase I/II trial in Japan in January 2016, and a Phase II exploratory trial in the U.S. in March. New products: Onetram® tablets (100mg), a treatment for cancer pain and chronic pain, and Opsumit® tablets (10mg), a treatment for PAH, were launched in June 2015. Construction of a new building for the manufacture of active pharmaceutical ingredients for clinical trials, including highly active substances and nucleic acid drugs, was completed in our Kyoto head office area in March 2016.

We will improve people's health by supplying unique and high-quality products

We are contributing to people's health through the pursuit of our pharmaceuticals and functional food businesses.
Pharmaceuticals: We target as yet unfulfilled therapeutic needs in our main fields of focus (urology, hematology, intractable and rare diseases, gynecology, and otorhinolaryngology), and supply unique and high-quality products that are a welcome relief for patients suffering from diseases in these fields.
Functional Food: We utilize the advanced technology we possess as a pharmaceuticals company to provide products with high added value to meet the needs of the market in our core areas (health food ingredients, preservatives, and nutritional ingredients).

In R&D, we proactively develop treatments in the fields other companies are reluctant to tackle, such as intractable and rare diseases. We utilize our nucleic acid synthesis technology, which we have accumulated over many years, to develop treatments for intractable and rare diseases such as muscular dystrophy. In sales, we will promote development of products in our three core areas (urology, hematology, and PAH), and improve both the quality and quantity of information provided to medical institutions. To bolster our supply chain, a manufacturing facility for highly active drugs is under construction at the Odawara Central Factory, for in-house production of selexipag, our original highly active drug product, and contracted manufacture. Meanwhile, in international business, we will select the best methods for expanding the global reach of original products we are planning to launch based on the conditions prevalent in each target country. For the functional food business, we will utilize the advanced technology we possess as a pharmaceuticals company to continue to provide high added value products which will contribute to healthy longevity, active lifestyles, food safety and food waste reduction.

Domestically, if all goes smoothly, selexipag will be approved and go on sale for the indication of PAH before the end of 2016. The process required to expand its applications to chronic thromboembolic pulmonary hypertension and arteriosclerosis obliterans is also underway. Furthermore, NS-065 is now in a Phase I/II trial. Internationally, Phase II trials of NS-018 (a treatment for myelofibrosis) and NS-065 are underway.

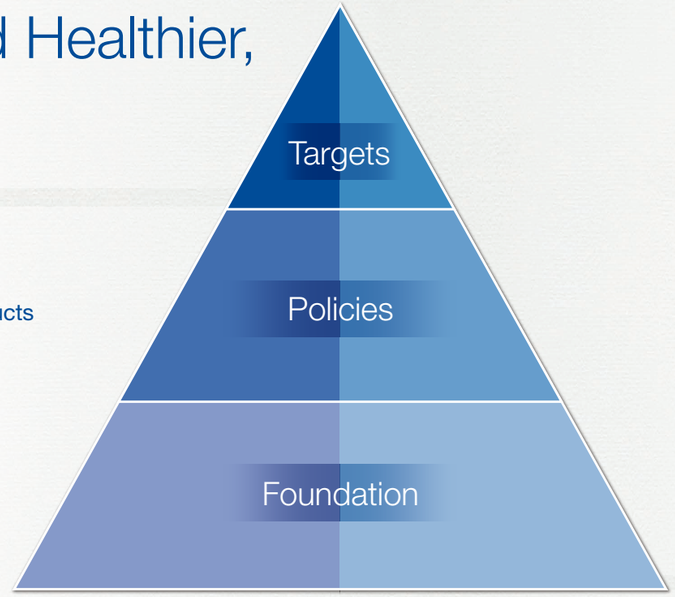
The Nippon Shinyaku Vision

CSR and the Promotion of Conscientious Corporate Activities

Our business philosophy, “helping people lead healthier, happier lives” is at the core of all our business activities. The entire Group is united in its aim to continually develop our pharmaceuticals and functional food businesses by wholeheartedly implementing all aspects of our management policy—supplying unique and high-quality products, earning the trust of society, and developing each employee. In order to achieve this, we fulfill our responsibilities vis-à-vis all our stakeholders—first and foremost patients, business partners, users, shareholders and investors, and employees—and attach the greatest importance to sustaining a trust-based relationship with all parties. We will further advance our sincere corporate activities by keeping a high ethical viewpoint and undertaking a range of CSR projects.

Business Philosophy

Helping People Lead Healthier, Happier Lives



Management Policy

Customers: Supply Unique and High-quality Products

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

Society: Earn the Trust of Society

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

Employees: Develop Each Employee

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

Guidelines for Action

Challenge: Meet Challenges

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

Speed: Speedy Action

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

Investigation: Spirit of Investigation

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

Corporate Vision

To be a company that plays a meaningful role in society in the healthcare sector

—To be a unique organization, trusted and valued by the community—

Pharmaceuticals To provide patients suffering from diseases with unique and high-quality products, targeting niche needs within our main fields of focus

Functional Food To utilize the high-level technology we possess as a pharmaceuticals company to provide high-added-value products to meet market needs, while focusing on our core areas

Code of Conduct

Relations with Business Partners

Through mutual trust and fair trade, we will maintain healthy and proper relations with business partners, so that we can grow together.

For Shareholders and Investors

We will strive to secure reasonable profits and return them to shareholders, while meeting the expectations of shareholders and investors through healthy and fair management practices, including timely and appropriate disclosure of corporate information.

For the Environment

We will strive to secure growth in harmony with the environment, by engaging in business activities that are friendly to the global environment and pursuing initiatives to conserve, maintain, and improve the environment.

For Patients

In the pharmaceuticals segment, we will develop and supply pharmaceuticals that are safe and highly effective, first and foremost for patients who suffer from illnesses.

For Users

In the functional food segment, we will develop and supply high-quality functional food that satisfies the needs of users, leveraging our advanced technology as a pharmaceuticals company.

Employee Relations

We will endeavor to provide safe and comfortable working conditions, and a motivating environment that makes each employee proud.

For Society

As a corporate citizen, we will closely communicate with and engage deeply with society, and actively pursue social initiatives.

Charter of Business Conduct

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 appropriate relationship with politicians, governments, and business partners.

VII We fully recognize the value of our corporate assets including information assets, 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.

(revised in July 2011)

Special Feature

The Development of Treatments for Intractable and Rare Diseases

Selexipag (NS-304) for pulmonary arterial hypertension

Obtained approval and began sales in the U.S. and Europe. Currently applying for approval in various other countries including Japan.

In our 5th Five-year Medium-term Management Plan launched in fiscal 2014, we are expanding our R&D pipeline and maximizing product value in our main fields of focus (urology, hematology, and intractable and rare diseases). Of these efforts, here we detail selexipag, a drug created by Nippon Shinyaku and developed as a treatment for pulmonary arterial hypertension (PAH), a rare and intractable condition.

2000–2003

Overview

PGI_2 receptor agonists

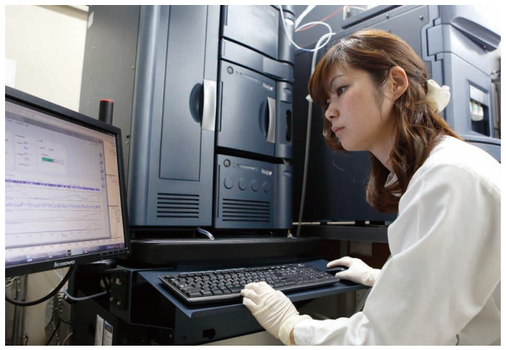
It has been over 15 years since we began research on selexipag, a prostacyclin (PGI_2) receptor agonist. PGI_2 is a physiologically active substance produced inside the body. It contributes to the maintenance of homeostasis by stimulating PGI_2 receptors expressed in blood vessels to produce a variety of effects including vasodilation and inhibition of vascular smooth muscle cell proliferation. It has been revealed that decreased production of PGI_2 is linked to various diseases, and PGI_2 continues to be a focus of attention as a target for drug discovery. However, as the substance PGI_2 itself is extremely unstable and difficult to handle, much research has been conducted toward creating a stable PGI_2 receptor agonist.

Basic research

Research starts from the mechanism of action: the long-acting oral drug eagerly anticipated by PAH patients

Our research team was working to develop an orally available, long-acting PGI_2 receptor agonist. Soon after starting, we discovered selexipag, a compound with favorable pharmacokinetic properties. The mechanism of action was the starting point for discovery in this research effort, so the next challenge after finding the target compound was to select an indication. Our research team learned of the disease PAH around 2000.

Until the 1990s, no drugs for specifically for PAH existed and lung transplant was essentially the only effective treatment. However, in the second half of the 1990s, continuous infusion of PGI_2 was developed as a treatment method and showed remarkably strong efficacy. Nevertheless, due to the unstable nature of PGI_2 as mentioned above, the treatment required an indwelling tube for infusing the drug solution into a wide vein near the heart. This caused problems such as decreased quality of life in patients and increased susceptibility to infections. Several PGI_2 derivatives had already been introduced into clinical practice as PAH therapeutic agents around the world, but most were administered by injection or inhalation, and there were no oral drugs with high efficacy targeting the PGI_2 pathway. In light of the above, the team concluded that PAH would be the best indication for selexipag due to its oral availability and superior pharmacokinetic properties.



Development strategy

Overcoming the rarity barrier of just 500 patients in Japan

In the 2000s, there were about 500 PAH patients in Japan, which meant that starting development in Japan would not be an easy task. When we worked out our development strategy, we decided to first develop selexipag for PAH outside of Japan in order to obtain POC[*1] and out-license the drug abroad. We would then start development in Japan and expand indications to a larger-scale disease in the future. In 2004, we performed our first microdose study[*2], which revealed that selexipag had a half-life of about 8 hours and showed favorable pharmacokinetic properties in a clinical trial.

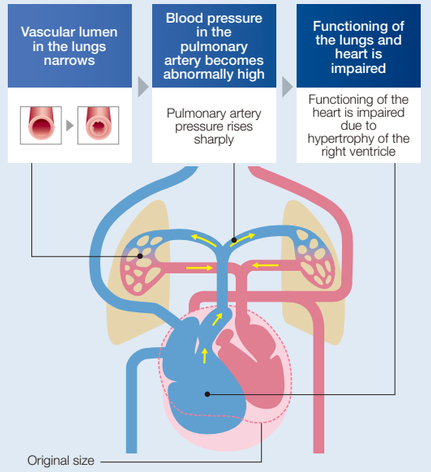
Also in the 2000s, treatment options for PAH significantly widened when oral drugs with different mechanisms of action, endothelin receptor antagonists (ERA) and phosphodiesterase type 5 inhibitors (PDE5i), were approved for the indication of PAH one after another. Advances in treatment and more active outreach led to an increase in PAH diagnoses, with the number of patients rising to between 10,000–20,000 in Japan and over 100,000 outside of Japan.

*1 Proof of concept: A study to assess pharmacokinetics and efficacy in humans
*2 Microdose study: A study in which a very small single dose of the trial drug is administered to healthy subjects in order to determine whether the drug exhibits the desired pharmacokinetic properties

Pulmonary Arterial Hypertension (PAH)

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 a contributing cause. While a mild case presents no particular subjective symptoms, the progression of the condition can present symptoms including breathing difficulty during physical activity and being prone to fatigue, 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



2004–2008

Clinical trials start

The harsh reality that selexipag must be administered alongside other drugs

From around 2004 to 2005, we attempted to obtain orphan drug designation for selexipag for PAH in Europe. We did not have any experience with this, but our team, led by the Clinical Development Department, International, succeeded in obtaining the designation. After that, we safely completed phase I trials inside and outside Japan and started a placebo-controlled phase II trial with pulmonary vascular resistance (PVR) as the primary endpoint in Europe in 2008. After starting the trial, it was discovered that all enrolled patients were receiving ERA or PDE5i treatment. By 2008, there were no more PAH patients in developed countries who had not received pharmacotherapy. Thus, we chose to administer selexipag alongside other drugs for the purposes of the trial. Even under these circumstances, selexipag decreased PVR with statistical significance compared to placebo, meeting the primary endpoint (Fig. 1).

Main steps of new drug development

Basic research

Discovery and creation of a candidate compound that will form the basis for a new drug. A candidate compound is found by searching through chemically synthesized compounds or natural ingredients.

Nonclinical studies

Assess the efficacy and safety of the candidate compound. Before clinical trials are conducted in humans, animals and cells cultured in test tubes are used to assess aspects of the compound such as its pharmacology, pharmacokinetics, and toxicity.

Clinical trials

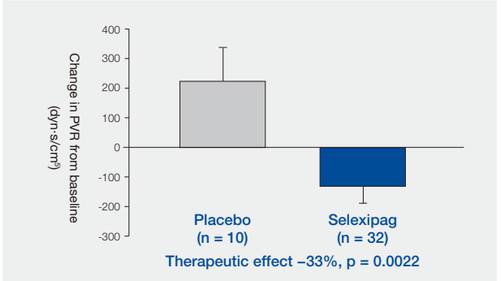
Trials are conducted to assess the efficacy and safety of the candidate compound in humans. Trials are usually divided into three phases. The potential of the compound to become a new drug is assessed through the following steps.

- **Phase I trial**: Assesses safety in healthy subjects
- **Phase II trial**: Assesses safety and efficacy in a small number of patients
- **Phase III trial**: Assesses safety and efficacy in a large number of patients

Application and review

After the efficacy and safety of a candidate compound are verified through clinical trials, an application for drug approval is submitted to the Pharmaceuticals and Medical Devices Agency (PMDA). Once the compound is approved through an expert review process, it can be manufactured and marketed as a new drug.

Figure 1 Effect of selexipag on pulmonary vascular resistance (PVR) in an overseas phase II trial



Simonneau G, et al. Eur Respir J, 40:874 (2012)

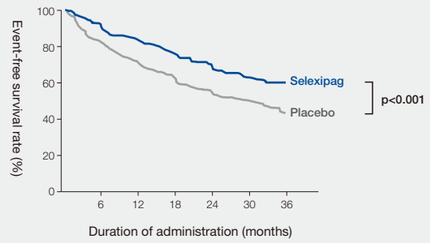
2009–2014

Global phase III trial

The largest-ever phase III trial in the field of PAH

In light of the favorable results of the phase II trial in Europe, our overseas licensee Actelion started a global phase III trial (GRIPHON study) in 39 countries at the end of 2009. Indicators often used in other phase III trials for PAH were not used, instead a measure of the essential effect of a drug on PAH (time to disease progression or death) was used as the primary endpoint. The number of enrolled patients was 1,156, the largest ever in a trial in the field of PAH. Of these patients, about 80% were also receiving ERA or PDE5i treatment. The plan for this trial was to continue the trial until a designated total number of disease progression or death events was reached. The designated number of events was reached in June 2014, more than four years after the start of the trial. The trial showed that selexipag was well tolerated and reduced the risk of disease progression and death events by 40% compared with placebo. Thus, the primary endpoint was met (Fig. 2). During this time, a small phase II trial was also conducted in Japan. As with the international trials, more than 80% of patients were taking selexipag in combination with other drugs, and selexipag showed efficacy in reducing PVR. Selexipag is highly evaluated among medical specialists inside and outside Japan because it has shown high efficacy despite initial concerns about coadministration.

