## NIPPON SHINYAKU CO., LTD.



The cover illustration is from Boku Shiranaiyo ("It's not me"), a picture book published through the 8th Nippon Shinyaku Children's Literary Awards contest. For more information about the contest, please refer to page 33 of this report.











# NO BORDER

Beyond conventional wisdom.

Beyond borders of nationality, race, and time.

Even beyond one's own limits.

Responding to the world's medical needs,

To brighten the futures of patients and their families.

Every day we push ourselves to the forefront of drug development.

Going beyond it all, to the future of medicine

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#### **Editorial Policy**

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

#### Period Covered

#### Companies Covered

Fiscal 2016 (April 1, 2016-March 31, Information in this report pertains to Nippon Shinyaku 2017). Some sections of the report also Co., Ltd. and its Japanese subsidiaries within the discuss initiatives from April 2017 Nippon Shinyaku Group. However, some sections apply only to Nippon Shinyaku Co., Ltd.

Figures presented in this report are taken from Nippon Shinyaku's Financial Report for the year ended March 31, 2017. As figures have been rounded, totals may not exactly equal the sum of their composite statistics.

#### Forward-Looking Statements

Statements contained in this report concerning plans, predictions, and strategies to improve future performance ("forward-looking statements") are based on information currently available to the Company's management, and inevitably involve a certain element of risk and uncertainties. Actual results may therefore differ from those in the forward-looking statements.



## To become a corporation essential to the community, Nippon Shinyaku will continue to provide drugs that will bring hope to patients struggling with illness and to their families.

Nippon Shinyaku's core business is pharmaceuticals. This business mainly targets the prescription drug market through research and 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.

#### **Drugs for Urological Diseases**



●Eviprostat ●Bladderon Estracyt
Cialis

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

#### **Drugs for Hematology**



- Cylocide
- Trisenox Amnolake

Vidaza is the world's only drug that extends survival time for patients with myelodysplastic the frequency of blood transfusions and raise patients'

#### Drugs for Intractable and Rare Diseases



Adcirca Opsumit Ouptravi Regtect

Nippon Shinyaku supplies three types of therapeutic medication with separate mechanisms of action for pulmonary arterial hypertension, an intractable disease with poor prognosis. In 2009 we launched Adcirca, in 2015 Opsumit, and in 2016 Uptravi.

#### Drugs for Gynecology



Lunabell Tablets LD Lunabell Tablets ULD

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

#### Drugs for Otorhinolaryngology



- Erizas
- Baynas
- Azunol Gargle Liquid Cephadol
- Livostin

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

#### Others



Onetram

Tramal OD

For cancer pain and chronic pain, we sell Tramal OD, a four-times daily formulation, and Onetram, a once-daily oral long-lasting formulation based on release technologies, both containing the active ingredient tramadol hydrochloride.

## Functional Food

## We help people to lead healthy, active, and rich lives through our safe and secure functional food ingredients.

Nippon Shinyaku utilizes advanced technological prowess we have built up as a pharmaceutical company to develop and supply high-quality, highly original functional food ingredients, firm in the belief that medicine and food share the same importance in maintaining good health.

#### Health Food for Consumers



WINZONE ENERGY × ENERGY



AGE-SHUT

We want to help people lead healthier, happier lives through diet. We communicate this directly to consumers by supplying original health foods for the sports market and anti-aging market that we develop in-house as a researchbased maker of new pharmaceuticals

#### **Health Food Ingredients**



- Mangosteen Aqua Hyaluronic Acid 3000
- Garcinia Powder J NS Amla Extract Powder
- Aronia TA

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.

#### **Protein Preparations**



- Milka MPI Lactocrystal ●PROGEL800
- ●Enlacto HG ●Fitness S

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

#### **Preservatives**



Mikaku Fine S Mikaku Fine W ■Mikaku Fine L ■Mikaku Fine Z Mikaku Fine BK Glycine GX-2

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

#### Spices and Condiments



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

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

#### Pharmaceuticals

Sales have been growing for new product suites such as Zalutia and Vidaza. The launch of Uptravi has also contributed to revenue growth.



#### Market Environment

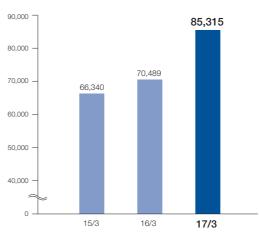
The domestic market for prescription drugs continues to grow tougher. High drug prices, which sparked debate over the reform of the National Health Insurance (NHI) drug price system, have led to special market-expansion repricing being introduced and an emergency NHI drug price revision in November 2016. At the end of last year, the national government adopted a basic policy to drastically reform the NHI drug price system, which is forecast to become a concrete plan during 2017.

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

### Situation in the Current Period

During the current period, sales of long-listed drugs decreased due to the influence of generics and competing products, but sales of new product suites increased, including Zalutia, a drug for urinary disorders caused by benign prostatic hypertrophy, Vidaza, a myelodysplastic syndrome treatment, and Tramal and Onetram for cancer pain and chronic pain. For treating pulmonary arterial hypertension, in addition to increased sales of Adcirca, in November 2016 we began selling our originally developed treatment. Uptravi, We also had one-time income from marketing approval of Uptravi in Europe, and both royalty income and active pharmaceutical ingredient sales overseas. The result was net sales of ¥85,315 million, up 21.0% year-on-year.





#### **Functional Food**

Sales increased in preservatives and health food ingredients, but fell in protein preparations and other areas, leading to lower net sales.

#### Market Environment

In the Japanese processed foods market, a slow economic recovery and continued lack of clarity with regard to future economic trends have caused greater budget-mindedness and a demand for lower prices among consumers. Processed food manufacturers are seeing costs continue to rise for ensuring safety, even as price competition has intensified, resulting in tough market conditions.

