The cover illustration is from Shirotake 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.
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.

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.
A Spirit Unchanged Since the Establishment of Nippon Shinyaku

The Path to Becoming a Corporation

Essential to the Community

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.

1950s

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

Recent New Products

2013

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

2014

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

2015

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

Nippon Shinyaku’s leading urological drug, Zalutia® tablets

2016

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

Recent New Products

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

Major product launches by decade

1950s

Isomytal® bulk powder, a hypnotic and sedative

Azunol® tablets for vertigo

Isomytal® bulk powder for hyperammonemia

1960s

Glycorm tablets, an oral diabetes medication

Eiprostat® tablets for benign prostatic hyperplasia

Selectol® tablets for hypertension and angina pectoris

Hypen® tablets, a nonsteroidal anti-inflammatory drug

Portakal® bulk powder for hyperammonemia

1970s

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

Corporate Data

Corporate Name
Nippon Shinyaku Co., Ltd.

Founded
November 20, 1911

Date of Incorporation
October 1, 1919

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

Paid-in Capital
¥5,174 million

Representative Director
Shigenobu Maekawa, President

Employees
1,950

ANNUAL REPORT 2016

Pharmaceuticals

Drugs for urological diseases

- Zoladex®
- Eviprolact®
- Blodex®
- Teniposide®
- Calcitriol®

Design, prostate hypertrophy (BPH) create issue, with degraded quality of life (QOL). Zoladex® is a drug for urinary disorders caused by BPH launched in April 2014, offers a new mechanism to relieve the symptoms of BPH and improve QOL.

Drugs for gynecology

- Lunabel® tablets LD
- Lunabel® tablets ULD

The Lunabel® combination tablet ULD, which combines low-dose estrogens and progestosterone, has been approved for insurance coverage in Japan. The Lunabel® 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

- Estracyt®
- Cyproterone®
- Tolnaftate®
- Imuran®

Estracyt®, a myelodysplastic syndrome (MDS) treatment, is permitting 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 improve QOL.

Drugs for intractable and rare diseases

- Erizas® Nasal Powder 200/uni-C
- Amnolake®
- Regtect®
- Trisenox®
- Cylocide®
- Vidaza®
- Cytoxan®
- Tramal® OD

Nippon Shinyaku provides drugs with differing mechanisms of action, including Adcirca®, a once-daily oral formulation long-acting agent that enables release technologies to branded hydrochloride, the active ingredient in Thalom® CD, a four-times daily formulation for cancer pain and chronic pain.

Drugs for otorhinolaryngology

- Cephadol®
- Nineace S
- Suncircle H
- R-88

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.

Others

- Cheflead V
- Glycine GX-2
- Mikaku Fine Z
- PROGEL800
- Milka MPI
- Lactocystal

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.

Health food ingredients

- Hylakels Acid 3000
- Garcia Powder 2
- Mangosteen Aqua
- Astax TA
- Phyto PC Aloe

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 various uses in the food industry.

Preservatives

- Nihaku Fine Z
- Nihaku Fine BR
- Milka Fine G-2
- Cheflead AC-00
- AC-20
- Milka MPI
- Lactocystal
- PROGEL800
- Lactocystal HG
- Finez S

Protein preparations and nutritional ingredients

Spices and condiments

- Kenda – chili pepper extract
- Nineace S
- Nineace H
- Fiveace S

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

Others

- Haskap Concentrate H
- Kenda – chili pepper extract
- Kenda – spice
- Onitake Concentrate H
- Haskapi Concentrate Miso

We utilize our extraction and formulation technologies developed in our natural products business to make spices, hot chilli extracts, spice concentrates, as well as taste products from wasabi and kantung melon produced in Honkaido.

Functional Food

Functional Food

16.3%

Pharmaceuticals

83.7%

Net Sales
¥84,209 million

Drugs for urological diseases

17.5%

Drugs for hematology

15.9%

Drugs for gynecology

10.9%

Drugs for otorhinolaryngology

7.2%

Drugs for intractable and rare diseases

4.8%

Drugs for intractable and rare diseases

27.4%

Others

05 ANNUAL REPORT 2016

ANNUAL REPORT 2016 06
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 syndromes, 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 selipelag (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%.

Selipelag, 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 II trial in Japan in January 2016, and a Phase II exploratory trial in the U.S. in March. New products: Onetrax® tablets (100mg), a treatment for cancer pain and chronic pain, and Opound® 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 selipelag, 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, selipelag 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 III trial. Internationally, Phase II trials of NS-018 (a treatment for myelofibrosis) and NS-065 are underway.

Message from the President

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

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—

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 consumers.

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.

Managerial Aspects
Societal Aspects

Targets
Policies
Foundation

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

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 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 ensure 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.

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 ensure 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.

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.

For Users
In the functional food segment, we will develop and supply high-quality functional food that satisfies the needs of consumers, 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

1. 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, and we will also achieve regulatory compliance and adhere to internal rules in building a relationship of trust with society.

2. We will make every effort to enhance our qualifications and quality of our work and act creatively.

3. 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.

4. We will maintain a safe and comfortable work environment by respecting each individual’s rights and personality.

5. We will promote business activities that are environmentally friendly, and will aim to maintain and improve the global environment.

6. We will build a trusting relationship with our stakeholders through timely and adequate communication of company information.

(revised in July 2011)
Selexipag (NS-304) for pulmonary arterial hypertension

Overview

PGL2, receptor agonists

It has been over 15 years since we began research on selexipag, a prostacyclin (PGL2) receptor agonist. PGL2 is a physiologically active substance produced inside the body. It contributes to the maintenance of homeostasis by stimulating PGL2 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 PGL2 is linked to various diseases, and PGL2 continues to be a focus of attention as a target for drug discovery. However, as the substance PGL2 itself is extremely unstable and difficult to handle, much research has been conducted toward creating a stable PGL2 receptor agonist.

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.

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 PGL2 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 PGL2 was developed as a treatment method and showed remarkably strong efficacy. Nevertheless, due to the unstable nature of PGL2 as mentioned above, the treatment required an indwelling tube for infusing the drug solution into a wide vein around 2000. Our research team learned of the disease PAH 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.