Figure 2 Reduction in disease progression and death events by selexipag



2015–Present

Maximizing product value

Development of selexipag proceeding smoothly

Our overseas licensee Actelion applied for approval of selexipag in the U.S. at the end of 2014 and was granted approval about one year later. Following launch in January 2016, the number of prescriptions is increasing satisfactorily. Actelion applied for approval in Europe at the same time. Marketing authorization was granted in May 2016, and selexipag was launched in Germany in June of the same year. Nippon Shinyaku applied for approval in Japan in January 2016, and currently the review process is underway. The previously unmet medical need for clinical application of an orally available drug with high efficacy targeting the PGI_2 pathway is poised to be met all over the world, and its dawn is anticipated to greatly expand the scope of treatment for PAH. This addition of selexipag to Adcirca® and Opsumit®, drugs we have already marketed, will enable us to propose treatments optimized for individual patients (Table 1).

Table 1 Offering drugs with all three different mechanisms of action expands pharmacotherapy options for the intractable disease PAH

Treatment category	Generic name (product name)	Mechanism of action
PGI_2 receptor agonist	**Selexipag** **Japan:** Application **Overseas:** Sold as Uptravi® by Actelion in Europe and the U.S.	Exhibits vasodilation action, platelet aggregation inhibitory action, etc.
Endothelin receptor antagonist (ERA)	**Macitentan** (Opsumit®)	Expands blood vessels by suppressing the effect of endothelin, a substance that is produced in the body and exhibits a vasoconstrictor action.
Phosphodiesterase type 5 inhibitor (PDE5i)	**Tadalafil** (Adcirca®)	Expands blood vessels by strengthening the effect of nitrogen monoxide (NO), a vasodilator substance produced in the body.

Researcher's Comments

General Manager, R&D Administration Department
R&D Administration Division
Research and Development Division
Keiichi Kuwano

My visit to a website of a family affected by PAH that overwhelms me with emotion on every read

Back around the year 2000, when there was not much awareness of pulmonary hypertension, I attended a meeting of medical specialists. I was strongly moved by being in the presence of these doctors eagerly engaged in discussion and passionately working to treat rare diseases. Also, when I was studying about PAH, I came across the website of a family affected by PAH. The site was run by a mother of two preschool-aged daughters whose older daughter had already passed away due to PAH. After that, her husband also developed PAH and fought a long battle while receiving PGI_2 infusions, but he ultimately was taken as well. In what seemed like a final blow, her younger daughter was found to have inherited the causal gene for PAH from her father, and she also soon developed PAH. In spite of all this, the mother continued to faithfully document the ups and downs of the family's fight with the disease and their normal everyday life in a positive writing style.

I began to feel frustrated that even though I had this drug selexipag at hand and I had the utmost confidence in its efficacy, I could not bring it to patients right away. The more I learned about the medical realities of patients, I came to believe that it was my mission to bring selexipag to the world to treat PAH.

Hoping to bring selexipag to patients around the world

Now that the development of selexipag is proceeding smoothly, I sometimes think about that mother and her daughter again. I have no way of knowing how they are doing as the website has been shut down, but I truly hope they are doing well. I have been working on developing selexipag for many years now. I believe that through this drug, I have learned the importance of listening to the voices of doctors and patients and understanding their needs and concerns in drug discovery. I sincerely hope to grow selexipag into a drug that brings hope to patients all over the world.

Enhancement of Corporate Value through Business Activities

Pharmaceuticals

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.

Business Outline

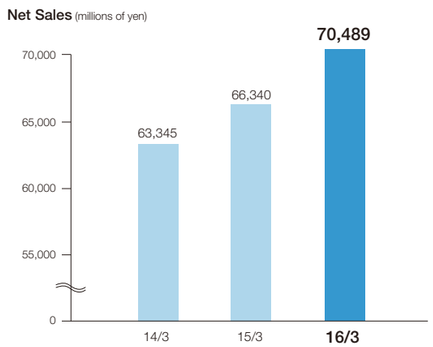
Market conditions remain challenging

The Japanese pharmaceuticals market environment has been affected in recent years by continuous strengthening of government policy to control medical costs. The domestic market environment is becoming ever more difficult with the implementation of the 2016 NHI price system reform, including policies aiming to increase the market share of generics to over 80% by the end of 2020, and policies to drastically reduce/recalculate prices in cases where the market has expanded far in excess of forecasts given at the time of NHI price listing*1. On the other hand, policies such as the SAKIGAKE Designation System*2 are being introduced to bolster the drug development capabilities of the industry by highly evaluating cutting-edge treatments with the potential for global rollout and innovative new drugs.

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 is continuing its efforts 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.

During the current period, sales of long-listed drugs decreased due to the influence of generics and competing products, but sales of new product suites increased, including Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy, Vidaza®, a myelodysplastic syndrome (MDS) treatment, and Tramal® and Onetram® for cancer pain and chronic pain. In addition, we posted the revenue from industrial property rights accompanying the partner-led U.S. approval of selexipag (code number: NS-304), our original pulmonary arterial hypertension (PAH) treatment. As a result, net sales were ¥70,489 million, an increase of 6.3% year-on-year.

*1 NHI price listing: Approved as a prescription drug covered by NHI
*2 A system under which approval is given priority if an innovative drug designated by the Japanese Ministry of Health, Labour and Welfare meets certain conditions, enabling the world's most advanced treatments to be provided to patients as quickly as possible.



Social Agenda

We strive to be a "pharmaceutical treatment partner," targeting conditions which have unmet treatment needs

We provide high-quality, unique drugs, targeting conditions which have unmet treatment needs. Urology, hematology, and PAH are our priority main fields of focus. In particular, our MDS treatment Vidaza®, and PAH treatments Adcirca® and Opsumit®, are used by highly specialized practitioners in specific hospital departments.

We also have a duty to provide evidence-based product information to further correct use, and to rapidly grasp the ever-changing needs of patients and medical professionals to provide them, in a timely manner, with the healthcare information they need. We strive to gain the trust of the whole community, not just healthcare providers, and to become a "pharmaceutical treatment partner" for both patients and medical professionals.

Pipeline

Japan

As of May 12, 2016

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase I	Phase II	Phase III	Application	Launch
NS-304 (Selexipag)	Application	Intractable and rare diseases	Pulmonary arterial hypertension (PAH)	Nippon Shinyaku	Co-development: Actelion Pharmaceuticals Japan Ltd.					
	Orally available, long-acting PGI_2 receptor agonist. Received orphan drug designation from the Ministry of Health, Labour and Welfare in September 2014, as a PAH treatment. Efficacy evaluation of PII trial targeting PAH, jointly conducted with Actelion Pharmaceuticals Japan Ltd., has been completed, and application for approval in Japan was submitted in January 2016.									
GA101 (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.									
NS-304 (Selexipag)	PII	Intractable and rare diseases	Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Co-development: Actelion Pharmaceuticals Japan Ltd.					
	Orally available, long-acting PGI_2 receptor agonist, currently in PII trial conducted together with Actelion Pharmaceuticals Japan Ltd.									
	PII	Cardiovascular and metabolic system	Arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku					
	Currently in PIIa trial.									
NS-141	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. Currently undergoing additional PIIa trial targeting itching caused by atopic dermatitis.									
NS-065	PI/II	Intractable and rare diseases	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. Following clinical trial notification submission in January 2016, PI/II trial is underway.									
NS-580	PI	Gynecological diseases	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_2. PI trial began in April 2015.									

Overseas

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase I	Phase II	Phase III	Application	Launch
NS-304 (Selexipag)	U.S. approved Europe approved	Intractable and rare diseases	Pulmonary arterial hypertension (PAH)	Nippon Shinyaku	Licensed-out to: Actelion Pharmaceuticals Ltd. (Switzerland)					
	Our licensing-out partner Actelion Pharmaceuticals Ltd. (Switzerland) received approval in the U.S. in December 2015, and the product was launched in January 2016. European marketing authorization was granted in May 2016.									
NM441 (Prulifloxacin)	In preparation for application	Infectious diseases	Synthetic antibacterial	Nippon Shinyaku	Licensed-out to: Lee's Pharmaceutical Holdings Ltd. (Hong Kong)					
NS-018	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. Currently undergoing PI/II trial in the U.S.									
NS-065	PII	Intractable and rare diseases	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. Following IND application submission to the FDA in March 2016, PII trial is underway.									

Enhancement of Corporate Value through Business Activities

Pharmaceuticals (Research & Development)

We are committed to providing unique drugs and creating a fully integrated pipeline, based on our three pillars: in-house drug discovery, in-licensing, and PLCM

We are committed to bringing new products to market, both steadily and continually, in areas which do not have established treatment methods

As a basic strategy, our core R&D is in the priority domains of urology, hematology, and intractable and rare diseases, which together with gynecology and otorhinolaryngology make up our five main fields of focus. We are committed to the rapid provision of treatments that fulfill unmet medical needs and bringing them to patients as soon as is feasibly possible.

At Nippon Shinyaku, we aim to create unique drugs and build our development pipeline on the three pillars of 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.

Initiatives to produce unique drugs

As an R&D-oriented pharmaceuticals corporation, we will apply our full capabilities to develop the original production of unique and superior drugs, concentrating on our specialized areas of expertise.

Scientific research and medical advances have led to a segmentalization of diseases, which has in turn made the development of therapies more difficult. We are proactive in the development of new technologies, particularly nucleic acid drugs, in order to discover effective medications. We are also committed to open innovation in conjunction with academia (i.e. universities and other academic research institutes) involved in the investigation of drug targets.

In the development of drugs for intractable and rare diseases, we fully utilize the Japanese government's SAKIGAKE Designation System and other implementation aids to make these drugs available as quickly as possible.

Nucleic acid drug research

Our Discovery Research Laboratories in Tsukuba (Ibaraki Prefecture) produces nucleic acid drug* products utilizing the technological foundation of nucleic acid research. It is anticipated that nucleic acid drugs, which directly target disease-causing genes, will be effective against intractable diseases which are difficult to treat using low molecular weight drugs and antibody drugs.

* 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

Enhancement of the R&D pipeline

We work actively to in-license both marketed products and development candidates in order to enhance the R&D pipeline that promises synergies with our product lineup. In terms of PLCM, we examine new indications, new formulations, and other possibilities for our products on the market and under development, in order to maximize product value.

Manufacturing Building for Active Pharmaceutical Ingredients for Clinical Trials

Discovery Research Laboratories in Tsukuba

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

Plans for more rapid R&D

We allocate appropriate management resources to our three pillars—in-house drug discovery, in-licensing, and PLCM, and steadily bring new products to market.

Actelion, the overseas licensing-out partner for our pulmonary arterial hypertension (PAH) medication selexipag (code number: NS-304), received approval from the U.S. Food and Drug Administration (FDA) in December 2015, and the drug entered the U.S. market in January 2016. Actelion received marketing authorization from the European Commission (EC) in May 2016, and Nippon Shinyaku submitted an application for manufacture and marketing approval to the Japanese Ministry of Health, Labour and Welfare in January 2016. Alongside Opsumit® 10mg tablets and Adcirca® 20mg tablets already on the market, the further addition of selexipag will complete a full lineup of drugs that exhibit the three different mechanisms of action (endothelin receptor antagonist, phosphodiesterase type 5 inhibitor and PGI_2 receptor agonist) generally used in PAH therapy at present.

In March 2016, a manufacturing building for active pharmaceutical ingredients for clinical trials, designed to be compliant with all legal regulations and the latest GMP standards, was completed in our head office area. This building is equipped with large-scale synthesis machinery, a containment facility, and a facility for isolation and purification. This building will be used to produce, in a rapid and flexible manner, the active pharmaceutical ingredients, including highly active substances and nucleic acid drugs, necessary for the development of pharmaceuticals, and thus help us accelerate our R&D.

Effective use of internal and external resources to enhance our R&D pipeline and accelerate development

The development of promising original drugs in our R&D main fields of focus is proceeding smoothly.

NS-065, Japan's first ever antisense nucleic acid drug, a Duchenne muscular dystrophy therapy which we developed in joint research with the National Center of Neurology and Psychiatry (NCNP), is now undergoing a PI/II trial in Japan, and a PII trial in the U.S. It was designated under the SAKIGAKE Designation System by the Japanese Ministry for Health, Labour and Welfare in October 2015. This support from the government will help us to continue developing the drug.

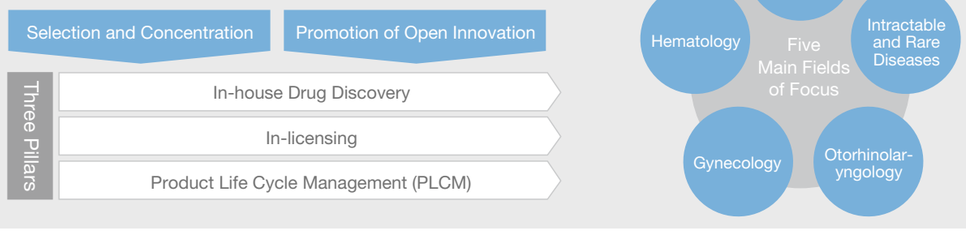
The Japanese PI trial of NS-580, an endometriosis drug with an anticipated analgesic effect brought about by the inhibition of PGE_2 production, is proceeding smoothly.

Similarly, the U.S. PI/II trial of NS-018, a myelofibrosis therapy with a JAK2 kinase inhibitory effect, is proceeding smoothly.

As an R&D-based manufacturer of new drugs, we focus on conditions with no established therapies, and proactively develop products which offer a welcome relief for patients.

Enhancement of the R&D pipeline in our main fields of focus

We will enhance our R&D pipeline in order to continually bring drug products to market in our main fields of focus



Enhancement of Corporate Value through Business Activities

Pharmaceuticals

(Sales)

Our aim is to be able to grasp the needs of patients and medical professionals and fulfill them as quickly as possible

Our organization sees things from the perspective of medical professionals, and this improves the quality of the information we provide

Our Marketing Division has set up three promotion departments for our main fields of focus, putting in place a system for providing specialists and doctors with high-quality information. Main products handled are: Zalutia® (Marketing & Development of Urology Department), Adcirca® and Opsumit® (Marketing & Development of Pulmonary Hypertension Department), and Vidaza® (Marketing & Development of Hematology Department). Through this arrangement, we are maximizing the value of our products by enhancing promotional campaigns targeting key opinion leaders (KOL)* throughout Japan, formulating strategies for the future of the drugs, and executing specific action plans.