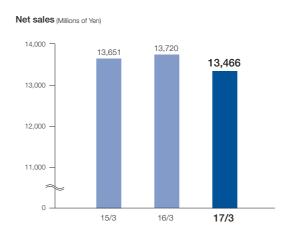
In the health food sector, in contrast, the new labeling system for foods with function claims was launched, leading to a range of new products reaching the market. Sales are strong for various products related to sports, and the forthcoming 2020 Tokyo Olympics presents a bright outlook.



#### Situation in the Current Period

We have continued to strengthen our resolve as a trusted R&D-based manufacturer to develop high-quality, highly original products.

We have focused in particular on health food ingredients, preservatives, protein preparations, and end products. The result has been increased sales of preservatives and health food ingredients. At the same time, a drop in the unit selling price of protein preparations has led to lower sales, resulting in net sales of ¥13,466 million, down 1.9% year-on-year.



#### FY2016 Business Performance

¥98,781 million

+17.3% y/y

Operating income

¥15,280 million

+78.7% y/y

Net income

attributable to

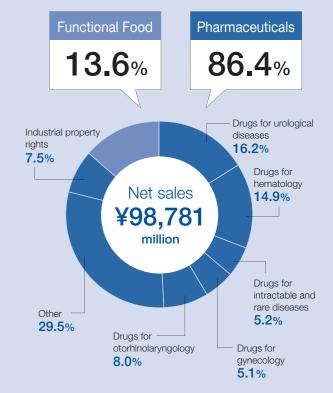
¥11,749 million

+85.3% v/v

expenses ¥14,903 million

15.1% of net sales ratio

Employees (As of March 31, 2017) 2,011





#### Situation in the Current Period

## Due to growing interest in healthy longevity, we have achieved revenue and profit growth again this year.

In the pharmaceuticals segment, net sales for the Nippon Shinyaku Group in the current period were ¥85,315 million, up 21.0% year-on-year. Increases in sales of Zalutia, Vidaza and other new product suites; one-time income from the marketing approval in Europe last year of the pulmonary arterial hypertension remedy selexipag (code number: NS-304); and royalty income and active pharmaceutical ingredient sales overseas, were all factors contributing to this growth. In the functional food segment, sales increased in preservatives and health food ingredients but decreased in protein preparations, leading to net sales of ¥13,466 million, down 1.9% year-on-year. Nonetheless, consolidated net sales were ¥98,781 million, up 17.3% year-on-year.

In terms of profit, operating income was ¥15,280 million, up 78.7% year-on-year and ordinary income was ¥16,244 million, up 81.4% year-on-year. Net income attributable to owners of the parent was ¥11,749 million, up 85.3% year-on-year. In all cases profits rose by a large margin to all-time highs.

Key topics include our original drug product Uptravi, licensed out to Actelion Pharmaceuticals Ltd. (Switzerland) and being granted marketing authorization in Europe in May 2016 with sales beginning in Europe in June, following launch earlier in the United States. Approval was then obtained in Japan in September 2016 and sales began in November. In October

2016 the U.S. FDA gave a fast track designation to our nucleic acid drug NS-065/NCNP-01, which received orphan drug designation and rare pediatric disease designation in January 2017.

We also licensed four products. In December 2016, we licensed NS-32, a treatment for iron deficiency anemia, from Pharmacosmos A/S (Denmark). In March 2017, we licensed NS-917, a treatment for relapsed/refractory acute myeloid leukemia, from Delta-Fly Pharma, Inc. (Japan). Also in March 2017, we licensed NS-73, a treatment for hepatic veno-occlusive disease, and NS-87, a treatment for secondary acute myeloid leukemia, from Jazz Pharmaceuticals PLC (Ireland).

#### The Corporate Value of Nippon Shinyaku

## We strive to be a company that plays a meaningful role in society as an essential member of the healthcare sector.

Nippon Shinyaku has been engaged in creating distinctive medicines as an R&D-based pharmaceuticals company for nearly 100 years since its establishment. Since 1961, utilizing our technology and knowhow from the pharmaceuticals business, we have been branching out into the functional food business, and today our functional foods are widely acclaimed and trusted. We aim to continue helping people to be healthy through both of these business areas.

In R&D, we proactively develop treatments in fields other companies are reluctant to tackle, such as intractable and rare diseases. We are currently developing NS-065/NCNP-01, utilizing our nucleic acid synthesis technology developed over many years, and clinical trials are underway both in Japan and abroad. To bolster our supply chain, we have built a manufacturing facility for highly active solid formulations at our Odawara Central Factory. The facility will carry out in-house manufacturing of highly active formulations such as our original Uptravi and following products, and will also carry out contract manufacturing. In the functional food segment we utilize the advanced technology we possess as a pharmaceuticals company to provide products with high added value.

In the area of human resources, we offer various training programs and motivation-boosting measures to acquire and cultivate employees who can always think critically and take necessary action on their own.

We consider our role to be more than supplying high-quality pharmaceuticals and functional foods to the marketplace. As a member of society and the communities in which we operate, we aim to contribute to the advancement of society. By advancing socially responsible efforts from the viewpoint of our stakeholders, we also aim to boost our corporate value.

Through such independent activities we act as an essential member of the healthcare sector, and as a unique organization, trusted and valued by the community, we aim to play a meaningful role in society.

#### Medium-to-Long-Term Vision

#### Having become an organization trusted and valued by the community, we are working toward sustainable growth in pharmaceuticals and functional foods.

Our business philosophy, "helping people lead healthier, happier lives" is at the core of all our business activities. By wholeheartedly implementing all aspects of our management policy, we are able to supply unique and high-quality products, earn the trust of society, and develop each employee. The entire Group is united in its aim to achieve growth in our two core businesses—pharmaceuticals and functional foods.