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 PGL2 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 PGL2 was developed as a treatment method and showed remarkably strong efficacy. Nevertheless, due to the unstable nature of PGL2 as mentioned above, the treatment required an indwelling tube for infusing the drug solution into a wide vein around 2000. However, in the second half of the 1990s, continuous infusion of PGL2 was developed as a treatment method and showed remarkably strong efficacy. Nevertheless, due to the unstable nature of PGL2 as mentioned above, the treatment required an indwelling tube for infusing the drug solution into a wide vein around 2000.

Our research team was working to develop an orally available, long-acting PGL2 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 PGL2 was developed as a treatment method and showed remarkably strong efficacy. Nevertheless, due to the unstable nature of PGL2 as mentioned above, the treatment required an indwelling tube for infusing the drug solution into a wide vein around 2000.
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 safety 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).

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 license Actelion started a global phase II trial (SIRIPHON study) in 39 countries at the end of 2009. Indicators often used in other phase II 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.

Development of selexipag proceeding smoothly

Our overseas license 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 satisfactory. 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 PGI2 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).

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

2015–Present

Maximizing product value
Development of selexipag proceeding smoothly

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 PGI2 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.
Business Activities

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.

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 NH1 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/adjust prices in cases where the market has expanded far in excess of forecasts given at the time of NH1 price listing*. On the other hand, policies such as the SAKIGAKE Designation System** 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 Zalutari®, a drug for urinary disorders caused by benign prostatic hypertrophy, Vidastr®, a myelodysplastic syndromes (MDS) treatment, and Frami® and Oraspir®, for cancer pain and chronic pain. In addition, we posted the revenue from industrial property rights accompanying the partner-led U.S. approval of seliprog (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.

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 MHD are our priority main fields of focus. In particular, our MDS treatment Vidastr®, 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.

<table>
<thead>
<tr>
<th>Code No. (generic name)</th>
<th>Developed company</th>
<th>Therapeutic field</th>
<th>Indications</th>
<th>Origin</th>
<th>Development</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV/ V</th>
<th>Launch</th>
</tr>
</thead>
</table>

*1 NH1 price listing: Approved as a prescription drug covered by NH1
**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.
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.

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.

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.

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.

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 otolaryngology 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.

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

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 selinexor (code number: NS-004), 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 Otsuvent® 10mg tablets and Astold® 20mg tablets already on the market, the further addition of selinexor will complete a full lineup of drugs that exhibit the three different mechanisms of action (endothelin receptor antagonist, phosphodiesterase type 5 inhibitor and P2Y 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.

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 Ph III trial in Japan, and a Ph 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 Ph trial of NS-580, an endometriosis drug with an anticipated analgesic effect brought about by the inhibition of PGE2 production, is proceeding smoothly. Similarly, the U.S. Ph III 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.
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 Oncology 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 prescribed 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.

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 suite 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-104 (generic name: salesipag), and provide up-to-date information in accordance with the needs of medical professionals to contribute to the treatment of PAH patients.

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

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

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* management. We have implemented policies to make employees more versatile and have put in place BSCI* 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 investigative new drugs to commercial production. In fact we have recently won contracts to manufacture two products. Japan’s accession to PIC/S* was approved in 2014. We are subsequently committed to improving our GMP levels in this era of ever greater PIC/S GMP requirements.

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 GMP* and implement a stringent risk management policy which measures which are constantly being improved in our moves to construct an ever-better product quality system. To guarantee safety, we strictly adhere to GMP* 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 accumulated as 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.

Shouzou Sano
Director, General Manager, Sales and Marketing Division

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

*1 Good Manufacturing Practice: Quality management standards for pharmaceutical products
*2 Good Sustained Practice: Safety management standards for pharmaceutical products after marketing approval
*3 Pharmaceutical Inspection Co-operation Scheme (PICS)
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.

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 products, 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, anna 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 Fino series, KC-20 and Glycine DK-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.

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

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 ensuring proper financial reporting, and, through the Internal Audit Department positioned directly under the President, evaluate the status 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 an auditing auditor to also audit the effectiveness of internal controls, compliance efforts, and risk management.

Corporate Governance Organization
The Nippon Shinyaku Group implements Compliance Operating System, which sets forth 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.

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

Compliance Initiatives
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

<table>
<thead>
<tr>
<th>Type of Training</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Departmental training</td>
<td>Conducted departmental training incorporating company-wide content and department-specific content.</td>
</tr>
<tr>
<td>Training for new employees (April)</td>
<td>Training that focuses on teaching new employees about compliance concepts and approaches, and stressing the importance of compliance.</td>
</tr>
<tr>
<td>Training for newly promoted managers (October)</td>
<td>Training that focuses on teaching compliance to newly promoted managers.</td>
</tr>
</tbody>
</table>

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 1st 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, there were “information management,” “disasters,” and “harassment,” which led us to build 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 have 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)

Risk management department

Director in charge of risk management

First employees to identify risk

Supervising manager of employee

Supervising manager of department

Director in charge of department where risk occurred

Supervising department for the specific risk

Director in charge of crisis management office

Working group

Department advised to cooperate

Supervising manager of group

Director in charge of crisis management office

Supervising manager of group

Director in charge of department where risk occurred

Supervising manager of employee

Supervising manager of department

Director in charge of department where risk occurred

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 initiatives for information security. We operate an Information Security Management System (ISMS) Committee that implements specific 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 initiatives for information security. We operate an Information Security Management System (ISMS) Committee that implements specific initiatives for information security. We operate an Information Security Management System (ISMS) Committee that implements specific initiatives for information security. We operate an Information Security Management System (ISMS) Committee that implements specific initiatives for information security.

Anti-Harassment Action
We consider harassment a serious issue that disrespects and intrudes 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 out of stock 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 (“E-up”) on the Japanese Shindo seismic intensity scale at the Dakeawa 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 we have 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 strictly manage third parties, which we ensure by carefully managing intellectual property rights through the examination of rights and other means.

Board of Directors, Corporate Officers and Corporate Auditors

President

Managing Directors

Corporate Auditors

Corporate Officers

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

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

I commend the Board of Directors in fiscal 2015 for engaging in lively, multi-faceted discussions that were rich in 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.
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, as a drug manufacturer going beyond supplying medicines—this 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://www.sda-support.jp/), we introduce medical institutions where individuals may 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 “Talking about Menstrual Cramps” (Japanese only; http://seiritsu.jp/) was established to relieve the anxiety and concerns of families. The site aims to relieve 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 pharmaceutical guidelines and information almost at improving advisement. 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.