We have expanded our hospital sales offices, increased the number of outreach personnel with extensive specialized knowledge, and bolstered our academic follow-up system to enable us to provide precise information, as quickly as possible, about the proper use of our specialized drug products such as Vidaza® and Adcirca®. Close collaboration between our medical reps and our academic liaison staff enhances the quality of this information even further, and helps us achieve our aim of providing medical professionals with the information they need when they need it.

Our medical reps are required to have a high level of knowledge and awareness of up-to-date information if they are to promote the proper use of highly specialized medical products and thus meet the needs of medical professionals in a pinpointed fashion. In fiscal 2013 we established an in-house accreditation examination system to ensure that medical practitioners can be properly provided with the information they need. Thus we are making efforts to create a culture of ambition and continuous pursuit of knowledge. There are a number of accreditation levels; medical reps who have passed the basic course can proceed to the advanced course and then the specialist level course.

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

Shouzou Sano
Director, General Manager,
Sales and Marketing Division

The provision of information regarding proper use helps us in our efforts to secure greater market penetration for our unique new product suite

We will focus all our energy on securing greater market penetration for our new product suites launched under our strategic R&D management initiative as set out in the 5th Five-year Medium-term Management Plan.

In the field of urology, we will develop consistent promotion activities, chiefly aimed at specialists, to deepen understanding of the new mechanism of action of Zalutia®.

In the field of hematology, we will provide medical professionals with information when they need it, regarding the proper use of Vidaza® (launched in 2011) and other blood cancer therapies.

In the field of PAH, in addition to the existing products Adcirca® and Opsumit®, we will focus our attention on the launch of NS-304 (generic name: selexipag), and provide up-to-date information in accordance with the needs of medical professionals to contribute to the treatment of PAH patients.

Enhancement of Corporate Value through Business Activities

Pharmaceuticals

(Production)

We are pursuing the stable provision of high-quality products to society

We will enhance our stable product supply system by improving productivity at all stages—procurement, manufacture and distribution

Our greatest mission is to provide a stable supply of high-quality products to society. Under the 5th Five-year Medium-term Management Plan, which commenced in fiscal 2014, stable supply of products will be guaranteed through tighter cost management and initiatives to improve productivity at all stages of the process—procurement, manufacture and distribution. We will enhance our credibility in terms of efficacy and safety, and firmly guarantee product quality. Our business continuity plan (BCP) will be strictly adhered to: inventory standard targets are being maintained and storage areas for product stock are being split to reduce risk, our Odawara Central Factory is being refurbished and all production equipment is being kept in good maintenance, and a manual is being compiled to help deal with natural disasters. Through these measures we will guarantee an uninterrupted supply of drugs which have significant social impact, such as anti-cancer drugs and treatments for rare diseases.

We are committed to improving our GMP levels through our formidable technological power as a manufacturer of new drugs

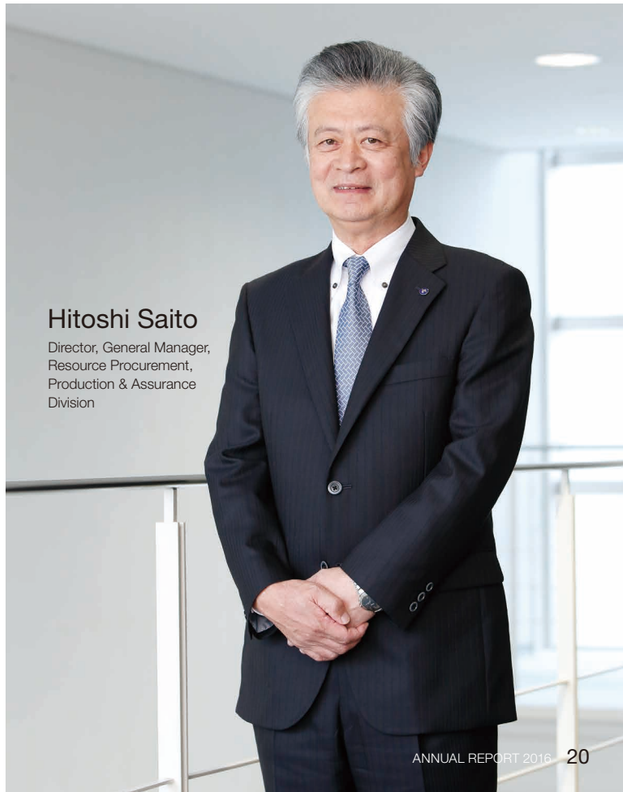
Continuing in our stride from last year, we are sourcing raw materials from two separate suppliers, and have undertaken initiatives to ensure stable operation of all manufacturing equipment and stringent GMP*1 management. We have implemented policies to make employees more versatile and have put in place BSC*2 mechanisms in order to make our Odawara Central Factory more competitive in terms of quality and costs. With regard to our consignment manufacturing business, by utilizing our technology we have accumulated over many years as a manufacturer of new drugs, and our microparticle coating machine, the largest of its kind in Japan, we will proactively develop our consignment manufacturing business, from formulation design of investigational new drugs to commercial production. In fact we have recently won contracts to manufacture two products. Japan's accession to PIC/S*3 was approved in 2014. We are subsequently committed to improving our GMP levels in this era of ever greater PIC/S GMP requirements.

*1 Good Manufacturing Practices: Production management and quality management standards for pharmaceutical products
*2 Balanced Scorecard: A method for comprehensively measuring the extent to which the corporate strategy has been implemented
*3 A general abbreviation for Pharmaceutical Inspection Convention (PIC) and Pharmaceutical Inspection Co-operation Scheme (PICS)

We implement stringent consolidated risk management, from development to after-sales

Moving forward, we continue to implement stringent measures to guarantee product quality and safety which are essential to us as a pharmaceuticals company. To guarantee quality, we strictly adhere to GQP*4 and implement a product quality risk management policy, measures which are constantly being improved in our moves to construct an ever-better product quality system. To guarantee safety, we strictly adhere to GVP*5 and implement a stringent risk management policy which encompasses the entire process from product development to after-sales. We are building a manufacturing facility for highly active solid formulations at our Odawara Central Factory, and manufacture of in-house products is due to commence in fiscal 2018. In addition to the advanced technology we have accrued so far, we intend to make the manufacture of highly active drugs one of our core areas and use this to expand our consignment manufacturing business. Our endeavors to further our stable product supply strategy will help the Odawara Central Factory to maintain its reputation as a facility which achieves high levels of customer satisfaction.

*4 Good Quality Practice: Quality management standards for pharmaceutical products
*5 Good Vigilance Practice: Safety management standards for pharmaceutical products after marketing approval



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

Enhancement of Corporate Value through Business Activities

Functional Food

As a pharmaceuticals company active in the functional food business, we contribute to healthy longevity, active lifestyles, food safety, and food waste reduction

Nippon Shinyaku launched its functional food business in 1961 with the belief that medicine and food share the same importance in maintaining good health. We utilize the advanced technological prowess we have built up as a pharmaceutical company to help people lead healthier, happier lives in terms of diet by developing and providing high-quality, highly original functional food ingredients.

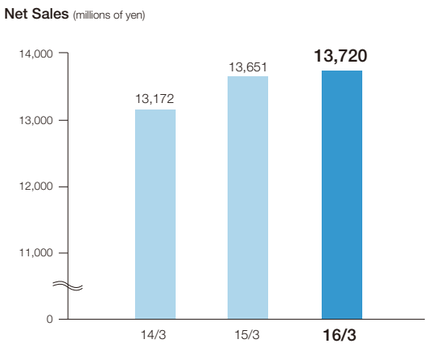
Business Outline

We have concentrated on flagship product initiatives and increased our revenue

In the Japanese processed foods market, the lack of clarity with regard to future economic trends has hit consumer confidence, and this has intensified price competition. Furthermore, recent incidents of food contamination and distribution of products which should have been discarded have increased food safety costs and responsibilities for processed food manufacturers, who now find themselves operating under a very tough environment.

On the other hand, in the health food sector, the new labeling system for foods with function claims has been launched, leading to a range of new products which promote a variety of functionalities going to market. We foresee growth in this field as people become more familiar with foods marketed under these labels.

Net Sales (millions of yen)



It is against this backdrop that we have strengthened our resolve, as an R&D-based manufacturer, trusted by customers, which provides high-quality, highly original products, to develop products for the processed foods and healthcare sectors.

In particular, we have given priority to initiatives to increase sales of our flagship products (health food ingredients, preservatives, nutritional ingredients, and soy protein). The result of these efforts was that although sales of nutritional ingredients decreased owing to reductions in selling price, sales for all other items are proceeding steadily, and net sales for the current period were ¥13,720 million (up 0.5% year-on-year).

Social Agenda

We must be ready to meet ever diversifying needs

Food needs are becoming increasingly diverse with lifestyle changes, aging society and increased health-consciousness, and this has led to more complex product expectations and requirements. Furthermore, we are now required to provide far more food safety information to guarantee food safety and give customers the peace of mind to which they are entitled.

We analyze these evolving needs as accurately as possible, and then use our knowledge of the pharmaceutical business to meet these needs through the development of new products and quality management, and thus contribute to society.

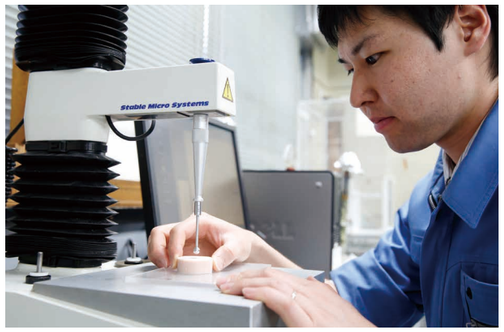
Central Themes

We aim to increase sales by defining clear targets

Health food ingredients, preservatives and protein ingredients have been set as our new flagship products, and we have defined clear targets in order to increase sales. We are committed to increasing sales of health food ingredients such as mangosteen extract, aronia extract and amla extract, and products eligible for functionality labels, such as garcinia extract and hyaluronic acid, and to enhancing our customer support systems. In the preservatives sector, we are actively expanding sales channels of the Mikaku Fine series, KC-20 and Glycine GX-2, all of which are produced using our unique formulation technology. In the protein ingredients sector, we are promoting sales of dairy protein for the sports nutrition and healthcare sectors, and are looking to expand our soy protein sales channels.

We provide unique high-quality, high-added-value ingredients

We see the provision of unique, high-quality, high-added-value ingredients, which contribute to healthy longevity, active lifestyles, food safety, and food waste reduction, as our mission. We contribute to healthy longevity and active lifestyles by providing protein ingredients and unique health food ingredients which have anti-aging and anti-locomotive syndrome properties. We contribute to food safety and food waste reduction by tightening our anti-contamination measures and improving our quality assurance system, and by developing preservatives for the processed foods market which have a minimal impact on flavor.



Our new systems enable us to improve customer support

For the upcoming period, we foresee a slight drop in net sales due to decreases in the selling price of certain products.

The corporate organization has been restructured into two groups: healthcare and daily foods—each group with specialized sales and R&D divisions. Under this new system, highly specialized information in each field will be provided to customers, and rapid and precise technical support, at a higher level than previously possible, will be achieved.

In addition, we aim to succeed in developing final products which directly convey our passion for food to customers, and further growing the Functional Food Division.

Corporate Governance

Basic Concepts of 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, in line with four clearly defined basic concepts (which are posted on our website), we are working non-stop to enhance corporate governance as a means of driving sustainable growth and increased value of our public presence, as well as mid-term and long-term corporate value.

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

Overview of Corporate Governance Organization

Nippon Shinyaku is a company with auditors, with nine directors (of whom two are external directors) and four corporate auditors (of whom two are outside auditors). Furthermore, a Nominating Committee and Remuneration Committee operate under the supervision of the Board of Directors.

Directors' terms of service are renewed on a yearly basis in order to better clarify their managerial responsibilities and to ensure an organization conducive to optimal governance in keeping with the business climate. Meanwhile, the appointment of two external directors is intended to further improve managerial transparency and objectivity and ensure stringent oversight of directors' performance.

Corporate auditors attend all meetings of the Board of Directors as well as important business-related meetings. The two outside auditors, whose independence from the Company is guaranteed, oversee management through the Board of Auditors.

Implementing the Corporate Governance Code

Adhering to the essence and spirit of the Corporate Governance Code spelled out by the Tokyo Stock Exchange in June 2015, Nippon Shinyaku assessed the state of our efforts to implement the code's principles for the sake of sustainable growth and improved corporate value in the mid-term and long-term. The Corporate Governance Report released the following December carries out "Disclosure Based on the Principles" and, where necessary, discloses "Reasons for Non-compliance with the Principles" at the present time.

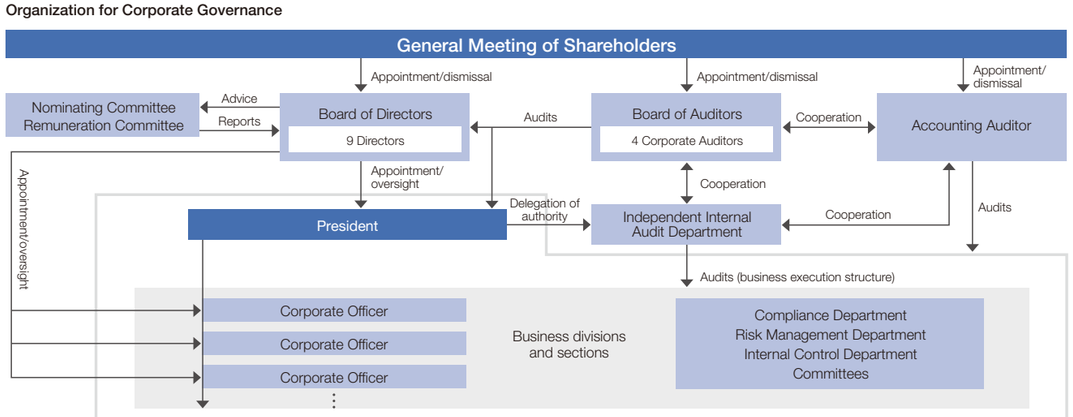
Internal Control System

The internal control system is stipulated under the Companies Act and prescribes the basic policy of the Board of Directors, while establishing a framework to ensure the proper execution of 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.

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.