In pharmaceuticals, we are focusing on three core areas in the medium-to-long-term—urology, hematology, and intractable and rare diseases. We are concentrating management resources on illnesses for which there is still a great need for effective treatment. Our three pillars are in-house drug discovery, in-licensing, and product life cycle management, through which we are improving our product pipeline and expanding market share. We are also setting the foundation for expanding our international business.

In the functional food segment we are utilizing the advanced technology we have developed as a pharmaceuticals company and focusing on business areas where customer needs are high, centering around high value-added products. Such efforts will transform our earnings structure into one with great stability.

July 2017

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## The Nippon Shinyaku Vision

#### CSR and the Promotion of Conscientious Corporate 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. 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.



Foundation

contribute to a better quality of life in patients, first and foremost for patients who suffer from illnesses. We will develop and supply high-quality functional food that meets the needs of customers.

#### Society: Earn the Trust of Society

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

#### Employees: Develop Each Employee

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

#### Guidelines for Action

#### Challenge: Meet Challenges

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

#### Speed: Speedy Action

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

#### Investigation: Spirit of Investigation

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

#### Corporate Vision

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

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

Pharmaceuticals

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

**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



#### **CSR Policy**

#### **Relations with Business Partners**

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

#### For Shareholders and Investors

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

#### For the Environment

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

#### For Patients

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



#### For Users

In the functional food seament, we will develop and supply high-quality functional food that satisfies the needs of users, leveraging our advanced technology as 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

- We will act with high ethical standards and in accordance with our business philosophy and management policy while always being conscious of our social responsibilities. We will also achieve regulatory compliance and adhere to internal rules and other regulations in fostering a relationship of trust with
- 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.
- We will maintain a safe and comfortable work environment by respecting each individual's human rights and personality.
- We will promote business activities that are environmentally friendly, and will aim to maintain and improve the global environment.
- We will build a trusting relationship with our stakeholders through timely and adequate communication of company

- We will implement unfettered competition that is fair and transparent by maintaining a healthy and appropriate relationship with politicians, governments, and business
- We fully recognize the value of our corporate assets including information assets, and will manage these appropriately.
- We will not comply with inappropriate or unlawful requests from antisocial forces or organizations who threaten the safety and order of civil society.
- As a member of society, we will take a proactive approach in social contribution activities.
- We will comply with international rules and local regulations, as well as respect local culture and customs in our global business activities.

(revised in April 2017)

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# For the Sake of Patients Struggling with Diseases with No Effective Treatment





Discovery Research Laboratories in Tsukuba

#### Nippon Shinyaku's R&D Structure

## Pushing Ahead with R&D at Our Two Core Research Centers

At Nippon Shinyaku, we have two research bases; the Discovery Research Laboratories in Kyoto, where our head office is located, and the Discovery Research Laboratories in Tsukuba, in Ibaraki Prefecture. The Discovery Research Laboratories in Kyoto are mainly involved in research into low molecular weight drugs, including exploratory research, research into non-clinical safety and in-vivo kinetics, drug substance synthesis and formulation development, as well as quality assessment. At the Discovery Research Laboratories in Tsukuba, the focus is particularly targeted on nucleic acid drugs and we are working on drug discovery research making use of the fundamental technologies that have been developed thus far, such as nucleic acid synthesis and array design.

Clinical development is mainly performed by the Clinical Development Division in Japan, and by our subsidiary NS Pharma, Inc. in the U.S. (Paramus, New Jersey), with the two working in conjunction.

The Licensing & Alliance Division is endeavoring to enhance the pipeline by in-licensing marketed products and products in development as well as undertaking licensing-out activities for our original drugs.

We built the manufacturing building for active pharmaceutical ingredients for clinical trials in 2016, and have put in place the systems for in-house manufacture of active pharmaceutical ingredients for investigational drugs, such as highly physiologically active drugs and nucleic acid drugs. Our aim is to further speed up research and development through the rapid and flexible manufacture of the active pharmaceutical ingredients required to develop new drugs.



Discovery Research Laboratories in Kyo

#### Nippon Shinyaku's R&D Initiatives

## Enhancing the Pipeline through In-House Drug Discovery and In-Licensing

Through joint research with the National Center of Neurology and Psychiatry (NCNP) and making practical use of our fundamental nucleic acid technologies developed by the Discovery Research Laboratories in Tsukuba over many years, Nippon Shinyaku has developed a drug NS-065/NCNP-01 for treatment of the hereditary intractable and rare disease Duchenne muscular dystrophy (see next page).

NS-018 is a product in development in the hematology field, which is a key area of focus for Nippon Shinyaku, and is a drug developed in-house for myelofibrosis therapy (see next page). In March 2017, we licensed NS-917, for the treatment of relapsed/refractory acute myeloid leukemia, from Delta-Fly Pharma (Tokushima, Japan), and NS-73 for the treatment of hepatic veno-occlusive disease, which occurs following hematopoietic cell transplantation, and NS-87 for the treatment of secondary acute myeloid leukemia from Jazz Pharmaceuticals (Dublin, Ireland), and are pro-actively pushing ahead with developing therapeutic agents in this field.

In the gynecological field, in December 2016, we licensed NS-32, for the treatment of iron-deficiency anemia, from Pharmacosmos (Holbæk, Denmark). The characteristic feature of this drug is that it can be used to safely administer large doses of iron supplement in a small number of doses, even to patients for whom treatment by existing intravenous iron injection was difficult.

Going forward we will continue to tackle new drug discovery as our mission, aiming to provide therapeutic agents as soon as possible that will offer hope to patients suffering from diseases for which no effective treatment exists.

#### What Are Nucleic Acid Drugs?

Nucleic acid drugs are medications that target patients' genes responsible for various diseases. These drugs have the effect of inhibiting the production and function of proteins made by those genes. Nucleic acid drugs can be used with patients for whom treatment by traditional low molecular weight drugs was difficult, and, because of their superiority in terms of safety due to their high specificity, there are great expectations for these drugs as the next-generation of pharmaceuticals after therapeutic antibodies.