Patients and Medical Professionals

Framework for Supplying Products
We implement a framework to secure the rapid and stable supply of high-quality pharmaceuticals through the use of sophisticated supply chain management (SCM), covering production and quality control through to logistics management. Our diverse initiatives in this area include efforts to reduce lead times by enhancing the efficiency of our overall production process including quality control processes, and sourcing ingredients from more than one supplier to ensure stable procurement.

Stable Supply of Products
All 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*3 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.

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 host press seminars for media-related parties, and are working to raise awareness of the issue through exhibits about counterfeit drugs at academic society meetings.

Additional, 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.
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 children’s, nursing care, and work circumstances.

We also have the Work Style Revival 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. 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.

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

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 training. 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 specialized 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 (CASAI) 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.

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
Research & Development Division

Editor’s note: This is a case study from the Overseas Training Program, which is designed to foster participants’ awareness.

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 children’s, nursing care, and work circumstances.

We also have the Work Style Revival 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. 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.

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

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 training. 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 specialized 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 (CASAI) 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.

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
Research & Development Division

Editor’s note: This is a case study from the Overseas Training Program, which is designed to foster participants’ awareness.
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 inherit our world. With this 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 Junior 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 view electronic versions of past and present books and hear them read aloud as they browse the pages.

At the awards ceremony held in October 2015, tying into the seventh children’s book produced in this way, Shintaku no Otetsu-sama (“The Curious Moon”), an Air Dome Planarium workshop was held for local children.

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 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 Junior 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 view electronic versions of past and present books and hear them read aloud as they browse the pages.

At the awards ceremony held in October 2015, tying into the seventh children’s book produced in this way, Shintaku no Otetsu-sama (“The Curious Moon”), an Air Dome Planarium workshop was held for local children.

Activities to Preserve and Maintain the Culture of Kyoto

For more than half a century Nippon Shinyaku has annually produced wash-ofuda with pictures made using katazome, a traditional Japanese 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.

Supporting Education through Sports

The Nippon Shinyaku amatuer 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 26 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. Though we are working to improve youths’ baseball skills and physical strength, while increasing our interaction with local communities.

Supporting Education through Sports

The Nippon Shinyaku amatuer 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 26 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. Though we are working to improve youths’ baseball skills and physical strength, while increasing our interaction with local communities.

Supporting Education through Sports

The Nippon Shinyaku amatuer 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 26 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. Though we are working to improve youths’ baseball skills and physical strength, while increasing our interaction with local communities.
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 reducing emissions of 16.2% in the fiscal year of 2015, including the achievement of reductions of 4.8% in energy consumption and 4.8% in CO₂ 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

<table>
<thead>
<tr>
<th>Objective</th>
<th>Results in FY 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promotion of energy conservation and global warming countermeasures</td>
<td>Reduce total energy consumption 4.8% in FY 2015 to be below 1990 levels.</td>
</tr>
<tr>
<td>Reduction of Waste</td>
<td>Pursue the 3Rs: Reduce, Reuse, Recycle and work to improve our resource recycling rate for waste disposal sites in FY 2015 by more than 55% from FY 2005 levels.</td>
</tr>
<tr>
<td>Promote Proper Management of Chemical Substances</td>
<td>Improve the risk assessment system of the Industrial Safety and Health Promotion Act (RISHPA) to continue reducing the amount of hazardous substances entering the natural environment.</td>
</tr>
<tr>
<td>Promote an Environmental Management System (EMS)</td>
<td>Ensure certified EMS management systems (ISO 14001 and KES Step 2).</td>
</tr>
<tr>
<td>Environmentally Conscious Product Upgrades and Materials Procurement</td>
<td>Reduce product packaging materials as part of pharmaceutical and first product package simplification efforts.</td>
</tr>
<tr>
<td>Communication with Society and Local Neighbors</td>
<td>Promote active participation in activities to give back to the areas where our facilities are situated.</td>
</tr>
</tbody>
</table>

### 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.

### Initiatives to Preserve Biodiversity
Nippon Shinyaku’s Yamashina Botanical Research Institute was founded in 1894 as the Yamashina Pilot Farm and is an important part of our R&D efforts. This 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 Santorini vermicide and greatly contributed to the growth of Nippon Shinyaku.

The Yamashina Botanical Research Institute is conveniently located near public transportation. The facility is a great place for tours for anyone because it lies entirely 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 experiments 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.

### Raising Corporate Value in the Eyes of Stakeholders
The Global Environment

Promotion of Energy Conservation and Global Warming Countermeasures
Nippon Shinyaku is continuously endeavoring to conserve energy and reduce emissions of CO₂. These efforts include switching to compact fluorescent lighting 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 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*1 in fiscal 2015 was 10.2% lower than in 2005, achieving a final landfill waste ratio of 0.5%.

Furthermore, CO₂ emissions*3 in fiscal 2015 were 10,059 tons. This was 1,058 tons lower, or 0.5% less than the 10,847 tons in fiscal 2014. We reduced electricity and energy consumption and CO₂ emissions by 4.8% and 4.8% respectively, compared with fiscal 1990 levels.*1

### 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 mileage and low CO₂ 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 CO₂ 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.

### 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 by the PRTR system under the Act on Continuation, etc. of Release of Specific Amounts of Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof.

Compared to fiscal 2014, in fiscal 2015 we handled 64.8% less dichromatmethane 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.

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 lies entirely 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 experiments 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.