Organization for Corporate Governance



The following items are posted on our website (Japanese only). **http://www.nippon-shinyaku.co.jp/company-profile/governance**

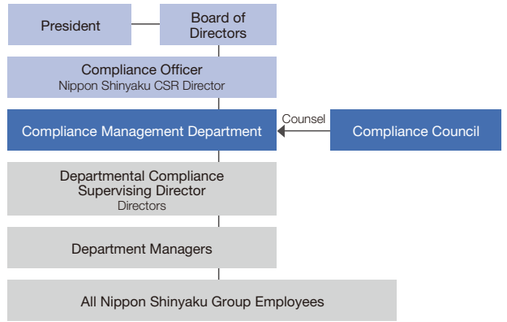
- Corporate Governance Report
- Corporate Governance Basic Policy

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 Framework Chart



Compliance Initiatives

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

In fiscal 2015, the President and compliance officer issued messages to employees in April and October to further promote compliance and raise awareness of its importance, and we implemented the training and educational activities outlined below.

Compliance Training in Fiscal 2015

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.
Enhanced Training (October–November)	Departmental compliance training in October followed-up by supplemental training through e-learning in November; the theme for fiscal 2015 was "The Compliance Reporting System."
Training on the Charter of Business Conduct for new employees	Call to enhance understanding of and compliance with the Charter of Business Conduct.

Education Initiatives

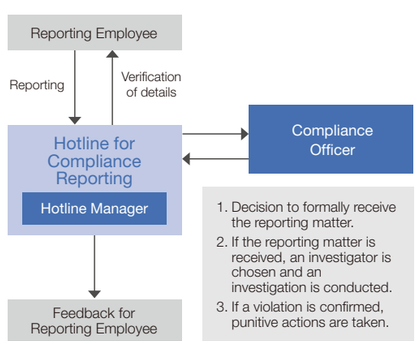
- Conducted e-learning education for compliance for employees in their 2nd year of employment.
- Prepared compliance education posters with slogans and designs solicited from employees, and put up posters in each department.
- Created compliance cards combined with safety contact cards and distributed 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. We have set up hotline call centers both within and outside the Company and these can be reached through a dedicated phone number or e-mail address, with guidelines in place to protect the privacy of reporting employees and to secure confidentiality.

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

Furthermore, we took up "The Compliance Reporting System" as the theme for enhanced compliance training in fiscal 2015 in order to further spread awareness throughout our group companies.



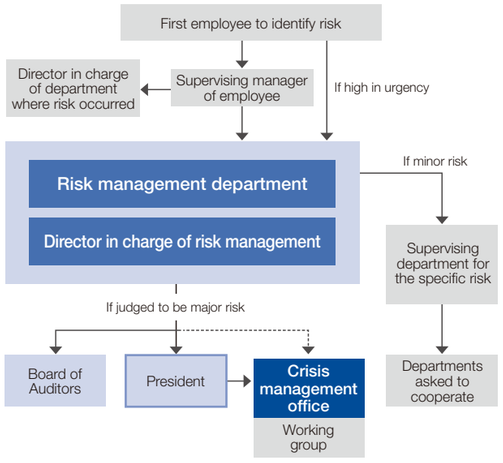
Risk Management

Framework for Risk Management

At the Nippon Shinyaku Group, departments managing risks formulate preventive policies and methods for responding to risks. This is done based on the Basic Risk Management Rules. Additionally, each year we identify highly critical risks. In fiscal 2015, these were “information management,” “disasters,” and “harassment,” which led us to beef up our management framework and raise awareness. Furthermore, every year we conduct a survey of all employees for the purpose of verifying each individual’s risk awareness.

When a risk does arise, the director in charge of risk management receives a report from the risk management department, and then assesses the effect the risk will exert on business operations. If the effect is considered minor, the department assigned to handle such a risk will be directed to respond. If, on the other hand, it is deemed that the risk will have a serious effect on business operations, the President will be immediately notified, while a temporary crisis management office will be established to deal with the risk and control it in a timely manner.

Path of Risk Notification (as of April 1, 2016)



Initiatives for Information Security

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.

We are also advancing technological measures tailored to advancements in IT and changes in society in order to protect the Nippon Shinyaku Group’s information assets from a variety of risks. At the same time, as a countermeasure against human risks, we have revised various company rules and educate our employees so they recognize the importance of information security.

In fiscal 2015 we focused our activities on computer viruses, cyberterrorism, and the corruption, disappearance, fabrication, and leakage of electronic data, and engaged in employee education, awareness-raising, and disclosure of information.

Since dealing with the new Japanese social security and tax number system will entail handling personal information both internally and externally, Nippon Shinyaku is using business process outsourcing (BPO) as a security measure to minimize the risk of information leakage as we collect, store and manage this information.

In the future we will continue to strengthen our information security.

Anti-Harassment Action

We consider harassment a serious issue that disrespects and infringes upon the human rights of its victims. In addition to establishing the Workplace Improvement & Human Rights Awareness Committee to prevent harassment in all forms and to maintain a positive working environment, the Nippon Shinyaku Group has written and enforces the Harassment Prevention Rules. There are other ways we work to prevent harassment, such as compliance training, as well as the production of an informative pamphlet about our anti-harassment policy which we distribute to all employees.

Disaster Planning (Formulating the BCP)

To make sure patients are not cut off from supplies of drugs in the event of an earthquake or other disaster, Nippon Shinyaku has formulated a business continuity plan (BCP) to deal with a powerful earthquake (“6 upper” on the Japanese Shindo seismic intensity scale) at the Odawara Central Factory, our primary pharmaceutical production center. In fiscal 2015 we revamped our efforts to strengthen the mutual support between us and storage locations for pharmaceutical products, as well as other partner companies involved in their handling. We will continue to further develop our BCP in the future as needed.

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

President

Shigenobu Maekawa

Directors

Yoshiro Yura
(General Manager, Administration Div.)

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

Kenro Kobayashi
(General Manager, Functional Food Div.)

Managing Directors

Tsugio Tanaka
(General Manager, Business Management)

Akira Matsuura
(General Manager, Research & Development Div.)

Shouzou Sano
(General Manager, Sales and Marketing Div.)

Yukio Sugiura
(External Director)

Hitoshi Sakata
(External Director)

Corporate Auditors

Tomoyuki Oota
(Standing Corporate Auditor)

Hideya Mukai
(Standing Corporate Auditor)

Kazuhiro Imai
(Outside Auditor)

Tsuyoshi Kondo
(Outside Auditor)

Corporate Officers

Taro Sakurai
(General Manager, Finance & Accounting Dept.)

Hirokata Harada
(General Manager, Clinical Development Div.)

Seiichiro Morimura
(General Manager, Licensing & Alliance Div.)

Takashi Takaya
(General Manager, Sales and Marketing Planning Div.)

Takanori Edamitsu
(General Manager, Corporate Planning Dept.)

Yuji Kamiyoshi
(General Manager, Nishinihon Div.)

Hisashi Suehara
(General Manager, Regulatory Affairs Supervision and Assurance Dept.)

Koji Honma
(General Manager, Personnel Dept.)

Hideki Sasaki
(Manager, Odawara Central Factory)

Current as of July 2016

Comments from External Directors

I use my knowledge as a pharmacologist to provide close supervision.

The reform of the drug price system implemented this past April was tough for the pharmaceutical industry. The Japanese market will have fewer long-listed drugs in the future, while growth is expected to slow. I believe Japanese pharmaceutical companies will be more active in expanding into the international market. Makers of new drugs will need to understand their strengths and really think about what groups of patients they are going to cater to. Expansion overseas will likely be a requirement for future growth. As an external director in these circumstances, what is demanded of me is that I use my expertise as a pharmacologist to check on the management and profitability of research and development—especially new drug development—and overseas expansion. I also feel it is important to contribute to stimulating the pharmaceutical business and improving corporate value by devoting efforts to enhancing corporate governance.

Yukio Sugiura

I want to work hard on enhancing corporate governance and help develop a sound managerial organization.

Hitoshi Sakata

In addition to creating new drugs and enhancing our domestic sales operations, I think that Nippon Shinyaku will be proactive in globalizing its corporate activities. As an external director in this new period of change, I would like to work hard on enhancing corporate governance and cooperate with all corporate officers to adapt quickly to new changes. I believe these actions will also help raise corporate value.

I commend the Board of Directors in fiscal 2015 for engaging in lively, multi-faceted discussions that were rich in their content. Continuing on into the current fiscal year we need to maintain that atmosphere, which will lead to Nippon Shinyaku achieving essential goals and overcoming challenges. I myself would like to help develop a sound managerial organization by maintaining my independence and exercising greater discernment.

Patients and Medical Professionals

Creating the unique medicines patients truly want

With a focus on patients with intractable conditions for which there is no effective treatment yet and on diseases where there is a strong desire to improve quality of life, Nippon Shinyaku is passionately committed to making unique medicines that only we can create. Furthermore, our job as a drug manufacturer goes beyond supplying medicines—it includes giving constant thought to what we can do for patients and medical professionals, providing information on the medicines we market, educating patients, and finding ways to eradicate counterfeit drugs. Our highest mission is to continue our many efforts to ensure the safety of our patients.

Providing Information

Disease Education Initiatives

At Nippon Shinyaku, we distribute information helpful for resolving health concerns through a number of websites.

On our "Support Site for Alcohol Dependence" (Japanese only; 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 to answer common questions and misunderstandings patients have about the condition.

On our "ED Care Support" website (Japanese only; 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.

A significant number of women endure menstrual cramps, with relatively few of them aware that endometriosis or other disorders are possible causes. That is why at "Talking about Menstrual Cramps" (Japanese only; http://seiritsu.jp/) we provide patients concerned about menstrual cramps with information and educational materials about the subject.

In fiscal 2016, we launch "Pulmonary 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 hypertension treatment.

"Support Site for Alcohol Dependence" website

"Talking About Menstrual Cramps" website

Providing Product Information

Nippon Shinyaku operates a Customer Call Center which receives inquiries from physicians and pharmacists, and replies 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 patients' and medical professionals' valuable 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 pharmaceuticals guides and information aimed at improving wellness.

We also contribute to a variety of media, such as our educational articles on ED in newspapers. 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

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 unfailingly secure the quality, efficacy, and safety that are indispensable to pharmaceutical products.

At the R&D stage of product development, we carry out clinical and non-clinical tests, and prepare application documents for manufacture and 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 fulfill our responsibilities to the market by assuring the quality of the product being manufactured and sold, affirming its safety, as well as working to maintain and manage such 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*4

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, etc.

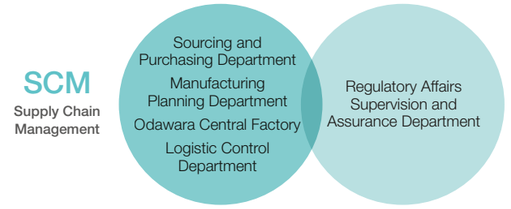
*3 GLP: Good Laboratory Practice *4 GCP: Good Clinical Practice

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



Stable Supply of Products

At the Odawara Central Factory, we introduced an original qualification certification system in fiscal 2014 and are working to enhance the versatility of employees' skills. Under a vision to be a factory that is competitive in terms of cost and quality, we have implemented the balanced scorecard (BSC) management method 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 2015, 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.

*5 Key performance indicators: Particularly important indicators among the business process monitoring indicators set under the 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 averse to unpleasant tastes and orally dissolving medicines without any need for water for patients who have difficulty swallowing tablets.

Measures Against Counterfeit Drugs

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 about 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.

Patient trust is won by listening carefully and giving a sincere response.

Medical care centers around the patient. At the Customer Call Center, we provide answers over the telephone to put patients at ease so they can receive safe and effective drug treatments. We also pass on what they tell us to relevant departments for the purposes of product improvement.

Patients talk to us about many different things. Some want to know when their medicine will start working, or what to do if they forget to take it. Others are concerned about side-effects or find their medicine unintuitive to use. Sometimes I cannot give them the answers they want, which is disappointing for them. And yet at other times, after listening carefully and giving a sincere response, in the end they are happy they called and express their gratitude.

I think it is an important role for us to earn patients' trust in this manner.

Akiko Nishimura
Customer Call Center, Pharmaceutical Information Department, Sales and Marketing Planning Division, Marketing Division

Creating a workplace where employees can grow and apply diverse individuality

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 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.

Promoting Work-Life Balance

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

To enable our employees to do their jobs properly while dealing with obligations such as child-rearing or nursing care, we have introduced a staggered working hours system that lets employees change their starting and ending hours of work according to their childcare, nursing care, and work circumstances.

We also have the Work Style Review Initiative, which aims to further improve working styles by examining current working styles through the setting of focused working hours and the use of self-inspection tools. The purpose is to achieve workplace approaches that improve the productivity of each individual employee. We are also further enhancing our system for taking leave from work and are encouraging employees to take long vacations.

Through these efforts we are pushing to standardize, share, and spread responsibilities among employees. Our idea is that creating this sort of working environment can promote better work-life balance. And this fiscal year we continue our work on the Good Job Initiative.

Promoting Diversity

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 2015 we analyzed how well we are adhering to the Act on Promotion of Women’s Participation and Advancement in the Workplace (the Women’s Participation Promotion Act), and we set a target of having at least 15% of managerial positions held by women.

To achieve this target, we need to get women thinking about career advancement. One way we do that is by holding information sharing meetings for our female employees. Since ideas and concerns about careers vary between generations, we began holding career advancement seminars for different age groups in fiscal 2014 to foster participants’ awareness.

Career advancement seminar

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 workers with disabilities. The consultants are stationed in the workplace to help promote an environment where those with disabilities will be able to productively work side by side with others. This is one example of how we are working to create comfortable work environments.

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

Workers posting internal mail

Linen work (laundering)

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 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 45 persons are active under the system in a variety of departments.

Personnel Training

We organize employee training based on our management policy of “developing each employee.” The aim is for individual employees to improve their skills by using the opportunity to learn and grow.

In fiscal 2015 we instituted an Overseas Training Program for employees engaged in research and development. Those taking advantage of this opportunity to challenge themselves by studying abroad at universities and research institutes are tasked with making their own preparations.

The study abroad program is an attempt to help these employees gain specialist knowledge and build up their professional networks. We expect this creation of global talent will make Nippon Shinyaku employees more capable of taking on challenges in a diversifying culture.

Career Support System: “Developing Each Employee”

Nippon Shinyaku has established a Career Support Academy (CASA) to supply employees with opportunities for development. This system is structured on the twin aspects of level-based education and training, and elite education and training. Elite education and training targeting core personnel includes the six-month Next-Generation Leader Development Program. Support is also available for employees seeking to attain higher level degrees such as a doctorate or MBA. Our intention is to upgrade the skills of our employees, as well as to create a challenging and active organizational environment.

Next-Generation Leader Development Program

Shaping the Work Environment

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, and we are practicing the “5S activities” by implementing a three-year plan, 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 toward preventing occupational accidents.

Health and safety meeting

Mental Healthcare

Nippon Shinyaku effectively promotes the four types of care noted in the guidelines for mental healthcare 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 healthcare.

I want to use the Overseas Training Program to open new doors for my future.