#### Main Products in Development

#### NS-065/NCNP-01 for Duchenne Muscular Dystrophy

#### The Antisense Nucleic Acid Drug from Japan

Duchenne muscular dystrophy (DMD) is the most frequently occurring hereditary muscle disorder in boys. A mutation occurs in the gene of dystrophin protein, which constructs the framework of muscle cells, and because normal dystrophin cannot be produced, severe muscular atrophy and muscular weakness progress. There is currently no effective method of treatment other than steroids to delay the progression of the disease in Japan, and it is anticipated new therapeutic agents will be developed.

NS-065/NCNP-01, which was discovered through joint research between Nippon Shinyaku and the National Center of Neurology and Psychiatry (NCNP), is an antisense nucleic acid drug, which restores misalignment of amino acid reading frames by skipping part of the genetic information of the dystrophin gene (exon skip). Although partially truncated compared to normal dystrophin, being able to generate functional dystrophin means there is hope for improved muscle function. This drug is aimed at patients who have a mutation type that responds to dystrophin gene exon 53 skipping and is expected to be an important option in the treatment of DMD.

NS-065/NCNP-01 is in a Phase I/II clinical trial in Japan, and undergoing a Phase II clinical trial in the U.S. In Japan, NS-065/NCNP-01 has received SAKIGAKE designation from the Ministry of Health, Labour and Welfare, and in the U.S. it has been granted fast track designation, orphan drug designation, and rare pediatric disease designation by the FDA. Nippon Shinyaku is putting these development support programs provided by the regulatory authorities to use with the aim of making this therapy available to patients as soon as possible.

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

| 2009 | Nippon Shinyaku and NCNP start joint research                                                                   |
|------|-----------------------------------------------------------------------------------------------------------------|
| 2013 | Investigator-initiated clinical trial starts                                                                    |
| 2015 | Receives SAKIGAKE designation                                                                                   |
| 2016 | Phase I/II clinical trial in Japan and Phase II clinical trial in the U.S. start Granted fast track designation |
| 2017 | Granted orphan drug designation and rare                                                                        |

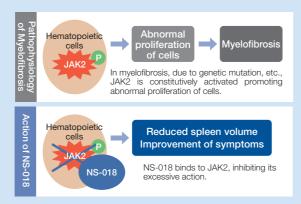
pediatric disease designation

NS-018 for Myelofibrosis

#### Selectively Inhibits Excessive Action of JAK2

NS-018 is a Janus Kinase 2 (JAK2) protein kinase inhibitor under development in the U.S. as a myelofibrosis therapy. Myelofibrosis is a hematological disorder in which an abnormality occurs in hematopoietic cells, and as the result of proliferation of fibrous tissue in the bone marrow, normal hematopoiesis is impaired. Myelofibrosis is a rare disease and patient numbers are low, with approximately 1,500 patients in Japan and around 26,000 patients worldwide. Anemia and enlargement of the spleen (hematopoiesis in the spleen instead of the bone marrow enlarging the spleen) reduce patients' QOL and the disease may be fatal within a few years. Although hematopoietic cell transplantation is being performed as a radical treatment, in cases where transplantation cannot be performed due to the patient's health or other reasons, the therapy is treatment of anemia or using JAK2 inhibitors. JAK2 is one of the enzymes involved in the mechanism of hematopoiesis and around half of patients with myelofibrosis have a mutation in this enzyme gene. It is hoped that by selectively inhibiting JAK2 that is overly active due to genetic mutation, NS-018 will relieve the various symptoms of myelofibrosis while reducing the side effects.

In the Phase I/II clinical trial conducted in the U.S., the safety and efficacy of NS-018 was examined in patients with intolerant (they could not tolerate the treatment with other JAK inhibitors), relapsed (prior treatment was effective but they became ill again) or refractory (prior treatment was ineffective) myelofibrosis. As a result, a reduction of spleen volume of 10% or more, which is said to be related to survival and improved QOL, was observed in 16 out of 26 cases (62%). Based on these results, we are now considering the next phase of clinical trials with a view to delivering NS-018 for use in clinical settings as soon as possible.



### Already Launched Products

## Three Types of Therapeutic Agents for Pulmonary Arterial Hypertension

## Providing Oral Dosage Forms with Different Mechanisms of Action

Pulmonary arterial hypertension (PAH) is a disease with a poor prognosis, in which blood pressure in the pulmonary artery, which sends blood from the heart to the lungs, becomes abnormally high causing death from right ventricular failure. PAH is a designated intractable disease for which in the past there were virtually no methods of treatment, however, since the late 1990s, effective treatments have come on the market. Nippon Shinyaku, as the only pharmaceutical company in the world which provides a range of PAH therapeutic agents that act on these three pathways; Uptravi (prostacyclin pathway), Opsumit (endothelin pathway), and Adcirca (nitric oxide pathway), mainly promotes these products to specialty hospitals and physicians. Earlier dual or triple combination therapy is now recommended for PAH treatment, but it is not yet in widespread use. Being able to provide comprehensive information on PAH treatment, we will promote earlier combination therapy and contribute to improving prognosis of patients by supporting specialists' research regarding optimal combination of PAH medication.