---

*1 Total energy consumption, which is not dependent on CO₂ emission coefficient and directly reflects energy-saving efforts, was chosen as the indicator for the three-year period.
*2 Promotion of energy conservation activities by encouraging salespeople in Tokyo to use public transport, while promoting awareness of eco-driving throughout the Company.
*3 Voluntary environmental targets have been established to help guide the entire company toward reducing environmental impacts and making contributions to society.
## Non-Financial Highlights

### Summary of Consolidated Financial Indicators

<table>
<thead>
<tr>
<th></th>
<th>2012/3</th>
<th>2013/3</th>
<th>2014/3</th>
<th>2015/3</th>
<th>2016/3</th>
<th>2016/3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For the year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net sales</td>
<td>67,304</td>
<td>69,941</td>
<td>76,517</td>
<td>79,991</td>
<td>84,209</td>
<td>745,212</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>55,746</td>
<td>58,318</td>
<td>63,345</td>
<td>66,340</td>
<td>70,489</td>
<td>623,796</td>
</tr>
<tr>
<td>Functional food</td>
<td>11,558</td>
<td>11,622</td>
<td>13,172</td>
<td>13,651</td>
<td>13,720</td>
<td>121,415</td>
</tr>
<tr>
<td>Operating income</td>
<td>6,012</td>
<td>6,901</td>
<td>8,038</td>
<td>8,562</td>
<td>8,549</td>
<td>75,654</td>
</tr>
<tr>
<td>Net income</td>
<td>3,715</td>
<td>4,647</td>
<td>5,750</td>
<td>5,862</td>
<td>6,340</td>
<td>56,106</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>2,948</td>
<td>2,769</td>
<td>2,704</td>
<td>2,665</td>
<td>2,462</td>
<td>21,699</td>
</tr>
<tr>
<td>Capital investment</td>
<td>967</td>
<td>1,302</td>
<td>1,072</td>
<td>1,239</td>
<td>3,554</td>
<td>31,451</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>9,414</td>
<td>9,049</td>
<td>9,530</td>
<td>8,968</td>
<td>9,739</td>
<td>86,185</td>
</tr>
</tbody>
</table>

### End of the year

<table>
<thead>
<tr>
<th></th>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total assets</td>
<td>106,304</td>
<td>113,730</td>
</tr>
<tr>
<td>Net assets</td>
<td>84,568</td>
<td>93,186</td>
</tr>
</tbody>
</table>

### Financial information per share

<table>
<thead>
<tr>
<th></th>
<th>Yen</th>
<th>U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earnings per share</td>
<td>55.04</td>
<td>68.87</td>
</tr>
<tr>
<td>Dividend per share</td>
<td>19</td>
<td>21</td>
</tr>
</tbody>
</table>

### Principal financial indicators

<table>
<thead>
<tr>
<th></th>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio of net worth</td>
<td>79.4</td>
<td>78.5</td>
</tr>
<tr>
<td>Return on equity</td>
<td>4.5</td>
<td>5.4</td>
</tr>
<tr>
<td>Pay-out ratio</td>
<td>34.5</td>
<td>30.5</td>
</tr>
</tbody>
</table>

### Summary of ESG Indices

<table>
<thead>
<tr>
<th></th>
<th>2012/3</th>
<th>2013/3</th>
<th>2014/3</th>
<th>2015/3</th>
<th>2016/3</th>
<th>2016/3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total energy consumption (thousands of GJ)</td>
<td>231</td>
<td>231</td>
<td>201</td>
<td>194</td>
<td>193</td>
<td>-</td>
</tr>
<tr>
<td>CO2 emissions (t)</td>
<td>9,568</td>
<td>11,272</td>
<td>10,412</td>
<td>10,203</td>
<td>10,059</td>
<td>-</td>
</tr>
<tr>
<td>CO2 per unit of revenue (million yen)</td>
<td>0.143</td>
<td>0.162</td>
<td>0.136</td>
<td>0.128</td>
<td>0.119</td>
<td>-</td>
</tr>
<tr>
<td>Number of employees (people)</td>
<td>1,898</td>
<td>1,895</td>
<td>1,899</td>
<td>1,939</td>
<td>1,950</td>
<td>-</td>
</tr>
</tbody>
</table>
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 ¥18 per share, comprising an interim dividend of ¥14 per share and year-end dividend of ¥4 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.

As a result, total assets increased by ¥5,612 million compared to the previous fiscal year end to ¥24,748 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 payable-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 and to ¥96,864 million.

Equity increased by ¥1,435 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 ¥335 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 ¥2,833 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 ¥1,571 million, and for the acquisition of license rights of ¥650 million.

Net cash used in financing activities amounted to ¥2,833 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.

Net assets 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 sales 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 payable-trade and income taxes payable, etc.

3. Summary of Consolidated Business Results
(1) Pharmaceuticals
In the pharmaceuticals segment, sales for long-listed drugs declined, while sales for new products including Salutan®4, a drug for urinary disorders caused by benign prostatic hyperplasia, Vidaza®, a remedy for myelodysplastic syndrome, and Tranil®/Ontron®5, 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.

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

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

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

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

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

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

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

Consolidated Balance Sheet (Assets) (millions of yen)

<table>
<thead>
<tr>
<th>Year</th>
<th>Fixed assets</th>
<th>Current assets</th>
<th>Total assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>49,334</td>
<td>80,422</td>
<td>129,757</td>
</tr>
<tr>
<td>2016</td>
<td>49,968</td>
<td>85,451</td>
<td>135,370</td>
</tr>
</tbody>
</table>

Consolidated Statement of Cash Flows (millions of yen)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cash and cash equivalents, beginning of year</th>
<th>Net cash provided by operating activities</th>
<th>Net cash used in investing activities</th>
<th>Net cash used in financing activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>21,915</td>
<td>8,915</td>
<td>2,833</td>
<td>1,907</td>
</tr>
<tr>
<td>2016</td>
<td>24,748</td>
<td>8,915</td>
<td>2,833</td>
<td>1,907</td>
</tr>
</tbody>
</table>

It could impact the business results of the Nippon Shinyaku Group.

Business Risks
Following are some of the risks that could impact the financial position and business results of the Nippon Shinyaku Group.