To assert our presence as a drug creation company as Nippon Shinyaku grows, our drug discovery research needs to be more original and distinctive from a global viewpoint. Today, when it comes to rare diseases like pulmonary hypertension, a focus of Nippon Shinyaku, we need to think about medical needs abroad as well as in Japan. I thought that studying at an overseas laboratory engaging in both clinical and research-related work would not only deepen my fundamental knowledge of pathologies, but also be a chance to gain a better understanding of the actual therapeutic environment. By joining the Overseas Training Program, I want to expose myself to a diversity of ideas about research and other topics that I can take in to stimulate my creativity and cognitive abilities so that I can open up new opportunities in an uncertain future.

Kazuya Kuramoto

Exploratory Research Department, Discovery Research Laboratories, Research & Development Division

Contributing to society and communities as a corporate citizen

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 ensure that the children who will lead our society in the future grow up healthy and strong. The ways we do this include educating patients, supporting organizations carrying out activities that benefit the public, sponsoring and hosting sporting and cultural events, and carrying out cultural preservation activities in our hometown of Kyoto.

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 compositions as either stories or illustrations. Winning submissions are selected in each category and a picture book is made based on the best compositions. This book is then distributed nationwide to places like medical institutions and public libraries. Also, visitors to our website (Japanese only) are able to see electronic versions of past and present books and hear them read aloud as they browse the pages.

Picture book *Shiritagari no Otsuki-sama*

At the awards ceremony held in October 2015, tying into the seventh children's book produced in this way, *Shiritagari no Otsuki-sama* ("The Curious Moon"), an Air Dome Planetarium workshop was held for local children.

Group photograph from the awards ceremony

Nippon Shinyaku & Seitaro Kuroda Smiles Art Project

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 Public Onotown General Hospital in Fukushima Prefecture in March 2013. We have subsequently carried it out across Japan at facilities including the Second Emergency Medical Clinic in Kitakyushu City and Hiroshima University Hospital.

We hope this project will continue to strengthen bonds and bring smiles by visiting local hospitals and drawing pictures together with people from all walks of life, including physicians, patients, senior citizens, children, and students.


Group photo with children at Hiroshima University Hospital

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 Kataezome, 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*


Washcloth featuring a motif of "Arashiyama in spring"

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 2015, the Kyoto High School Baseball Federation winter training was held at Wakasa Stadium Kyoto. There we provided coaching for about 310 team members from 78 high school teams in Kyoto Prefecture. In January 2016, we held our 6th Youth Baseball Workshop for 28 teams and about 330 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.

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.


At the Kyoto High School Baseball Federation winter training

Business practices in harmony with the earth's 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

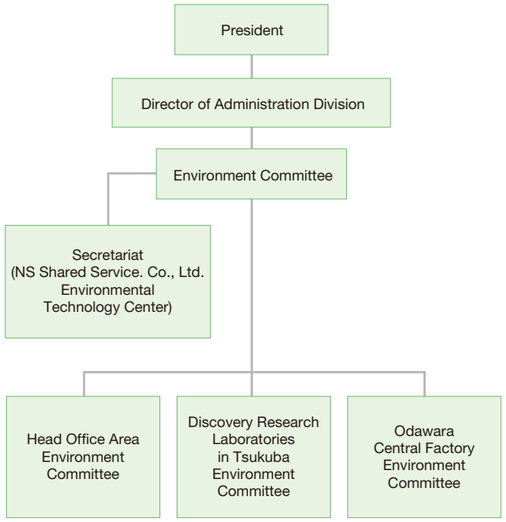
As a corporate citizen and to help people lead healthier and happier lives, Nippon Shinyaku will work to enrich society by establishing a policy for sustainable conservation of the environment, and setting goals for the entire company to pursue.

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 Environment Committee, chaired by the director of the 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



Putting Environmental Management System Certification into Action

At our Odawara Central Factory production site, Nippon Shinyaku acquired ISO 14001 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 Two of the 4th Nippon Shinyaku Environmental Targets Plan (FY 2014–2016)

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 fiscal 2015, including the achievement of reductions of 16.2% in total energy consumption and 4.8% in CO_2 emissions compared with fiscal 1990. We will continue engaging in environmental preservation activities to achieve our voluntary environmental targets.

Objective	Targets	Results in FY 2015
Promotion of energy conservation and global warming countermeasures	●Reduce total energy consumption (GJ) in FY 2016 to below 1990 levels.*1 ●Medium- to long-term target: The target for reducing CO_2 emissions shall be the same as that of the Japan Pharmaceutical Manufacturers Association.	●Total energy consumption*2 in FY 2015 was 16.2% lower than in FY 1990. ●CO_2 emissions*3 were 4.8% lower than in FY 1990.
Reduction of Waste	●Actively pursue the 3Rs (Reduce, Reuse, Recycle) and work to increase our usage ratio of recycled materials. ●Reduce the final amount of landfilled waste in FY 2016 by more than 65% of FY 2005 levels. ●Keep the final landfill waste ratio below 1% in FY 2016.	●In FY 2015, final amount of landfilled waste was reduced to 2.1 tons, 86% lower than in FY 2005, achieving a final landfill waste ratio of 0.5%.
Promote Proper Management of Chemical Substances	●Promote the proper management of chemical substances, including those stipulated under the Pollutant Release and Transfer Register (PRTR) system, and continuously reduce their emission into the natural environment.	●Dichloromethane and chloroform handled in FY 2015 decreased 64.6% and 48.8%, respectively, over FY 2014. Meanwhile, hexane increased by 32%.
Promote an Environmental Management System (EMS)	●Effectively improve the results of our environmental performance by maintaining certifications for environmental management systems (ISO 14001 and KES Step 2).	●We maintained certification and registration for ISO 14001 and KES Step 2.
Environmentally Conscious Product Upgrades and Materials Procurement	●Reduce product packaging materials as part of pharmaceutical and food product package simplification efforts. ●Promote green purchasing and procurement practices.	●We installed equipment to remove pills from PTP sheets, thus separating an annual 27,000 defective pill-containing PTP sheets that normally we would have disposed of. ●Green purchasing ratio: 93%
Communication with Society and Local Neighbors	●Actively participate in activities to give back to the areas where we do business. ●Appropriately disclose information (through our corporate website and Annual Report) to society and to the local areas of our business offices.	●We participated in regional volunteer cleanup activities. ●We issued the Nippon Shinyaku Report 2015 and updated our website.

*1 Total energy consumption, which is not dependent on CO_2 emission coefficient and directly reflects energy-saving efforts, was chosen as the indicator for the three-year period.
*2 Among total energy consumption of 235,073 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 sales offices, etc.).
*3 This figure is for the business locations to which the fiscal 1990 emission amounts are applicable (i.e., our main business locations apart from sales offices, etc.); total emissions were 12,756 tons. Calculations are made using the CO_2 real emission coefficients from the Ministry of Economy, Trade and Industry.

Promotion of Energy Conservation and Global Warming Countermeasures

Nippon Shinyaku is continuously endeavoring to conserve energy and reduce emissions of CO_2. 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 2015, in addition to company-wide efforts to conserve electricity and energy, at the Discovery Research Laboratories No. 1 Bldg. we replaced all the lighting with LED bulbs and set up a wasteless air-conditioning control system by installing variable airflow valves that supply air to cleanrooms. Furthermore, in an effort to conserve energy in the No. 2 Bldg. we installed secondary pumps for cold and hot water that are more compact.

Total energy consumption*2 in fiscal 2015 was 193,171 GJ. This was 1,058 GJ lower, or 0.5% less than the 194,229 GJ in fiscal 2014, and 37,261 GJ lower, or 16.2% less than consumption in the base year of fiscal 1990 when it was 230,432 GJ.

Furthermore, CO_2 emissions*3 in fiscal 2015 were 10,059 tons. This was 144 tons lower, or 1.4% less than the 10,203 tons in fiscal 2014, and 366 tons lower, or 4.8% less than emissions in the base year of fiscal 1990 when they were 10,569 tons.

●Introducing Low-Emission Vehicles in Our Sales Fleet

Our policy is to use low-emission conventional models (with 4-star ratings for a 75% emissions reduction based on 2005 standards), as well as hybrid vehicles with good gas mileage and low CO_2 emissions. As of the end of fiscal 2015, 98.1% of the 738 automobiles used by our sales force were low-emission vehicles. Additionally, in fiscal 2015 we put an electric vehicle in service for general use at our head office as a further effort to reduce CO_2 emissions.

Furthermore, we stepped up our environmental conservation activities by encouraging salespeople in Tokyo to use public transport, while promoting awareness of eco-driving throughout the Company.

Sales force hybrid vehicle

Reducing Volume of Waste

The amount of waste generated in fiscal 2015 was 414.7 tons, a decrease of 4.6 tons from fiscal 2014. Due to proper disposal of unrecyclable equipment containing asbestos, our final amount of landfill waste increased to 2.1 tons, 0.5 tons more than in fiscal 2014. However, we did achieve our target with an 86% reduction from the 14.6 tons in fiscal 2005. The higher final amount of landfill waste raised the final landfill waste ratio to 0.5%, or 0.1% higher than the prior fiscal year, but we did meet our target of a waste ratio under 1.0% for the sixth year straight.

For waste with low PCB concentrations we have carried out final disposal in accordance with all applicable laws. As for waste with high PCB concentrations, we are stringently following storage protocols in the head office area and the Odawara Central Factory.

Odawara Central Factory

Proper Management of Chemical Substances

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.

Compared to fiscal 2014, in fiscal 2015 we handled 64.6% less dichloromethane due to reduced production of compounds requiring the substance, as well as 48.8% less chloroform.

Furthermore, beginning in fiscal 2016 we are installing solvent adsorption equipment at the manufacturing building for active pharmaceutical ingredients for clinical trials in an effort to suppress atmospheric emissions of chemicals produced during the manufacture of active pharmaceutical ingredients.

●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. Research materials that are genetically modified or are considered pathogenic are handled carefully by biohazard compliant facilities. 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.

Initiatives to Preserve Biodiversity

Yamashina Botanical Research Institute

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 (*Artemisia maritima*), 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 160 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 hollyhock and *Chrysanthemum seticuspe*.

I have high hopes for educational activities and events that make use of a wonderful setting and botanical resources.

The Yamashina Botanical Research Institute is conveniently located near public transportation. The facility is a great place for tours for anyone because it rests largely on flat ground. There are many gardens throughout Japan for medicinal plants that pharmaceutical universities and drug companies have set up, but the setting here is exceptional. I have high hopes for the educational activities geared toward young people that make effective use of this wonderful setting and the valuable botanical resources kept here, and in particular the seminars for pharmacy students and other related events. What I am specifically looking forward to is the continuation and growth of the Yamashina Botanical Research Institute seminars that began in 2015, and even better pharmacological events using real samples. People involved in teaching pharmacology are so very grateful for these events in such a well-managed garden. Moving forward, I am eager to continue offering my support to this endeavor.

Associate Professor
Michiho Ito
Department of Pharmacognosy, Graduate School of Pharmaceutical Sciences, Kyoto University

Summaries and Highlights

Summary of Consolidated Financial Indicators

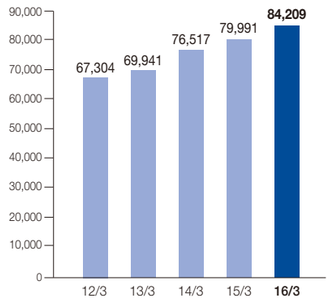
	2012/3	2013/3	2014/3	2015/3	2016/3	2016/3
For the year					Millions of Yen	Thousands of U.S. Dollars
Net sales	67,304	69,941	76,517	79,991	**84,209**	**745,212**
Pharmaceuticals	55,746	58,318	63,345	66,340	**70,489**	**623,796**
Functional food	11,558	11,622	13,172	13,651	**13,720**	**121,415**
Operating income	6,012	6,901	8,038	8,562	**8,549**	**75,654**
Net income	3,715	4,647	5,750	5,882	**6,340**	**56,106**
Depreciation and amortization	2,948	2,759	2,704	2,665	**2,452**	**21,699**
Capital investment	967	1,332	1,072	1,239	**3,554**	**31,451**
R&D expenses	9,414	9,049	9,530	8,968	**9,739**	**86,185**
End of the year					Millions of Yen	Thousands of U.S. Dollars
Total assets	106,304	113,730	118,188	129,757	**135,370**	**1,197,964**
Net assets	84,566	89,529	93,186	101,207	**102,762**	**909,398**
Financial information per share					Yen	U.S. Dollars
Earnings per share	55.04	68.87	85.25	87.26	**94.10**	**0.83**
Dividend per share	19	21	23	25	**28**	**0.25**
Principal financial indicators					%	%
Ratio of net worth	79.4	78.5	78.7	77.8	**75.8**	**-**
Return on equity	4.5	5.4	6.3	6.1	**6.2**	**-**
Pay-out ratio	34.5	30.5	27.0	28.7	**29.8**	**-**

Summary of ESG Indices

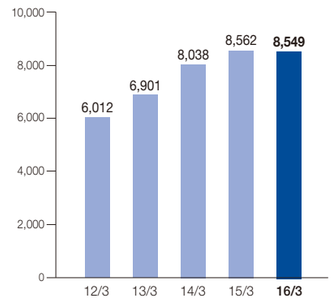
Total energy consumption (thousands of GJ)	231	231	201	194	**193**	**-**
CO_2 emissions (t)	9,568	11,272	10,412	10,203	**10,059**	**-**
CO_2 per unit of revenue (t/million yen)	0.143	0.162	0.136	0.128	**0.119**	**-**
Number of employees (people)	1,898	1,895	1,899	1,939	**1,950**	**-**

Financial Highlights

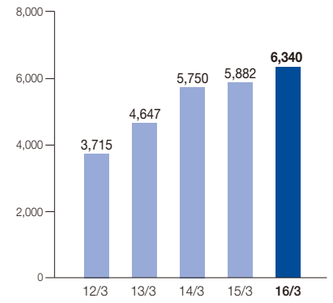
Net Sales (millions of yen)



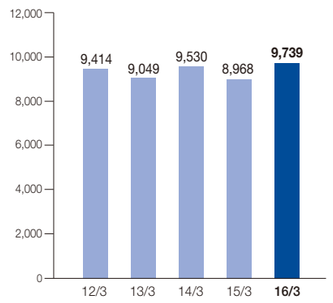
Operating Income (millions of yen)



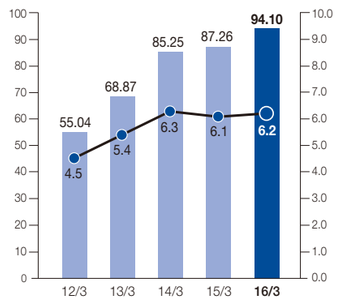
Net Income (millions of yen)



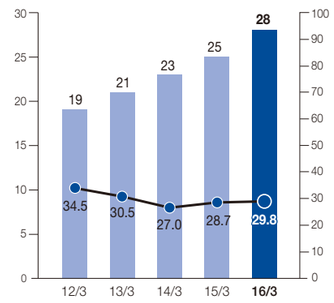
R&D Expenses (millions of yen)



EPS / ROE

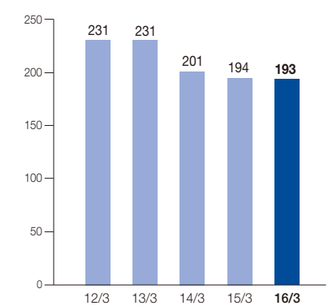


Dividend Per Share / Pay-Out Ratio

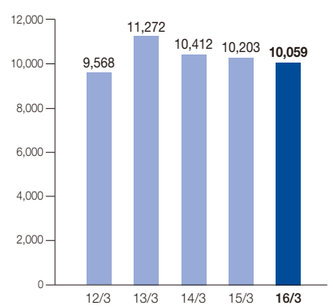


Non-Financial Highlights

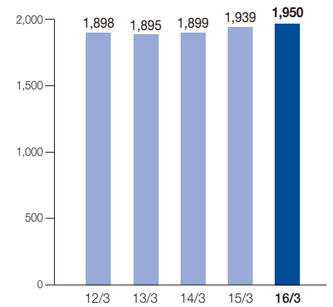
Total Energy Consumption (thousands of GJ)



CO_2 Emissions (t)



Number of Employees (people)



Financial Section

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 considering a balance of the investment and return of profits 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, 2016, we issued an annual cash dividend of ¥28 per share, comprising an interim dividend of ¥14 per share and year-end dividend of ¥14 per share.