| Treatment Pathway/Type                                          | Generic Name<br>(product name)                                                                                                                                                 | Mechanism of Action                                                                                                                    |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Prostacyclin pathway/<br>IP receptor agonists                   | Selexipag<br>(Uptravi) In Japan:<br>Launched in<br>November 2016.<br>Co-promoted with<br>Actelion Japan. Overseas:<br>Sold as Uptravi by<br>Actelion in Europe<br>and the U.S. | Dilates blood<br>vessels by<br>selectively<br>stimulating the<br>weakened<br>prostacyclin<br>pathway in patients.                      |
| Endothelin pathway/<br>Endothelin<br>receptor antagonists       | Macitentan<br>(Opsumit)<br>Licensed from<br>Actelion and<br>co-promoted with<br>Actelion Japan<br>in Japan.                                                                    | Dilates blood vessels by inhibiting the effect of endothelin, a substance produced in the body that exhibits a vasoconstrictor action. |
| Nitric oxide pathway/<br>Phosphodiesterase<br>type 5 inhibitors | Tadalafil<br>(Adcirca)                                                                                                                                                         | Dilates blood vessels by enhancing the effect of nitric oxide (NO), a vasodilator substance produced in the body.                      |

#### Vidaza for Myelodysplastic Syndrome (MDS)

## The Only Drug That Has Extended the Survival Time for MDS Patients

Vidaza is a therapeutic agent for MDS that was launched in 2011. Overseas, it was first approved in the U.S. in 2004, and is currently sold in over 79 countries. MDS is a disease in which an abnormali-



ty occurs in hematopoietic cells and normal blood cells can no longer be produced. Fewer normal blood cells result in development of symptoms such as anemia, bleeding, and fever from infection, and as the disease progresses patients cannot live without blood transfusions. In some cases, the disease may develop into acute leukemia. Although hematopoietic cell transplantation is available as a complete cure, as MDS is a disease that is prevalent in the elderly, active treatment such as transplantation is not an option for many MDS patients, thereby making MDS a disease with an extremely poor prognosis.

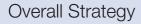
Vidaza exhibits the effect of inhibiting the proliferation of abnormal blood cells and increasing production of normal blood cells. In a comparative study with conventional treatment conducted in Europe, it was proven to extend the survival time. Also, in a clinical trial in Japan, it led to half of the patients needing a red blood cell transfusion to no longer needing a transfusion. One of the characteristic features of Vidaza is that this treatment can be used on an outpatient basis. Vidaza, which can also be used to treat elderly patients, is currently being used by many patients and is helping to improve their QOL. We hope that Vidaza will bring hope to many patients in future.



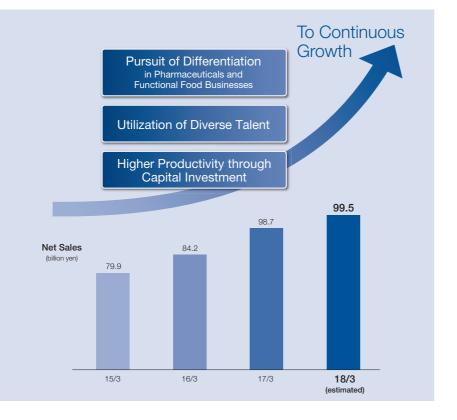
#### **Growth Strategy**

## To Enhance Corporate Value

Nippon Shinyaku's stated aim is to be a company that plays a meaningful role in society. We bring unique strengths to the healthcare sector in particular, where we strive to earn wide trust and acclaim for our pharmaceuticals and functional food businesses, which in turn further raises corporate value.



Nippon Shinyaku carries out business in pharmaceuticals and functional food by steadily applying our business philosophy. Based on our guidelines for action-challenge, speed, and investigation-we encourage every one of our employees to work to achieve their targets with promptness and a strong sense of ethics. In this way we are able to build relationships of trust with patients and our many other stakeholders and carry out business activities with full integrity.



#### **Business Strategies**

We aim to differentiate our products from those of other companies in our two businesses of pharmaceuticals and functional food and we aim to grow by launching new products and improving profitability. In the pharmaceuticals business, we focus management resources on five fields—urology; hematology; intractable and rare diseases (pulmonary arterial hypertension (PAH), muscular dystrophy, alcohol dependence, etc.); gynecology; and otorhinolaryngology. We aim to expand our share of sales in these areas and build our development pipeline on three pillars: in-house drug discovery, in-licensing, and product life cycle management (PLCM). We are also building a management structure for expanding our business outside of Japan.

In the functional food business, we utilize advanced technologies that we possess as a pharmaceuticals company to create products with high added value, focusing on areas where customers' needs are high-healthy longevity, active lifestyles, food safety, and food waste reduction. Such business efforts will help us to achieve a stable earnings structure.

#### Personnel Strategies

The types of employees we want are those who are able to make decisions and take action autonomously. We hire individuals of solid and diverse character and help them to develop high market value. We actively hire women and reemploy retired workers; we also promote motivation management. To utilize diverse talents, in addition to hiring a large pool of new graduates, we take other measures such as conducting mid-career recruitment of exceptional individuals and recruiting individuals from other countries who are studying in Japan. We train our employees to carry out the core business tasks of the company and to develop strong international sensibilities. We also provide business leader training and offer study programs to build English-language skills so that our employees can do a good job both in and out of the office. We do not discriminate by gender, age, or disability; rather, we utilize a diverse range of individuals to boost productivity and raise our value as a company. We try to create a climate in which all of our employees can take pride in their work, are able to grow personally, and are motivated to work toward achieving goals.

### Capital Investment Strategies

Construction of a manufacturing building for active pharmaceutical ingredients for clinical trials was completed in March 2016. This facility can manufacture anti-cancer drugs and other highly active pharmaceutical ingredients and nucleic acid drugs through to a Phase II trial. After its completion, the facility began to manufacture active pharmaceutical ingredients of nucleic acid drugs such as NS-065/NCNP-01 to treat Duchenne muscular dystrophy, and NS-580 for endometriosis, leading to a reduction in the cost of such ingredients and the speeding up of R&D. Also, a new facility was completed at the Odawara Central Factory in July 2017 to manufacture highly active solid formulations in-house for our own pharmaceutical products, as well as to perform contract manufacturing.