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

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

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

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

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

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

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

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

### ASSETS

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CURRENT ASSETS:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents (Note 10)</td>
<td>¥ 24,748</td>
<td>¥ 21,914</td>
<td>¥ 219,008</td>
</tr>
<tr>
<td>Time deposits (Note 10)</td>
<td>387</td>
<td>227</td>
<td>3,424</td>
</tr>
<tr>
<td>Marketable securities (Notes 3 and 10)</td>
<td>2,926</td>
<td>900</td>
<td>25,893</td>
</tr>
<tr>
<td>Notes and accounts receivables (Note 10):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade notes</td>
<td>412</td>
<td>274</td>
<td>3,646</td>
</tr>
<tr>
<td>Trade accounts</td>
<td>34,723</td>
<td>34,736</td>
<td>307,283</td>
</tr>
<tr>
<td>Other</td>
<td>242</td>
<td>147</td>
<td>2,141</td>
</tr>
<tr>
<td>Total notes and accounts receivables</td>
<td>35,378</td>
<td>35,158</td>
<td>313,079</td>
</tr>
<tr>
<td>Inventories (Note 4)</td>
<td>18,929</td>
<td>19,658</td>
<td>187,513</td>
</tr>
<tr>
<td>Deferred tax assets (Note 9)</td>
<td>1,881</td>
<td>1,698</td>
<td>16,469</td>
</tr>
<tr>
<td>Other current assets</td>
<td>1,168</td>
<td>1,265</td>
<td>10,336</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>85,401</td>
<td>80,422</td>
<td>755,761</td>
</tr>
</tbody>
</table>

| **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 | 8,555 | 8,814 | 75,743 |
| Construction in progress | 130 | 74 | 1,150 |
| **Total** | 51,193 | 50,990 | 453,035 |
| Accumulated depreciation | (33,568) | (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 |

See notes to consolidated financial statements.

### LIABILITIES AND EQUITY

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CURRENT LIABILITIES:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes and accounts payables (Note 10):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade notes</td>
<td>¥ 1,761</td>
<td>¥ 1,792</td>
<td>$ 15,584</td>
</tr>
<tr>
<td>Trade accounts</td>
<td>4,998</td>
<td>5,328</td>
<td>44,200</td>
</tr>
<tr>
<td>Other</td>
<td>4,793</td>
<td>2,904</td>
<td>42,416</td>
</tr>
<tr>
<td>Total notes and accounts payables</td>
<td>11,553</td>
<td>10,022</td>
<td>102,238</td>
</tr>
<tr>
<td>Income taxes payable (Note 10)</td>
<td>1,029</td>
<td>2,161</td>
<td>17,070</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>3,721</td>
<td>3,759</td>
<td>30,829</td>
</tr>
<tr>
<td>Deposits from customers</td>
<td>295</td>
<td>284</td>
<td>2,610</td>
</tr>
<tr>
<td>Other current liabilities</td>
<td>3,069</td>
<td>1,542</td>
<td>27,159</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>20,569</td>
<td>17,770</td>
<td>182,026</td>
</tr>
</tbody>
</table>

| **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 | 86,137 | 793,433 |
| Treasury stock – at cost, 2,888,330 shares in 2016 and 2,869,940 shares in 2015 | (2,413) | (2,337) | (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

<table>
<thead>
<tr>
<th></th>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
<td>2015</td>
</tr>
<tr>
<td>COST AND EXPENSES:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of sales</td>
<td>¥ 44,016</td>
<td>$ 2,354</td>
</tr>
<tr>
<td>Salaries, general, and administrative expenses (Notes 7 and 8)</td>
<td>¥ 31,643</td>
<td>$ 1,765</td>
</tr>
<tr>
<td>Total</td>
<td>¥ 75,659</td>
<td>$ 4,119</td>
</tr>
<tr>
<td>Operating income (Note 14)</td>
<td>¥ 8,549</td>
<td>$ 458</td>
</tr>
<tr>
<td>OTHER INCOME (EXPENSES):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest and dividends income</td>
<td>¥ 416</td>
<td>$ 0.02</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(43)</td>
<td>(0.01)</td>
</tr>
<tr>
<td>Other – net</td>
<td>(9)</td>
<td>(0.01)</td>
</tr>
<tr>
<td>Other income – net</td>
<td>¥ 403</td>
<td>$ 0.02</td>
</tr>
<tr>
<td>INCOME BEFORE INCOME TAXES</td>
<td>¥ 8,952</td>
<td>$ 0.46</td>
</tr>
<tr>
<td>INCOME TAXES (Note 9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income taxes</td>
<td>¥ 25,000</td>
<td>$ 1,379</td>
</tr>
<tr>
<td>Deferred</td>
<td>¥ 207</td>
<td>$ 0.01</td>
</tr>
<tr>
<td>Total income taxes</td>
<td>¥ 25,207</td>
<td>$ 1,380</td>
</tr>
<tr>
<td>NET INCOME</td>
<td>¥ 3,462</td>
<td>$ 18,076</td>
</tr>
<tr>
<td>NET INCOME ATTRIBUTABLE TO OWNERS OF THE PARENT</td>
<td>¥ 6,340</td>
<td>$ 3,456</td>
</tr>
<tr>
<td>NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTERESTS</td>
<td>¥ 4,340</td>
<td>$ 2,994</td>
</tr>
</tbody>
</table>

#### Consolidated Statement of Comprehensive Income

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

<table>
<thead>
<tr>
<th></th>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
<td>2015</td>
</tr>
<tr>
<td>OTHER COMPREHENSIVE INCOME (LOSS) (Note 11):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealized gain (loss) on available-for-sale securities</td>
<td>(509)</td>
<td>(4,504)</td>
</tr>
<tr>
<td>Deferred gain (loss) on derivatives under hedge accounting</td>
<td>0</td>
<td>70</td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>(2,296)</td>
<td>500</td>
</tr>
<tr>
<td>Deferral retirement benefit plan</td>
<td>(2,044)</td>
<td>21,007</td>
</tr>
<tr>
<td>Total other comprehensive income (loss)</td>
<td>(2,846)</td>
<td>21,157</td>
</tr>
<tr>
<td>COMPREHENSIVE INCOME</td>
<td>$ 3,462</td>
<td>$ 30,857</td>
</tr>
<tr>
<td>COMPREHENSIVE INCOME ATTRIBUTABLE TO:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Owners of the parent</td>
<td>$ 3,456</td>
<td>$ 30,857</td>
</tr>
<tr>
<td>Noncontrolling interests</td>
<td>6</td>
<td>50</td>
</tr>
</tbody>
</table>