For the year ending March 31, 2017, we are projecting an annual dividend of ¥35 per share, comprising an interim dividend of ¥17 per share and year-end dividend of ¥18 per share.

2. Financial Condition

Decreases in marketable securities and inventory assets, and increases in cash and deposits compared to the previous fiscal year end caused current assets to rise by ¥4,978 million.

Fixed assets increased by ¥633 million due to an increase in tangible fixed assets despite deceases in investment securities and long-term prepaid expenses, etc. compared to the previous fiscal year end.

As a result, total assets increased by ¥5,612 million compared to the previous fiscal year end to ¥135,370 million.

Current liabilities increased by ¥2,798 million compared to the previous fiscal year end, due to an increase in accrued liabilities, despite decreases in notes and accounts payables–trade and income taxes payable, etc.

Fixed liabilities increased by ¥1,258 million compared to the previous fiscal year end, due to an increase in liabilities for retirement benefits, despite decreases in deferred tax liabilities, etc. As a result, total liabilities increased by ¥4,057 million compared to the previous fiscal year end to ¥32,607 million.

Equity increased by ¥4,435 million compared to the previous fiscal year end to ¥96,864 million. Accumulated other comprehensive income decreased by ¥2,884 million to ¥5,684 million.

As a result, net assets increased by ¥1,554 million to ¥102,762 million. The equity ratio was 75.8%.

Net cash provided by operating activities amounted to ¥8,915 million. The main cash inflows were income before income taxes of ¥8,952 million, depreciation costs of ¥2,452 million, and an increase in other current liabilities of ¥835 million, while the main outflows were income tax, etc. paid of ¥2,657 million and a decrease in liabilities for retirement benefits of ¥1,021 million.

Net cash used in investing activities amounted to ¥3,978 million. The main cash outflows were expenditures for the acquisition of marketable securities of ¥1,450 million, for the acquisition of tangible fixed assets of ¥1,517 million, and for the acquisition of license rights of ¥650 million.

Net cash used in financing activities amounted to ¥1,907 million, primarily comprising cash payment of dividends.

As a result, cash and cash equivalents as of March 31, 2016 increased by ¥2,833 million compared to the previous fiscal year end, to ¥24,748 million.

3. Summary of Consolidated Business Results

(1) Pharmaceuticals

In the pharmaceuticals segment, sales for long-listed drugs declined, while sales for new products including Zalutia®, a drug for urinary disorders caused by benign prostatic hypertrophy, Vidaza®, a remedy for myelodysplastic syndrome, and Tramal®/Onetram®, remedies for cancer pain and chronic pain increased. Moreover, we recorded income from industrial property rights accompanying the partner-led overseas approval of our original product in the U.S.

As a result, net sales were ¥70,489 million, a year-on-year increase of 6.3%.

(2) Functional Food

In the functional food segment, sales of nutritional ingredients decreased, while sales of protein preparations and health food ingredients, etc. increased. As a result, net sales increased by 0.5% year-on-year to ¥13,720 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

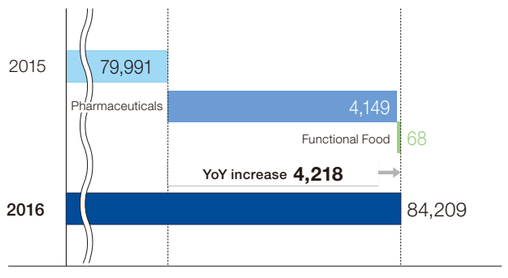
The selling price of drugs used for medical care is set based on drug price standards under the national health insurance system. Drug price standards are generally revised downward every two years. Depending on extent of the price decrease, it could impact the business results of the Nippon Shinyaku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

5. Manufacturing and Procurement Risks

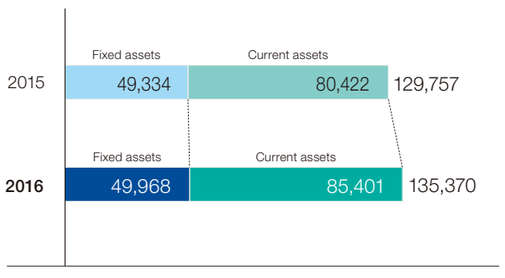
The Nippon Shinyaku Group is improving its production efficiency by concentrating its manufacturing facilities. At the same time, if operations at manufacturing facilities cease due to a natural disaster or other circumstance, it could interrupt the supply of products and impact our business results.

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

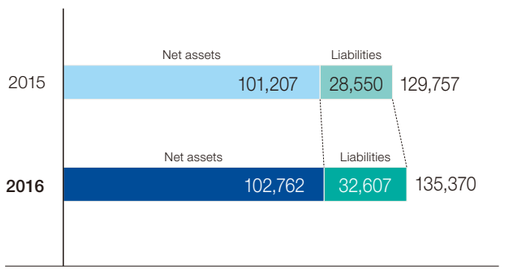
Sales Breakdown (millions of yen)



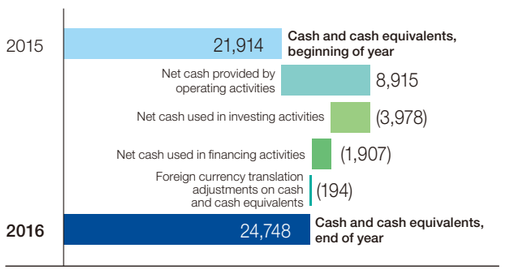
Consolidated Balance Sheet (Assets) (millions of yen)



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



Consolidated Statement of Cash Flows (millions of yen)



Consolidated Financial Statements

Consolidated Balance Sheet

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
March 31, 2016

ASSETS	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2016	2015	**2016**
CURRENT ASSETS:			
Cash and cash equivalents (Note 10)	**¥ 24,748**	¥ 21,914	**$ 219,008**
Time deposits (Note 10)	**387**	227	**3,424**
Marketable securities (Notes 3 and 10)	**2,926**	500	**25,893**
Notes and accounts receivables (Note 10):			
Trade notes	**412**	274	**3,646**
Trade accounts	**34,723**	34,736	**307,283**
Other	**242**	147	**2,141**
Total notes and accounts receivables	**35,378**	35,158	**313,079**
Inventories (Note 4)	**18,929**	19,658	**167,513**
Deferred tax assets (Note 9)	**1,861**	1,698	**16,469**
Other current assets	**1,168**	1,265	**10,336**
Total current assets	**85,401**	80,422	**755,761**
PROPERTY, PLANT, AND EQUIPMENT:			
Land	**7,509**	7,449	**66,451**
Buildings and structures	**24,210**	23,645	**214,247**
Machinery, equipment, and vehicles	**10,783**	11,006	**95,424**
Tools, furniture, and fixtures	**8,559**	8,814	**75,743**
Construction in progress	**130**	74	**1,150**
Total	**51,193**	50,990	**453,035**
Accumulated depreciation	**(33,569)**	(35,596)	**(297,070)**
Net property, plant, and equipment	**17,624**	15,393	**155,964**
INVESTMENTS AND OTHER ASSETS:			
Investment securities (Notes 3 and 10)	**21,497**	22,078	**190,238**
Long-term prepaid expenses	**7,521**	8,287	**66,557**
Deferred tax assets (Note 9)	**55**	57	**486**
Other assets	**3,269**	3,518	**28,929**
Total investments and other assets	**32,344**	33,941	**286,230**
TOTAL	**¥ 135,370**	¥ 129,757	**$ 1,197,964**

LIABILITIES AND EQUITY	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2016	2015	**2016**
CURRENT LIABILITIES:			
Notes and accounts payables (Note 10):			
Trade notes	**¥ 1,761**	¥ 1,792	**$ 15,584**
Trade accounts	**4,998**	5,326	**44,230**
Other	**4,793**	2,904	**42,415**
Total notes and accounts payables	**11,553**	10,022	**102,238**
Income taxes payable (Note 10)	**1,929**	2,161	**17,070**
Accrued expenses	**3,721**	3,759	**32,929**
Deposits from customers	**295**	284	**2,610**
Other current liabilities	**3,069**	1,542	**27,159**
Total current liabilities	**20,569**	17,770	**182,026**
LONG-TERM LIABILITIES:			
Liability for retirement benefits (Note 5)	**10,410**	7,997	**92,123**
Deferred tax liabilities (Note 9)	**1,192**	2,286	**10,548**
Other long-term liabilities	**434**	495	**3,840**
Total long-term liabilities	**12,037**	10,779	**106,522**
EQUITY (Notes 6 and 13)**:**			
Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares	**5,174**	5,174	**45,787**
Capital surplus	**4,445**	4,445	**39,336**
Retained earnings	**89,658**	85,137	**793,433**
Treasury stock – at cost, 2,888,330 shares in 2016 and 2,868,940 shares in 2015	**(2,413)**	(2,327)	**(21,353)**
Accumulated other comprehensive income:			
Unrealized gain on available-for-sale securities	**9,091**	9,600	**80,451**
Deferred loss on derivatives under hedge accounting	**(2)**	(11)	**(17)**
Foreign currency translation adjustments	**17**	17	**150**
Defined retirement benefit plans	**(3,421)**	(1,037)	**(30,274)**
Total	**102,549**	100,998	**907,513**
Noncontrolling interests	**213**	208	**1,884**
Total equity	**102,762**	101,207	**909,398**
TOTAL	**¥ 135,370**	¥ 129,757	**$ 1,197,964**

See notes to consolidated financial statements.

Consolidated Financial Statements

Consolidated Statement of Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2016

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2016	2015	**2016**
NET SALES (Note 14)	**¥ 84,209**	¥ 79,991	**$ 745,212**
COST AND EXPENSES:			
Cost of sales	**44,016**	41,226	**389,522**
Selling, general, and administrative expenses (Notes 7 and 8)	**31,643**	30,202	**280,026**
Total	**75,660**	71,429	**669,557**
Operating income (Note 14)	**8,549**	8,562	**75,654**
OTHER INCOME (EXPENSES):			
Interest and dividends income	**416**	385	**3,681**
Interest expense	**(3)**	(3)	**(26)**
Other – net	**(9)**	(15)	**(79)**
Other income – net	**403**	365	**3,566**
INCOME BEFORE INCOME TAXES	**8,952**	8,928	**79,221**
INCOME TAXES (Note 9)**:**			
Current	**2,398**	2,705	**21,221**
Deferred	**207**	333	**1,831**
Total income taxes	**2,605**	3,039	**23,053**
NET INCOME	**6,346**	5,889	**56,159**
NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTERESTS	**6**	7	**53**
NET INCOME ATTRIBUTABLE TO OWNERS OF THE PARENT	**¥ 6,340**	¥ 5,882	**$ 56,106**

	Yen		U.S. Dollars
PER SHARE OF COMMON STOCK (Notes 2.p and 12)**:**			
Basic net income	**¥ 94.10**	¥ 87.26	**$ 0.83**
Cash dividends applicable to the year	**28.00**	25.00	**0.25**

See notes to consolidated financial statements.

Consolidated Statement of Comprehensive Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2016

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2016	2015	**2016**
NET INCOME	**¥ 6,346**	¥ 5,889	**$ 56,159**
OTHER COMPREHENSIVE INCOME (LOSS) (Note 11)**:**			
Unrealized gain (loss) on available-for-sale securities	**(509)**	3,758	**(4,504)**
Deferred gain (loss) on derivatives under hedge accounting	**8**	(13)	**70**
Foreign currency translation adjustments		22	
Defined retirement benefit plans	**(2,384)**	369	**(21,097)**
Total other comprehensive income (loss)	**(2,884)**	4,136	**(25,522)**
COMPREHENSIVE INCOME	**¥ 3,462**	¥ 10,026	**$ 30,637**
TOTAL COMPREHENSIVE INCOME ATTRIBUTABLE TO:			
Owners of the parent	**¥ 3,455**	¥ 10,018	**$ 30,575**
Noncontrolling interests	**6**	7	**53**

See notes to consolidated financial statements.