#### Strategies by Function

Pharmaceuticals (R&D)

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

of focus

We try to make effective use of both internal and external resources, with a focus on three main fields-urology, hematology, and intractable and rare diseases—to strengthen our in-house drug development. We are working to strengthen our development pipeline by overviewing the state of in-house drug discovery, and by carrying out in-licensing and PLCM.



#### Pharmaceuticals (Sales)

Bolstering three product suites to be growth drivers

With our sights on a mid-term and long-term plan for bringing new drugs to market, we are investing management resources in three fields (urology, hematology, and PAH), developing product suites to lead the way to sustainable growth.



#### Pharmaceuticals (Production)

Stable product supply and improving productivity

At every stage-procurement, manufacturing, and distribution—we seek to provide a stable supply of product and by improving efficiency and implementing cost management, we aim to boost productivity overall. We are also expanding contract manufacturing business at the Odawara Central Factory.

Productivity will be improved through tighter cost management and initiatives to improve efficiency at all stages of the process-procurement, manufacturing, and distribution.

Stable Product Supply



Facility for manufacturing highly active solid formulations built at Odawara Central Factor

<u>Investment</u>

of managemen

▶ P.17

▶ P.19

▶ P.20

▶ P.21

#### Functional Food

Provision of high-quality, high added-value original ingredients

We are pouring management resources into R&D on health food ingredients as a field of focus, along with preservatives and protein preparations to supply high-quality, high added-value original ingredients and original products to meet customers' needs.

#### The values we endeavor to offer society

Healthy longevity Active lifestyles Food safety Food waste reduction

## Core areas Health food ingredients Preservatives Protein preparations

Bring to market high-quality, high added-value, distinctive functional food ingredients

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## We are committed to providing unique drugs and creating a fully integrated pipeline by clarifying our main fields of focus



## NS-304 reached the market in FY2016 and R&D proceeded steadily in Japan and internationally

Actelion, based in Allschwil, Switzerland, is the overseas licensing-out partner for our pulmonary arterial hypertension (PAH) medication NS-304 (product name: Uptravi; generic name: selexipag). The company received approval in the U.S. in December 2015 and marketing authorization in Europe in May 2016. Nippon Shinyaku received manufacture and marketing approval in Japan in September 2016. Alongside Opsumit and Adcirca already on the market, the addition of Uptravi completes a full lineup of drugs that exhibit the three different mechanisms of action generally used in PAH therapy at present—an endothelin receptor antagonist, a PDE5 inhibitor, and an IP receptor agonist. We thus endeavor to offer a range of choices in PAH therapy to patients and medical institutions.

NS-065/NCNP-01, Japan's first ever antisense nucleic acid drug and a Duchenne muscular dystrophy therapy that we developed through joint research with the National Center of Neurology and Psychiatry (NCNP), is now undergoing a Phase



I/II trial in Japan and a Phase II trial in the U.S. with both proceeding smoothly. It was designated under the SAKIGAKE designation system by the Japanese Ministry for Health, Labour and Welfare in October 2015. In the United States, the U.S. Food and Drug Administration gave it fast track designation in October 2016, and in January 2017 it received orphan drug designation and rare pediatric disease designation, key supports for commercialization while the drug continues to be developed.

Similarly, the U.S. Phase I/II trial of NS-018, a myelofibrosis therapy with a JAK2 kinase inhibitory effect, has been proceeding smoothly, and a portion of the results were presented at a meeting of the American Society of Hematology in December 2016.

Meanwhile, the Japanese Phase I trial is proceeding for NS-580, an endometriosis drug with an anticipated analgesic effect and effect against lesions brought about by the inhibition of PGE2 production.

## We are utilizing commercialization support to gain early approval

We are aiming to apply for approval in Japan in fiscal 2017 for GA101, a treatment for indolent non-Hodgkin's lymphoma that is being co-developed with Chugai Pharmaceutical Co., Ltd.

We will utilize the SAKIGAKE designation system in Japan and the U.S. fast track designation system to try to get early approval of NS-065/NCNP-01.

For NS-018 we plan to optimize the development strategy to maximize product value. As an R&D-oriented new drug manufacturer, we are actively working to develop treatments for intractable and rare diseases that do not yet have therapies.

#### Pipeline

Japan As of May 11, 2017

| Code No.<br>(generic name) | Development phase              | Therapeutic field                         | Indications                                   | Origin                                                     | Development                                               | Phase I | Phase ∐ | Phase <u>II</u> | Application | Launch |
|----------------------------|--------------------------------|-------------------------------------------|-----------------------------------------------|------------------------------------------------------------|-----------------------------------------------------------|---------|---------|-----------------|-------------|--------|
| GA101<br>(Obinutuzumab)    | P∭                             | Hematologic malignancies                  | Indolent non-Hodgkin's lymphoma               | Licensed-in from:<br>Chugai<br>Pharmaceutical<br>Co., Ltd. | Co-development:<br>Chugai Pharmaceutical<br>Co., Ltd.     |         |         |                 |             |        |
| NS-304                     | PⅢ                             | Intractable<br>and rare<br>diseases       | Chronic thromboembolic pulmonary hypertension | Nippon Shinyaku                                            | Co-development:<br>Actelion Pharmaceuticals<br>Japan Ltd. |         |         |                 |             |        |
| (Selexipag)                | PΙΙ                            | Cardiovascular<br>and metabolic<br>system | Arteriosclerosis obliterans                   | Nippon Shinyaku                                            | Nippon Shinyaku                                           |         |         |                 |             |        |
| NS-065/<br>NCNP-01         | PI/II                          | Intractable<br>and rare<br>diseases       | Duchenne muscular dystrophy                   | Co-development:<br>NCNP*                                   | Nippon Shinyaku                                           |         |         |                 |             |        |
| NS-580                     | PI                             | Gynecological diseases                    | Endometriosis                                 | Nippon Shinyaku                                            | Nippon Shinyaku                                           |         |         |                 |             |        |
| NS-32                      | PI                             | Gynecological diseases                    | Iron deficiency anemia                        | Licensed-in from:<br>Pharmacosmos<br>A/S                   | Nippon Shinyaku                                           |         |         |                 |             |        |
| NS-917                     | In preparation for development | Hematologic malignancies                  | Relapsed/refractory acute myeloid leukemia    | Licensed-in<br>from: Delta-Fly<br>Pharma, Inc.             | Nippon Shinyaku                                           |         |         |                 |             |        |
| NS-73                      | In preparation for development | Hematologic malignancies                  | Hepatic veno-occlusive disease                | Licensed-in<br>from: Jazz<br>Pharmaceuticals<br>PLC        | Nippon Shinyaku                                           |         |         |                 |             |        |
| NS-87                      | In preparation for development | Hematologic malignancies                  | Secondary acute myeloid leukemia              | Licensed-in<br>from: Jazz<br>Pharmaceuticals<br>PLC        | Nippon Shinyaku                                           |         |         |                 |             |        |