#### Consolidated Statement of Changes in Equity

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

<table>
<thead>
<tr>
<th></th>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
<td>2015</td>
</tr>
<tr>
<td>BALANCE, MARCH 31, 2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NYK</td>
<td>(Note 1)</td>
<td></td>
</tr>
<tr>
<td>Outstanding Number of Common Stock</td>
<td>67,463</td>
<td>67,482</td>
</tr>
<tr>
<td>Capital Stock</td>
<td>$ 5,174</td>
<td>$ 5,041</td>
</tr>
<tr>
<td>Preferred Stock</td>
<td>$ 4,445</td>
<td>$ 4,445</td>
</tr>
<tr>
<td>Retained Earnings</td>
<td>$ 83,873</td>
<td>$ 84,581</td>
</tr>
<tr>
<td>Treasury Stock</td>
<td>(2,173)</td>
<td>(2,173)</td>
</tr>
<tr>
<td>Unrealized gain (loss) on available-for-sale securities</td>
<td>(509)</td>
<td>(509)</td>
</tr>
<tr>
<td>Deferred income from sales</td>
<td>(1,819)</td>
<td>(1,819)</td>
</tr>
<tr>
<td>Defined benefit plan</td>
<td>(1,617)</td>
<td>(1,617)</td>
</tr>
<tr>
<td>Defined benefit from sales</td>
<td>(85)</td>
<td>(85)</td>
</tr>
<tr>
<td>Total</td>
<td>(2,884)</td>
<td>(2,884)</td>
</tr>
<tr>
<td>Net change during the year</td>
<td>(2,327)</td>
<td>(2,327)</td>
</tr>
<tr>
<td>BALANCE, MARCH 31, 2015</td>
<td>¥ 67,382</td>
<td>$ 60,159</td>
</tr>
<tr>
<td>NYK</td>
<td>(Note 1)</td>
<td></td>
</tr>
<tr>
<td>Outstanding Number of Common Stock</td>
<td>67,363</td>
<td>67,382</td>
</tr>
<tr>
<td>Capital Stock</td>
<td>$ 5,174</td>
<td>$ 5,041</td>
</tr>
<tr>
<td>Preferred Stock</td>
<td>$ 4,445</td>
<td>$ 4,445</td>
</tr>
<tr>
<td>Retained Earnings</td>
<td>$ 83,137</td>
<td>$ 83,873</td>
</tr>
<tr>
<td>Treasury Stock</td>
<td>(2,173)</td>
<td>(2,173)</td>
</tr>
<tr>
<td>Unrealized gain (loss) on available-for-sale securities</td>
<td>(11)</td>
<td>(11)</td>
</tr>
<tr>
<td>Deferred income from sales</td>
<td>(1,037)</td>
<td>(1,037)</td>
</tr>
<tr>
<td>Defined benefit plan</td>
<td>(232)</td>
<td>(232)</td>
</tr>
<tr>
<td>Defined benefit from sales</td>
<td>(1,617)</td>
<td>(1,617)</td>
</tr>
<tr>
<td>Total</td>
<td>(2,884)</td>
<td>(2,884)</td>
</tr>
<tr>
<td>Net change during the year</td>
<td>(2,327)</td>
<td>(2,327)</td>
</tr>
<tr>
<td>BALANCE, MARCH 31, 2016</td>
<td>¥ 65,106</td>
<td>$ 57,832</td>
</tr>
</tbody>
</table>

#### Notes to Consolidated Financial Statements

See notes to consolidated financial statements.
See notes to consolidated financial statements.
a. Consolidation

All significant intercompany balances and transactions have been eliminated. The investment in one unconsolidated subsidiary is stated at the lower of cost or fair value, which is determined using fair value as of the determination date.

b. Inventories

Cash equivalents are short-term investments in high-quality securities or other assets with maturities of three months or less. Cash equivalents include time deposits, certificates of deposit, and other instruments that are exposed to insignificant risk of changes in value. Cash equivalents are carried at cost plus or minus any unrealized gains or losses.

c. Asset Retirement Obligations

The asset retirement obligation is recognized as the present value of the estimated future cash outflows required to retire an asset. The present value is calculated using the risk-free interest rate for the related remaining service period.

d. Income Taxes

Deferred tax assets and liabilities are recognized for the expected tax consequences of temporary differences between the financial statements and the tax bases of assets and liabilities. Deferred taxes are recognized at the tax rates that are expected to apply in the year in which the asset or liability is realized or settled.

e. Foreign Currency Financial Statements

The financial statements of foreign subsidiaries are translated into the reporting currency at the exchange rate prevailing 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.

f. Foreign Currency Transactions

Foreign currency transactions are translated at the exchange rate prevailing at the date of the transaction. Foreign currency financial assets and liabilities are translated at the exchange rate prevailing 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.

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.

g. 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) 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 accounted for as part of the basis in the hedged transactions. The foreign currency forward contracts are utilized to hedge foreign currency exposures in procurement of raw materials from overseas suppliers. The foreign currency forward contracts qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are accounted for as part of the basis in the hedged transactions. The foreign currency forward contracts are utilized to hedge foreign currency exposures in procurement of raw materials from overseas suppliers. The foreign currency forward contracts qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are accounted for as part of the basis in the hedged transactions.

h. 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 the 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.
includes specific transitional provisions, in which case the entity shall comply with the specific transitional provisions.

(a) 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.

(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.

5. New Accounting Pronouncements

(a) 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.

5. New Accounting Pronouncements

(a) 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.

(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.

5. New Accounting Pronouncements

(a) 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.

(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.

(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.

(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.

5. New Accounting Pronouncements

(a) 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.
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 component of plan assets.

(b) Assumptions used for the years ended March 31, 2016 and 2015, are set as follows:

<table>
<thead>
<tr>
<th>Component of Plan Assets</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan assets as of March 31, 2016 and 2015, respectively.</td>
<td>¥15,851</td>
<td>¥14,970</td>
</tr>
<tr>
<td>Unrecognized prior service cost</td>
<td>¥326</td>
<td>¥372</td>
</tr>
<tr>
<td>Interest cost</td>
<td>¥1,042</td>
<td>¥1,042</td>
</tr>
<tr>
<td>Recognition of actuarial losses</td>
<td>¥45</td>
<td>¥52</td>
</tr>
<tr>
<td>Other</td>
<td>¥5</td>
<td>¥68</td>
</tr>
<tr>
<td>Net periodic benefit costs</td>
<td>¥1,089</td>
<td>¥1,024</td>
</tr>
</tbody>
</table>

(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:

<table>
<thead>
<tr>
<th>Component of Plan Assets</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign shares</td>
<td>¥3,478</td>
<td>¥3,478</td>
</tr>
<tr>
<td>Foreign bonds</td>
<td>¥1,525</td>
<td>¥1,525</td>
</tr>
<tr>
<td>Home shares</td>
<td>¥1,035</td>
<td>¥1,035</td>
</tr>
<tr>
<td>Total</td>
<td>¥6,043</td>
<td>¥6,027</td>
</tr>
</tbody>
</table>