Consolidated Statement of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2016

	Thousands	Millions of Yen										
						Accumulated Other Comprehensive Income						
	Outstanding Number of Shares of Common Stock	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available-for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Defined Retirement Benefit Plans	Total	Noncontrolling Interests	Total Equity
BALANCE, MARCH 31, 2014 (April 1, 2014, as previously reported)	67,430	¥ 5,174	¥ 4,445	¥ 81,105	¥ (2,175)	¥ 5,841	¥ 1	¥ (4)	¥ (1,406)	¥ 92,982	¥ 204	¥ 93,186
Cumulative effect of accounting change				(232)						(232)		(232)
BALANCE, APRIL 1, 2014 (as restated)	67,430	5,174	4,445	80,873	(2,175)	5,841	1	(4)	(1,406)	92,749	204	92,954
Net income attributable to owners of the parent				5,882						5,882		5,882
Cash dividends, ¥24.00 per share				(1,617)						(1,617)		(1,617)
Purchase of treasury stock	(48)				(152)					(152)		(152)
Net change during the year						3,758	(13)	22	369	4,136	4	4,141
BALANCE, MARCH 31, 2015	67,382	5,174	4,445	85,137	(2,327)	9,600	(11)	17	(1,037)	100,998	208	101,207
Net income attributable to owners of the parent				6,340						6,340		6,340
Cash dividends, ¥27.00 per share				(1,819)						(1,819)		(1,819)
Purchase of treasury stock	(19)				(85)					(85)		(85)
Net change during the year						(509)	8		(2,384)	(2,884)	4	(2,880)
BALANCE, MARCH 31, 2016	**67,363**	**¥ 5,174**	**¥ 4,445**	**¥ 89,658**	**¥ (2,413)**	**¥ 9,091**	**¥ (2)**	**¥ 17**	**¥ (3,421)**	**¥ 102,549**	**¥ 213**	**¥ 102,762**

	Thousands of U.S. Dollars (Note 1)										
					Accumulated Other Comprehensive Income						
	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available-for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Defined Retirement Benefit Plans	Total	Noncontrolling Interests	Total Equity
BALANCE, MARCH 31, 2015	$ 45,787	$ 39,336	$ 753,424	$ (20,592)	$ 84,955	$ (97)	$ 150	$ (9,176)	$ 893,787	$ 1,840	$ 895,637
Net income attributable to owners of the parent			56,106						56,106		56,106
Cash dividends, $0.23 per share			(16,097)						(16,097)		(16,097)
Purchase of treasury stock				(752)					(752)		(752)
Net change during the year					(4,504)	70		(21,097)	(25,522)	35	(25,486)
BALANCE, MARCH 31, 2016	**$ 45,787**	**$ 39,336**	**$ 793,433**	**$ (21,353)**	**$ 80,451**	**$ (17)**	**$ 150**	**$ (30,274)**	**$ 907,513**	**$ 1,884**	**$ 909,398**

See notes to consolidated financial statements.

Consolidated Financial Statements

Consolidated Statement of Cash Flows

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2016

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2016	2015	**2016**
OPERATING ACTIVITIES:			
Income before income taxes	**¥ 8,952**	¥ 8,928	**$ 79,221**
Adjustments for:			
Income taxes – paid	**(2,657)**	(2,087)	**(23,513)**
Depreciation and amortization	**2,452**	2,665	**21,699**
Changes in assets and liabilities:			
Increase in trade notes and trade accounts receivables	**(125)**	(873)	**(1,106)**
Decrease (increase) in inventories	**728**	(3,925)	**6,442**
Decrease in other current assets	**96**	92	**849**
(Decrease) increase in trade notes and trade accounts payables	**(358)**	1,019	**(3,168)**
(Decrease) increase in other current liabilities	**(793)**	465	**(7,017)**
Decrease in liability for retirement benefits	**(1,021)**	(547)	**(9,035)**
Other – net	**1,641**	375	**14,522**
Total adjustments	**(37)**	(2,814)	**(327)**
Net cash provided by operating activities	**8,915**	6,113	**78,893**
INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	**(1,517)**	(1,156)	**(13,424)**
Purchases of investment securities	**(501)**	(1,000)	**(4,433)**
Purchases of software	**(187)**	(109)	**(1,654)**
Acquisition of license rights	**(650)**	(1,070)	**(5,752)**
Other – net	**(1,121)**	(381)	**(9,920)**
Net cash used in investing activities	**(3,978)**	(3,718)	**(35,203)**
FINANCING ACTIVITIES:			
Cash dividends paid	**(1,819)**	(1,618)	**(16,097)**
Increase in treasury stock	**(85)**	(152)	**(752)**
Other – net	**(2)**	(2)	**(17)**
Net cash used in financing activities	**(1,907)**	(1,773)	**(16,876)**
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS	**(194)**	63	**(1,716)**
NET INCREASE IN CASH AND CASH EQUIVALENTS	**2,833**	684	**25,070**
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	**21,914**	21,229	**193,929**
CASH AND CASH EQUIVALENTS, END OF YEAR	**¥ 24,748**	¥ 21,914	**$ 219,008**

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

1. BASIS OF PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act, and its related accounting regulations, and in accordance with accounting principles generally accepted in Japan, which are different in certain respects as to 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 2015 consolidated financial statements to conform to the classifications used in 2016.

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 ¥113 to $1, the approximate rate of exchange at March 31, 2016. 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, 2016 and 2015, include the accounts of the Company and its two significant domestic subsidiaries and one overseas subsidiary (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 of property, plant and equipment of the Companies is computed by the straight-line method based on the estimated useful lives of the assets. The range of useful lives is principally from 10 to 50 years for buildings and structures, from eight to 10 years for machinery, equipment, and vehicles, and from four to six years for tools, furniture, and fixtures.

Effective April 1, 2015, the Companies have adopted the straight-line method of depreciation for property, plant and equipment (except for lease assets), which were previously depreciated principally by the declining-balance method while the straight-line method had been applied to buildings acquired after April 1, 1998.

The Companies evaluated the status of property, plant and equipment at the start of a large-scale capital investment from the fiscal year ended March 31, 2016 based on the Fifth Medium-term Management Plan. As a result, since the changes in the business environment surrounding the Companies related to the development and production of pharmaceutical products will result in a more stable operation of those assets, we expect that allocating the acquisition cost of assets equally over the estimated useful life will reflect the operational status of each asset in the financial statements

more rationally. Accordingly, the Companies have adopted the straight-line method from the current fiscal year.

Due to the adoption of the straight-line method, while depreciation decreased by ¥313 million ($2,769 thousand), operating income and income before income taxes increased by ¥290 million ($2,566 thousand) and ¥291 million ($2,575 thousand), respectively, for the year ended March 31, 2016.

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, and retained earnings as of April 1, 2014, decreased by ¥232 million. 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 attributable to common shareholders by the weighted-average number of common shares outstanding for the period.

Cash dividends per share presented in the accompanying consolidated 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. Business Combinations - In October 2003, the Business Accounting Council issued a Statement of Opinion, "Accounting for Business Combinations," and in December 2005, the ASBJ issued ASBJ Statement No. 7, "Accounting Standard for Business Divestitures" and ASBJ Guidance No. 10, "Guidance for Accounting Standard for Business Combinations and Business Divestitures."

In December 2008, the ASBJ issued a revised accounting standard for business combinations, ASBJ Statement No. 21, "Accounting Standard for Business Combinations." Major accounting changes under the revised accounting standard are as follows: (1) The revised standard requires accounting for business combinations only by the purchase method. As a result, the pooling-of-interests method of accounting is no longer allowed. (2) The previous accounting standard required research and development costs to be charged to income as incurred. Under the revised standard, in-process research and development costs (IPR&D) acquired in the business combination are capitalized as an intangible asset. (3) The previous accounting standard provided for a bargain purchase gain (negative goodwill) to be systematically amortized over a period not exceeding 20 years. Under the revised standard, the acquirer recognizes the bargain purchase gain in profit or loss immediately on the acquisition date after reassessing and confirming that all of the assets acquired and all of the liabilities assumed have been identified after a review of the procedures used in the purchase price allocation. The revised standard was applicable to business combinations undertaken on or after April 1, 2010.

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) Presentation of the consolidated balance sheet - In the consolidated balance sheet, "minority interest" under the previous accounting standard is changed to "noncontrolling interest" under the revised accounting standard.

(b) Presentation of the consolidated statement of income - In the consolidated statement of income, "income before minority interest" under the previous accounting standard is changed to "net income" under the revised accounting standard, and "net income" under the previous accounting standard is changed to "net income attributable to owners of the parent" under the revised accounting standard.

The above accounting standards and guidance for (a) presentation of the consolidated balance sheet and (b) presentation of the consolidated statement of income, are effective for the beginning of annual periods beginning on or after April 1, 2015, and shall be applied to all periods presented in financial statements containing the first-time application of the revised standards and guidance, the applicable line items in the 2015 consolidated financial statements have been accordingly reclassified and presented in line with those in 2016.

s. New Accounting Pronouncements
Tax Effect Accounting - On December 28, 2015, the ASBJ issued ASBJ Guidance No. 26, "Guidance on Recoverability of Deferred Tax Assets," which included certain revisions of the previous accounting and auditing guidance issued by the Japanese Institute of Certified Public Accountants. While the new guidance continues to follow the basic framework of the previous guidance, it provides new guidance for the application of judgment in assessing the recoverability of deferred tax assets.

The previous guidance provided a basic framework which included certain specific restrictions on recognizing deferred tax assets depending on the company's classification in respect of its profitability, taxable profit and temporary differences, etc.

The new guidance does not change such basic framework but, in limited cases, allows companies to recognize deferred tax assets even for a deductible temporary difference for which it was specifically prohibited to recognize a deferred tax asset under the previous guidance, if the company can justify, with reasonable grounds, that it is probable that the deductible temporary difference will be utilized against future taxable profit in some future period.

The new guidance is effective for the beginning of annual periods beginning on or after April 1, 2016. Earlier application is permitted for annual periods ending on or after March 31, 2016. The new guidance shall not be applied retrospectively and any adjustments from the application of the new guidance at the beginning of the reporting period shall be reflected within retained earnings or accumulated other comprehensive income at the beginning of the reporting period.

The Company expects to apply the new guidance on recoverability of deferred tax assets effective April 1, 2016, and is in the process of measuring the effects of applying the new guidance in future applicable periods.

3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2016 and 2015, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Current:			
Government and corporate bonds	**¥ 1,800**	¥ 500	**$ 15,929**
Other	**1,126**		**9,964**
Total	**¥ 2,926**	¥ 500	**$ 25,893**
Noncurrent:			
Equity securities	**¥ 21,497**	¥ 22,078	**$ 190,238**
Total	**¥ 21,497**	¥ 22,078	**$ 190,238**

The costs and aggregate fair values of marketable and investment securities at March 31, 2016 and 2015, were as follows:

	Millions of Yen			
March 31, 2016	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	**¥ 8,310**	**¥ 12,856**		**¥ 21,166**
Held-to-maturity	**2,926**		**¥ 8**	**2,917**

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

	Thousands of U.S. Dollars			
March 31, 2016	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	**$ 73,539**	**$113,769**		**$187,309**
Held-to-maturity	**25,893**		**$ 70**	**25,814**

4. INVENTORIES

Inventories at March 31, 2016 and 2015, consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Finished products and merchandise	**¥ 12,730**	¥ 12,936	**$ 112,654**
Work in process	**1,519**	2,058	**13,442**
Raw materials	**4,679**	4,663	**41,407**
Total	**¥ 18,929**	¥ 19,658	**$ 167,513**

5. RETIREMENT BENEFITS

1. Defined Benefit Pension Plan
(1) The changes in defined benefit obligation for the years ended March 31, 2016 and 2015, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Balance at beginning of year (as previously reported)	**¥ 27,589**	¥ 25,769	**$ 244,150**
Cumulative effect of accounting change		360	
Balance at beginning of year (as restated)	**27,589**	26,129	**244,150**
Current service cost	**963**	936	**8,522**
Interest cost	**326**	378	**2,884**
Actuarial losses	**2,969**	1,290	**26,274**
Benefits paid	**(1,830)**	(1,145)	**(16,194)**
Balance at end of year	**¥ 30,019**	¥ 27,589	**$ 265,654**

(2) The changes in plan assets for the years ended March 31, 2016 and 2015, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Balance at beginning of year	**¥ 19,592**	¥ 16,911	**$ 173,380**
Expected return on plan assets	**780**	673	**6,902**
Actuarial gains (losses)	**(1,024)**	1,404	**(9,061)**
Contributions from the employer	**1,422**	1,408	**12,584**
Benefits paid	**(1,161)**	(808)	**(10,274)**
Others		1	
Balance at end of year	**¥ 19,609**	¥ 19,592	**$ 173,530**

(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
	2016	2015	**2016**
Funded defined benefit obligation	**¥ 27,573**	¥ 24,928	**$ 244,008**
Plan assets	**(19,609)**	(19,592)	**(173,530)**
	7,964	5,336	**70,478**
Unfunded defined benefit obligation	**2,445**	2,661	**21,637**
Net liability arising from defined benefit obligation	**¥ 10,410**	¥ 7,997	**$ 92,123**

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Liability for retirement benefits	**¥ 10,410**	¥ 7,997	**$ 92,123**
Net liability arising from defined benefit obligation	**¥ 10,410**	¥ 7,997	**$ 92,123**

(4) The components of net periodic benefit costs for the years ended March 31, 2016 and 2015, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Service cost	**¥ 963**	¥ 936	**$ 8,522**
Interest cost	**326**	378	**2,884**
Expected return on plan assets	**(780)**	(673)	**(6,902)**
Amortization of prior service cost	**515**	45	**4,557**
Recognized actuarial losses	**45**	512	**398**
Others	**19**	5	**168**
Net periodic benefit costs	**¥ 1,089**	¥ 1,204	**$ 9,637**

(5) Amounts recognized in other comprehensive income (before income tax effect) in respect of defined retirement benefit plans for the years ended March 31, 2016 and 2015

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Prior service cost	**¥ (45)**	¥ (45)	**$ (398)**
Actuarial (gains) losses	**3,478**	(627)	**30,778**
Total	**¥ 3,433**	¥ (672)	**$ 30,380**

(6) Amounts recognized in accumulated other comprehensive income (before income tax effect) in respect of defined retirement benefit plans as of March 31, 2016 and 2015

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Unrecognized prior service cost	**¥ 110**	¥ 156	**$ 973**
Unrecognized actuarial losses	**4,848**	1,369	**42,902**
Total	**¥ 4,959**	¥ 1,525	**$ 43,884**

(7) Plan assets

a. Components of plan assets
Plan assets as of March 31, 2016 and 2015, consisted of the following:

	2016	2015
Domestic bonds	**18.5%**	20.6%
Home shares	**15.6**	20.4
Foreign bonds	**13.7**	14.1
Foreign shares	**11.5**	16.4
General accounts	**26.6**	25.3
Alternative	**9.9**	
Others	**4.2**	3.2
Total	**100.0%**	100.0%

b. Method of determining the expected rate of return on plan assets
The expected rate of return on plan assets is determined considering the long-term rates of return 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, 2016 and 2015, are set forth as follows:

	2016	2015
Discount rate	**0.1 - 0.7%**	0.2 - 1.3%
Expected rate of return on plan assets	**4.0%**	4.0%

2. Defined Contribution Pension Plan
Premiums for defined contribution pension plan were ¥55 million ($486 thousand) and ¥48 million for the years ended March 31, 2016 and 2015, respectively.

6. EQUITY

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

(a) Dividends

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

The Companies Act permits companies to distribute dividends in kind (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 ¥9,739 million ($86,185 thousand) and ¥8,968 million for the years ended March 31, 2016 and 2015, respectively.

8. LEASES

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

Total rental expenses for the years ended March 31, 2016 and 2015, were ¥1,263 million ($11,177 thousand) and ¥1,257 million, respectively.