\*NCNP: National Center of Neurology and Psychiatry

#### Overseas

| Code No.<br>(generic name) | Development phase              | Therapeutic field                   | Indications                 | Origin                              | Development     | Phase I | Phase II | Phase Ⅲ | Application | Launch |
|----------------------------|--------------------------------|-------------------------------------|-----------------------------|-------------------------------------|-----------------|---------|----------|---------|-------------|--------|
| NM441<br>(Prulifloxacin)   | In preparation for application | Infectious<br>diseases              | Synthetic antibacterial     | netic antibacterial Nippon Shinyaku |                 |         |          |         |             |        |
| NS-065/<br>NCNP-01         | PΙΙ                            | Intractable<br>and rare<br>diseases | Duchenne muscular dystrophy | Co-development:<br>NCNP             | Nippon Shinyaku |         |          |         |             |        |
| NS-018                     | PI/II                          | Hematologic malignancies            | Myelofibrosis               | Nippon Shinyaku                     | Nippon Shinyaku |         |          |         |             |        |

#### Main steps of new drug development Application and Basic Clinical trials studies Discovery and Assess the efficacy Trials are conducted to After the efficacy and creation of a and safety of the assess the efficacy Phase I trial safety of a candidate candidate compound candidate compound. and safety of the compound are verified ses safety in healthy subjects that will form the Before clinical trials are candidate compound through clinical trials, an basis for a new drug. conducted in humans, in humans. Trials are application for drug Phase II trial approval is submitted to A candidate animals and cells usually divided into compound is found cultured in test tubes Assesses safety and efficacy in a small number of patients the Pharmaceuticals and three phases. by searching through are used to assess The potential of the Medical Devices Agency. chemically syntheaspects of the compound to become Once the compound is compound such as its approved through an sized compounds or a new drug is Phase III trial natural ingredients. pharmacology, assessed through the expert review process, Assesses safety and efficacy in a large number of patients pharmacokinetics, and steps shown on the it can be manufactured toxicity. right. and marketed as a new drua.

Enhancement of
Corporate Value through
Business Activities

Pharmaceuticals
Sales

## Reforming our sales structure to improve mobility and the quality of information we provide



## Market penetration is deepening as more people come to understand the features of our main product suites

We offer Zalutia for urinary disorders, Vidaza for hematological use, and Adcirca and Opsumit for pulmonary arterial hypertension (PAH); in November 2016 we launched Uptravi in Japan. Our sales efforts revolve around these key products.

Zalutia, a PDE5 inhibitor, offers a novel mechanism of action. Partly for this reason, it has taken much longer than anticipated to penetrate the market, but gradually people's understanding of its mechanism of action and effect has expanded. In April 2017, The Japanese Urological Association issued a new clinical guideline for male lower urinary tract symptoms and benign prostatic hypertrophy. Since Zalutia is positioned as a first-line therapy, we believe it will further permeate the market.

We have been educating people on myelodysplastic syndrome (MDS) and products to treat it. Vidaza is widely known as the first choice for patients with high-risk MDS who are not candidates for transplantation, and sales are growing steadily.

We launched Uptravi into the PAH field, making Nippon Shinyaku the only drug maker in the world to offer a full lineup of oral agents for PAH therapy that exhibit three different mechanisms of action. This is highly appealing to specialists,

and with the opportunity to provide comprehensive information on PAH treatments, we provide optimal treatment options to medical practitioners.

## A major restructuring to further improve the quality of information provision amidst a rapidly changing external environment

The Sales & Marketing Division has set up three promotion departments to focus on our three main fields, and has created a system that enables us to provide high-quality information to medical practitioners. Also, we offer an in-house accreditation examination system to ensure an improvement in the academic level of all sales employees.

To accommodate rapid changes in the external environment and a shift in the company's main fields to specialty products, we have undertaken a major reform of the sales organization. The Japanese government launched a corporation system to promote regional medical cooperation in April 2017 that will make it possible to jointly purchase pharmaceuticals and other medicines by bringing together under one umbrella hospitals, clinics, dispensing pharmacies, and other medical facilities, including home-visit nursing stations, health centers for the elderly, and other nursing and personal care facilities. In such a climate, merely top-down strategies issued by our head office will be insufficient. We have created subdivisions into 119 teams nationwide to carry out area-based strategies that take into consideration medical districts. Sales office managers, together with team managers and leaders work to draft and implement strategies that are well-suited to the situation in each area. Also, by changing from a top-down to a bottom-up model of sales we aim to boost mobility as we strive to supply more detailed information.