(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:

<table>
<thead>
<tr>
<th>Component of Plan Assets</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior service cost</td>
<td>¥450</td>
<td>¥450</td>
</tr>
<tr>
<td>Actuarial (gain) losses</td>
<td>¥3,769</td>
<td>¥3,773</td>
</tr>
<tr>
<td>Total</td>
<td>¥4,219</td>
<td>¥4,223</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Category</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic bonds</td>
<td>10.5%</td>
<td>10.5%</td>
</tr>
<tr>
<td>Foreign bonds</td>
<td>13.7%</td>
<td>13.7%</td>
</tr>
<tr>
<td>Foreign shares</td>
<td>11.5%</td>
<td>11.5%</td>
</tr>
<tr>
<td>General accounts</td>
<td>20.6%</td>
<td>25.3%</td>
</tr>
<tr>
<td>Alternative</td>
<td>9.9%</td>
<td>9.9%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Component of Plan Assets</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred tax assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retirement benefits</td>
<td>¥3,230</td>
<td>¥2,559</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>¥963</td>
<td>¥1,023</td>
</tr>
<tr>
<td>Property, plant, and equipment</td>
<td>51</td>
<td>51</td>
</tr>
<tr>
<td>Other</td>
<td>¥1,592</td>
<td>¥1,406</td>
</tr>
<tr>
<td>Less valuation allowance</td>
<td>¥316</td>
<td>¥325</td>
</tr>
<tr>
<td>Deferred tax assets</td>
<td>¥4,185</td>
<td>¥4,257</td>
</tr>
<tr>
<td>Deferred tax liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealized gain on available-for-sale securities</td>
<td>¥3,769</td>
<td>¥4,185</td>
</tr>
<tr>
<td>Deferred gains on sales of property</td>
<td>¥997</td>
<td>¥1,095</td>
</tr>
<tr>
<td>Other</td>
<td>¥16</td>
<td>¥23</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>¥4,836</td>
<td>¥5,395</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Component of Plan Assets</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal effective statutory tax rate</td>
<td>33.0%</td>
<td>35.5%</td>
</tr>
<tr>
<td>Expenses not deductible for income tax purposes</td>
<td>1.4</td>
<td>1.6</td>
</tr>
<tr>
<td>Income not taxable for income tax purposes</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Tax credits for research and development costs</td>
<td>0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>Tax effects of tax rate reduction</td>
<td>1.0</td>
<td>3.7</td>
</tr>
<tr>
<td>Per Capita Levy municipal tax</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Other – net</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Actual effective tax rate</td>
<td>29.1%</td>
<td>34.0%</td>
</tr>
</tbody>
</table>

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 ¥230 million ($220 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 ¥97 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.
Payments term 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 financial 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 primarily 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 valuation techniques are used instead.

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

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

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

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

For the years ended March 31, 2016 and 2015, were as follows:

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

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

Millions of Yen

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 ¥ 67,495 ¥ 87,26
13. 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 ($2,492 thousand) and by ¥96 million ($83 thousand), respectively, for the year ended March 31, 2016.

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

- **Segment assets**: ¥745,212 million ($6,655 thousand).
- **Segment profit**: ¥1,008 million ($8,777 thousand).
- **Depreciation**: ¥15,485 million ($135,370 thousand).

### Related Information

#### 1. Information about products and services

<table>
<thead>
<tr>
<th>Segment</th>
<th>2016 Sales</th>
<th>2015 Sales</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>¥133,120</td>
<td>¥132,651</td>
<td>0.4%</td>
</tr>
<tr>
<td>Functional Food</td>
<td>¥ 4,905</td>
<td>¥ 5,745</td>
<td>-14.6%</td>
</tr>
<tr>
<td>Total</td>
<td>¥138,025</td>
<td>¥138,401</td>
<td>-0.3%</td>
</tr>
</tbody>
</table>

#### 2. Information about geographical area

- **Pharmaceuticals**: Sales to external customers: ¥131,415 million ($1,159 thousand).
- **Functional Food**: Sales to external customers: ¥4,212 million ($37 thousand).
- **Total**: Sales to external customers: ¥135,627 million ($1,196 thousand).

#### 3. Information about major customers

<table>
<thead>
<tr>
<th>Name of Customers</th>
<th>Sales to external customers (¥ millions)</th>
<th>Segment</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDICEO CORPORATION</td>
<td>¥150,465</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>Ajinomoto Co., Ltd.</td>
<td>¥13,969</td>
<td>Functional Food</td>
</tr>
<tr>
<td>Suntory Co., Ltd.</td>
<td>¥19,770</td>
<td>Functional Food</td>
</tr>
</tbody>
</table>

Note: The amounts and related information are presented in the consolidated financial statements for the years ended March 31, 2016 and 2015, respectively, in millions of yen, thousands, and tens of millions of yen, thousands, and tens of thousands of yen, respectively, and consist primarily of funds, such as cash equivalents, investment securities, assets for administrative functions, and deferred tax assets.
INDEPENDENT AUDITORS’ 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 misstatement, 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.

June 29, 2016

Deloitte Touche Tohmatsu LLC
Member of Deloitte Touche Tohmatsu Limited

ANNUAL REPORT 2016
## Offices in Japan

**Head Office**
- 14, Nishinosho-Monguchi-cho, Koshim, Minami-ku, Kyoto 607-8550, Japan
  - Phone: +81-7-3121-1111
  - Fax: +81-7-3121-0678

**Tokyo Office**
- 3-6-4, Nihombashi, Chuo-ku, Tokyo 103-0027, Japan
  - Phone: +81-3-3241-2154
  - Fax: +81-3-3246-2308

**Sales Offices**

### Sapporo Business Office
- 5-10-1, Nipponkan-4-chome, Nord-ku, Sapporo, Hokkaido 060-0864, Japan
  - Phone: +81-116-611-2408
  - Fax: +81-116-611-2408

### Tokyo Business Office
- 1-21-1, Akebono-cho, Tachikawa, Tokyo 190-0012, Japan
  - Phone: +81-42-528-3702
  - Fax: +81-42-528-3702