Future minimum payments under noncancelable operating leases were as follows:

	Operating Leases	
	2016	
	Millions of Yen	Thousands of U.S. Dollars
Due within one year	**¥ 4**	**$ 35**
Due after one year	**5**	**44**
Total	**¥ 10**	**$ 88**

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 33.0% and 35.5% for the years ended March 31, 2016 and 2015, 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, 2016 and 2015, are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Deferred tax assets:			
Retirement benefits	**¥ 3,230**	¥ 2,559	**$ 28,584**
Accrued expenses	**963**	1,023	**8,522**
Property, plant, and equipment	**36**	51	**318**
Other	**1,592**	1,406	**14,088**
Less valuation allowance	**(314)**	(325)	**(2,778)**
Deferred tax assets	**5,508**	4,715	**48,743**
Deferred tax liabilities:			
Unrealized gain on available-for-sale securities	**3,769**	4,185	**33,353**
Deferred gains on sales of property	**997**	1,035	**8,823**
Other	**16**	23	**141**
Deferred tax liabilities	**4,783**	5,245	**42,327**
Net deferred tax assets (liabilities)	**¥ 724**	¥ (529)	**$ 6,407**

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, 2016, with the corresponding figures for 2015, is as follows:

	2016	2015
Normal effective statutory tax rate	**33.0%**	35.5%
Expenses not deductible for income tax purposes	**1.4**	1.6
Income not taxable for income tax purposes	**(0.8)**	(1.1)
Tax credits for research and development costs	**(5.5)**	(6.7)
Effect of tax rate reduction	**1.0**	3.7
Per Capita Levy municipal tax	**0.7**	0.7
Other – net	**(0.7)**	0.3
Actual effective tax rate	**29.1%**	34.0%

New tax reform laws enacted in 2016 in Japan changed the normal effective statutory tax rate for the fiscal year beginning on or after April 1, 2016, to approximately 31.0%. The effect of this change was to decrease deferred tax liabilities, net of deferred tax assets, by ¥26 million ($230 thousand), in the consolidated balance sheet as of March 31, 2016, and to increase income taxes-deferred in the consolidated statement of income for the year then ended by ¥87 million ($769 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 certificates of deposit, are exposed to little or no risk of market price fluctuations. Investment securities, mainly equity instruments, are exposed to the risk of market price fluctuations. Marketable and investment securities, mainly held-to-maturity securities of customers and suppliers of the Companies, are exposed to the issuer's credit risk.

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

The Company's derivative transactions are specific foreign exchange forward contracts. The Company has entered into foreign exchange forward contracts to hedge foreign 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

	Millions of Yen		
March 31, 2016	Carrying Amount	Fair Value	Unrealized Loss
Cash and cash equivalents	**¥ 24,748**	**¥ 24,748**	
Time deposits	**387**	**387**	
Notes and accounts receivables	**35,378**	**35,378**	
Marketable and investment securities	**24,093**	**24,084**	**¥ 8**
Total	**¥ 84,607**	**¥ 84,597**	**¥ 8**
Notes and accounts payables	**¥ 11,553**	**¥ 11,553**	
Income taxes payable	**1,929**	**1,929**	
Total	**¥ 13,483**	**¥ 13,483**	

	Millions of Yen		
March 31, 2015	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	
Total	¥ 79,397	¥ 79,397	
Notes and accounts payables	¥ 10,022	¥ 10,022	
Income taxes payable	2,161	2,161	
Total	¥ 12,184	¥ 12,184	

	Thousands of U.S. Dollars		
March 31, 2016	Carrying Amount	Fair Value	Unrealized Loss
Cash and cash equivalents	**$219,008**	**$219,008**	
Time deposits	**3,424**	**3,424**	
Notes and accounts receivables	**313,079**	**313,079**	
Marketable and investment securities	**213,212**	**213,133**	**$ 70**
Total	**$748,734**	**$748,646**	**$ 70**
Notes and accounts payables	**$102,238**	**$102,238**	
Income taxes payable	**17,070**	**17,070**	
Total	**$119,318**	**$119,318**	

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 because fair values and unrealized gains were immaterial for the years ended March 31, 2016 and 2015.

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

	Carrying Amount		
	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Investments in equity instruments that do not have a quoted market price in an active market	**¥331**	¥332	**$2,911**

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

	Due in One Year or Less	
March 31, 2016	Millions of Yen	Thousands of U.S. Dollars
Cash and cash equivalents	**¥ 24,748**	**$ 219,008**
Time deposits	**387**	**3,424**
Marketable securities	**2,950**	**26,106**
Notes and accounts receivables	**35,378**	**313,079**
Total	**¥ 63,464**	**$ 561,628**

11. OTHER COMPREHENSIVE INCOME (LOSS)

The components of other comprehensive income (loss) for the years ended March 31, 2016 and 2015, were as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2016	2015	**2016**
Unrealized gain (loss) on available-for-sale securities:			
Gains (losses) arising during the year	**¥ (667)**	¥ 5,014	**$ (5,902)**
Reclassification adjustments to profit or loss	**(258)**		**(2,283)**
Amount before income tax effect	**(925)**	5,014	**(8,185)**
Income tax effect	**416**	(1,255)	**3,681**
Total	**¥ (509)**	¥ 3,758	**$ (4,504)**
Deferred gain (loss) on derivatives under hedge accounting:	**¥ 13**	¥ (20)	**$ 115**
Gains (losses) arising during the year	**(4)**	7	**(35)**
Income tax effect			
Total	**¥ 8**	¥ (13)	**$ 70**
Foreign currency translation adjustments:			
Adjustments arising during the year	**¥**	¥ 22	**$**
Total	**¥**	¥ 22	**$**
Defined retirement benefit plans:			
Adjustments arising during the year	**¥ (3,994)**	¥ 114	**$ (35,345)**
Reclassification adjustments to profit or loss	**560**	557	**4,955**
Amount before income tax effect	**(3,433)**	672	**(30,380)**
Income tax effect	**1,049**	(303)	**9,283**
Total	**¥ (2,384)**	¥ 369	**$ (21,097)**
Total other comprehensive income (loss)	**¥ (2,884)**	¥ 4,136	**$ (25,522)**

12. NET INCOME PER SHARE

Net EPS for the years ended March 31, 2016 and 2015, was as follows:

	Millions of Yen	Thousands of Shares	Yen	Dollars
	Net Income Attributable to Owners of the Parent	Weighted-Average Shares	EPS	
For the year ended March 31, 2016 - Basic EPS				
Net income available to common shareholders	**¥ 6,340**	**67,372**	**¥ 94.10**	**$ 0.83**
For the year ended March 31, 2015 - Basic EPS				
Net income available to common shareholders	¥ 5,882	67,405	¥ 87.26	

13. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 29, 2016, the Company's shareholders approved the following:

Payment of year-end cash dividends of ¥14 ($0.12) per share to holders of record at March 31, 2016, for a total of ¥943 million ($8,345 thousand).

14. SEGMENT INFORMATION

Under ASBJ Statement No. 17, "Accounting Standard for Segment Information Disclosures," and ASBJ Guidance No. 20, "Guidance on Accounting Standard for Segment Information Disclosures," an entity is required to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. Operating segments are components of an entity about which separate financial information is available and 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. 'The 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. 'The Functional Food' industry consists of the manufacturing and sale of health food ingredients, preservatives, protein preparations, nutritional ingredients, seasonings and spices, sterilization cleaning agents, and others.

2. Methods of measurement for the amounts of sales, profit, 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."

Note: As discussed in Note 2.e, effective April 1, 2015, the Companies have adopted the straight-line method of depreciation for property, plant and equipment (except for lease assets), which were previously depreciated principally by the declining-balance method.

Due to the adoption of the straight-line method, segment profit of Pharmaceuticals and Functional Food increased by ¥282 million ($2,495 thousand) and by ¥8 million ($70 thousand), respectively, for the year ended March 31, 2016.

3. Information about sales, profit, assets, and other items is as follows:

	Millions of Yen				
	2016				
	Reportable Segment				
	Pharmaceuticals	Functional Food	Total	Reconciliations	Consolidated
Sales:					
Sales to external customers	**¥ 70,489**	**¥ 13,720**	**¥ 84,209**		**¥ 84,209**
Intersegment sales or transfers					
Total	**70,489**	**13,720**	**84,209**		**84,209**
Segment profit	**8,389**	**159**	**8,549**		**8,549**
Segment assets	**76,037**	**10,167**	**86,205**	**¥ 49,164**	**135,370**
Other:					
Depreciation	**2,214**	**211**	**2,425**	**26**	**2,452**
Increase in property, plant, and equipment and intangible assets	**3,439**	**114**	**3,554**		**3,554**

	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	13,720	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

	Thousands of U.S. Dollars				
	2016				
	Reportable Segment				
	Pharmaceuticals	Functional Food	Total	Reconciliations	Consolidated
Sales:					
Sales to external customers	**$ 623,796**	**$ 121,415**	**$ 745,212**		**$ 745,212**
Intersegment sales or transfers					
Total	**623,796**	**121,415**	**745,212**		**745,212**
Segment profit	**74,238**	**1,407**	**75,654**		**75,654**
Segment assets	**672,893**	**89,973**	**762,876**	**$ 435,079**	**1,197,964**
Other:					
Depreciation	**19,592**	**1,867**	**21,460**	**230**	**21,699**
Increase in property, plant, and equipment and intangible assets	**30,433**	**1,008**	**31,451**		**31,451**

Notes: Unallocated corporate assets included under "Reconciliations" for 2016 and 2015 are ¥49,164 million ($435,106 thousand) and ¥44,598 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		
	2016		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	**¥ 70,489**	**¥ 13,720**	**¥ 84,209**

	Thousands of U.S. Dollars		
	2016		
	Pharmaceuticals	Functional Food	Total
Sales to external customers	**$ 623,796**	**$ 121,415**	**$ 745,212**

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, 2016.

(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, 2016.

3. Information about major customers

	2016		
	Sales		Related Segment Name
Name of Customers	Millions of Yen	Thousands of U.S. Dollars	
MEDICEO CORPORATION	**¥15,485**	**$137,035**	**Pharmaceuticals**
Alfresa Corporation	**13,966**	**123,592**	**Pharmaceuticals**
Suzuken Co., Ltd.	**13,480**	**119,292**	**Pharmaceuticals**
Toho Pharmaceutical Co., Ltd.	**8,777**	**77,672**	**Pharmaceuticals**

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INDEPENDENT AUDITOR'S REPORT

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

We have audited the accompanying consolidated balance sheet of Nippon Shinyaku Co., Ltd. (the "Company") and its consolidated subsidiaries as of March 31, 2016, 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 Nippon Shinyaku Co., Ltd. and its consolidated subsidiaries as of March 31, 2016, 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.

Emphasis of Matter

As discussed in Note 2.e, effective April 1, 2015, the Company and its consolidated subsidiaries have adopted the straight-line method of depreciation for property, plant and equipment (except for lease assets), which had previously been depreciated by the declining-balance method. Our opinion is not modified in respect of this matter.

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 29, 2016

Member of
Deloitte Touche Tohmatsu Limited

Investor Information

Independent and Certified Public Accountants

Deloitte Touche Tohmatsu
Shijokarasuma FT Square
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Share Register

Mitsubishi UFJ Trust and Banking Corporation
3-6-3, Fushimi-machi, Chuo-ku, Osaka 541-8502, Japan

Issued and Outstanding Number of Shares

70,251,484

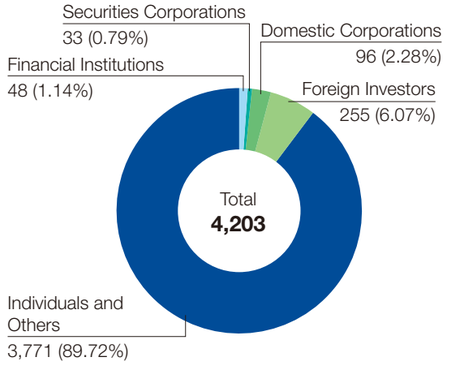
Number of Shareholders

4,203

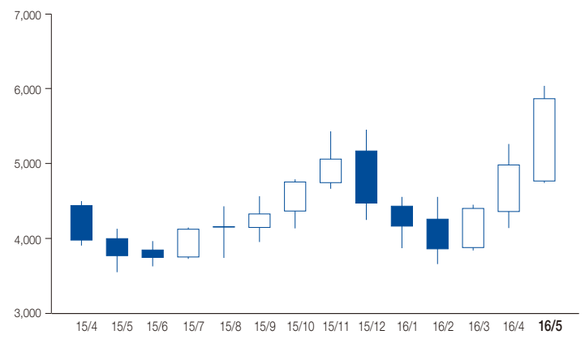
Major Shareholders

Meiji Yasuda Life Insurance Company
The Master Trust Bank of Japan, Ltd. (trust account)
Japan Trustee Services Bank, Ltd. (trust account)
The Bank of Tokyo-Mitsubishi UFJ, Ltd.
The Bank of Kyoto, Ltd.
Goldman, Sachs & Co. Reg
Nippon Life Insurance Company
J.P. Morgan Bank Luxembourg S.A. 380578
Japan Trustee Services Bank, Ltd. (trust account 9)
JPMC Oppenheimer JASDEC Lending Account

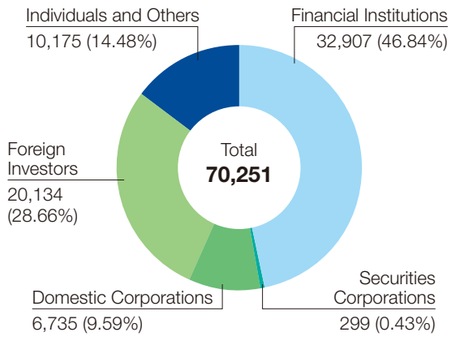
Distribution of Shareholders



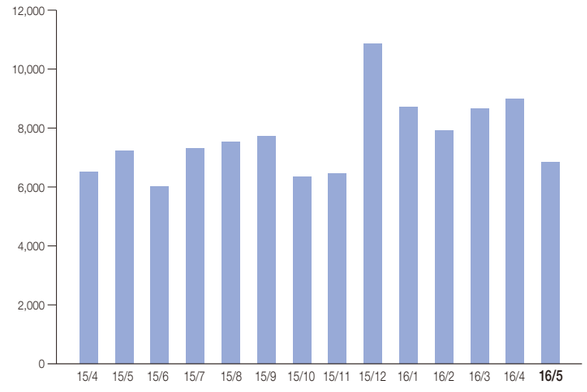
Stock Price (Yen)



Distribution of Shares Issued (Thousands of shares)



Trading Volumes (Thousands of shares)



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Hamamatsu, Kanazawa-Toyama, Himeji,
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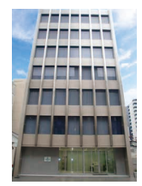

Head Office ● Branch Office ● Business Office ● Business Branch ● Plant ● Research Laboratories ● Subsidiary