### Shinetsu Business Office
- 8-24, Tenya-machi, Hakuba-cho, Fukuoka 812-0025, Japan
  - Phone: +81-92-836-2925
  - Fax: +81-92-836-2925

### Nishitakai Business Office
- 2-11-1, Akebono-cho, Tachikawa, Tokyo 190-0012, Japan
  - Phone: +81-42-528-3701
  - Fax: +81-42-528-3702

### Saitama Business Office
- 1-50, Saito-cho, Omiya-ku, Saitama 330-0844, Japan
  - Phone: +81-48-649-5201
  - Fax: +81-48-649-5201

### Chiba Business Office
- 15-8, Tsunawari-cho, Chuo-ku, Chiba 260-0003, Japan
  - Phone: +81-43-226-3768
  - Fax: +81-43-226-3341

### Yokohama Business Office
- 2-12-15, Chigasaki-mura, Tsuraki-ku, Yokohama, Kanagawa 224-0037, Japan
  - Phone: +81-45-948-5173
  - Fax: +81-45-945-1822

### Nagoya Business Office
- 3-41, Shinkucho-cho, Nagashin-ku, Nagoya, Aichi 461-0014, Japan
  - Phone: +81-52-931-7535
  - Fax: +81-52-931-7536

### Kei-Hokusetsu Business Office
- 8, Takada Jibunbashi-cho, Fushimi-ku, Kyoto 601-0445, Japan
  - Phone: +81-7-321-4477
  - Fax: +81-7-321-4477

### Osaka Business Office
- 2-5-7, Docho-machi, Chuo-ku, Osaka 541-0045, Japan
  - Phone: +81-6-6203-3812
  - Fax: +81-6-6203-3812

### Kobe Business Office
- 3-1-7, Sodebori-cho, Chuo-ku, Kobe, Hyogo 651-0084, Japan
  - Phone: +81-6-6203-3812
  - Fax: +81-6-6203-3812

### Shikoku Business Office
- 1-1, Daikokumachi, Takamatsu, Kagawa 760-0042, Japan
  - Phone: +81-85-811-3307
  - Fax: +81-85-811-3307

### Chugoku Business Office
- 19-27, Masaoka-machi, Higashi-ku, Hiroshima 733-0006, Japan
  - Phone: +81-82-236-2054
  - Fax: +81-82-236-2054

### Fukuoka Business Office
- 8-24, Taniyama-machi, Hakata-ku, Fukuoka 810-0205, Japan
  - Phone: +81-92-281-2525
  - Fax: +81-92-281-2525

### Minamiasahi Business Office
- 14-23, Suzuki Koen, Chuo-ku, Kumamoto 862-0055, Japan
  - Phone: +81-8-865-5811
  - Fax: +81-8-865-5838

### Business Branches
- Asahikawa, Akita, Koyama, Utsunomiya, Iwate, Matsumoto, Jihoku, Jihoku, Jihoku, Jihoku, Jihoku, Iwasaki, Atsugi, Shio, Shio, Shio, Hamamatsu, Kanazawa-Toya, Hirota, Matsumoto, Oyama, Yutaka, Kita, Kitakyushu, Oita, Nagasaki, Miyazaki, Kagoshima, Okinawa

### Logistic Centers

#### East Logistic Center
- 3-3, Nishinbukuro, Yashio, Saitama 340-0833, Japan
  - Phone: +81-48-624-0044
  - Fax: +81-48-803-3070

#### West Logistic Center
- 2-15-3, Fujikawato, Isaki, Oita 877-0054, Japan
  - Phone: +81-7-72-640-5655
  - Fax: +81-7-72-640-5666

### Research & Development Facilities

**Discovery Research Laboratories**
- 14, Nishinosho-Monguchi-cho, Koshim, Minami-ku, Kyoto 607-8550, Japan
  - Phone: +81-7-3121-1111
  - Fax: +81-7-3121-0678

**Discovery Research Laboratories in Tsukuba**
- 3-14-1, Sakurav, Tsukuba, Ibaraki 305-0003, Japan
  - Phone: +81-7-321-4927
  - Fax: +81-7-321-4927

**Food Development Laboratories**
- 14, Nishinosho-Monguchi-cho, Koshim, Minami-ku, Kyoto 607-8550, Japan
  - Phone: +81-7-3121-9207
  - Fax: +81-7-3121-9208

### Production Facilities

**Odawara Central Factory**
- 670-1, Kitasawa, Odawara, Kanagawa 250-0861, Japan
  - Phone: +81-58-28-3411
  - Fax: +81-58-37-1033

**Discovery Research Laboratories**
- In Tsukuba
  - Facsimile: +81-75-321-9027
  - Phone: +81-75-321-9027

**Discovery Research Laboratories / Food Development Laboratories**

- Chiba Business Office
- Chibako Business Office
- Sendai Business Office
- Osaka Business Office
- Yokohama Business Office

**Domestic Subsidiaries and Affiliates**
- Sioe Pharmaceutical Co., Ltd.
  - 3-1-11, Shio, Amagasaki, Hyogo 661-0076, Japan
  - Phone: +81-6-6499-2001
  - Fax: +81-6-6499-8205

- Tajma Shokuhin Kogyo Co., Ltd.
  - 435, Higashinakano, Higashicho, Toyosu, Hyogo 669-5300, Japan
  - Phone: +81-7-9784-1095
  - Fax: +81-7-9786-4273

- NS Shared Services, Co., Ltd.
  - 14, Nishinosho-Monguchi-cho, Koshim, Minami-ku, Kyoh 601-8550, Japan
  - Phone: +81-7-75-314-8558
  - Fax: +81-7-75-314-8558

**Overseas Offices and Subsidiaries**

- **NS Pharma, Inc.**
  - Mack-Call Centre III-South Tower, 2nd Floor, 140 East Ridgewood Avenue, Paramus, NJ 07652, U.S.A.
  - Phone: +1-201-986-3860
  - Fax: +1-201-986-3865

- **Beijing Representative Office**
  - 2015, Changlingyong Building, No. 28, Jian Guo Men Wai Street, Chaoyang District, Beijing, 100022, China
  - Phone: +86-10-627-8650
  - Fax: +86-10-627-8650

- **London Office**
  - Building 3, Chiswick Park, 100, Chiswick High Road, Chiswick, London, W4 5YA, U.K.