## The stable provision of high-quality products to society is our top mission



## Lowering manufacturing costs and using our technological capabilities as a new drug maker to expand contract manufacturing

As a result of the Japanese government putting in place a policy to promote generic medicines, the production volume of long-listed products has been declining at the Odawara Central Factory. Although the overall decline in production has led to rising manufacturing costs, the introduction of a qualification certification system at the factory is helping to cross-train workers, and we are able to carry out manufacturing with fewer capable workers. This, combined with the acquisition of new manufacturing contracts, is helping us to lower manufacturing costs. We also provide an e-Learning program on cost control to raise awareness of costs among every employee working in Resource Procurement, Production & Assurance Division. To lower distribution costs, we are reviewing contracts at our Logistic Centers and realizing major cost reductions.

At the Odawara Central Factory, making use of a dormant injection packaging line, in fiscal 2016 we took on contracts to manufacture nine products for three companies. All of the contracting companies gave Nippon Shinyaku high ratings for both technological capabilities and product quality. In fiscal 2017 we will begin to manufacture four more products for three additional companies. For three of these items we will utilize our development capabilities as a manufacturer of new drugs from the stage of formulation design. We are thus able to utilize

specialized facilities and a developmental capability that other contract manufacturers do not possess. We also plan to further expand these efforts with the cooperation of departments outside of Resource Procurement, Production & Assurance Division.



## We implement stringent consolidated risk management

We carry out risk management in accordance with a pharmaceutical risk management plan (RMP). The RMP identifies important risks in individual post-market drugs, and lists in a single document all of the efforts being taken by the company to reduce those risks. The RMP is created with the purpose of maintaining the safety of post-market drugs by evaluating the benefits and risks through all periods from the development phase to post-marketing and we carry out necessary safety measures based on the results. The RMP is open to the public, and information is shared with medical practitioners and patients to implement improved post-market safety measures. At present, Nippon Shinyaku has created RMPs for the tramadol formulations Tramal OD and Onetram, as well as Uptravi. This information is made public on the websites of both the Pharmaceuticals and Medical Devices Agency and Nippon Shinyaku.

#### The completion of a manufacturing facility for highly active solid formulations will allow us to further expand stable supply and business

In July 2017, a facility for manufacturing highly active solid formulations was constructed on the premises of the Odawara Central Factory. To prevent possible damage from flooding of the Sakawa River, a vibration-damping structure was used for earthquake-proofing among the many disaster prevention measures adopted for the facility. The new building will be responsible for manufacturing highly active formulations that are currently on the market and original anti-cancer drugs that are being developed. It also aims to establish a general contract manufacturing business to take advantage of the uniqueness of the Odawara Central Factory.

Enhancement of Corporate Value through Business Activities

Functional Food

Developing and providing unique ingredients with high added value through the R&D capabilities of a pharmaceutical company



## Focusing on sales of high-added-value products as people become more interested in health

With the aging of society and recent health-conscious trends, people are becoming more interested in health and there is strong demand in the health food market. In 2015 the Japanese government instituted a labeling system for foods with function claims, driving the expansion of the health food market. In this climate we are concentrating on sales of high-added-value products in health food ingredients, preservatives, and protein preparations.

In the field of health food ingredients, we are concentrating on promoting sales of anti-aging ingredients such as hyaluronic acid and developing supplement ingredients with unique anti-aging properties. We also plan to actively develop products in collaboration with users.

In the field of preservatives, we are strengthening our efforts for ready-made meals sold at convenience stores and supermarkets (bento box lunches and prepared foods, and processed foods for commercial use) with a focus on our



Mikaku Fine series, which extends shelf life with minimal impact on flavor. We are establishing new technologies for improving shelf life and will build other brands in addition to the Mikaku Fine series.

In the field of protein preparations, various companies are working to extend healthy longevity. We are one of these players in the area of sports nutrition, where we develop protein products for athletes and active seniors. We stock a great variety of milk proteins, and are able to develop unparalleled high-added-value products by utilizing the strengths of our research division, which sets us apart from other companies.

## Start of a new business to supply final products to consumers and contribute to society through foods

As a pharmaceuticals company active in the functional food business, through foods we endeavor to contribute to healthy longevity and active lifestyles. We incorporate that intent into final products that we develop and provide for consumers. In the process, we are turning our functional food business into a more profitable enterprise. Our first effort was the sports supplement WINZONE ENERGY  $\times$  ENERGY, released in October 2016, followed by the glycation care supplement AGE-SHUT, released in March 2017. The products have been selling well since their release and we plan to promote them even more vigorously to make the brands better known in the marketplace.

Our increased efforts in preservatives are helping to reduce food waste. We develop original technologies to extend the recommended best-before date of foods while maintaining their flavor, thereby helping to reduce the amount of food that goes to waste.

#### Start of the final product sales business in health foods

Reaching consumers directly through online sales of original products in the fields of sports and anti-aging supplements

#### WINZONE ENERGY × ENERGY Sports Supplement

A concern of athletes who run marathons or compete in other long-distance races is slowing down in the latter half of a race—running out of energy. Because of this they might eat too much and feel heavy or sluggish. One reason why performance drops in the latter half of a race is a shortage of sugar in the body. Sugar and fat are two sources of energy for physical exercise. In terms of energy yield, fat is the more promising energy source when compared to sugar. However, sugar is needed to convert fat into energy, and the problem lies in the time it takes for the conversion to take place.

A solution to this issue for athletes is hydroxycitric acid, a natural component found in the fruit garcinia cambogia. It stimulates the use of fat energy when exercising and speeds up replenishment of glycogen\*. If considered using the metaphor of a hybrid vehicle, electricity (fat) provides support for running the car for a long time with high fuel efficiency by saving gasoline (sugar). WINZONE ENERGY × ENERGY contains hydroxycitric acid and is



expected to lead to greater endurance by turning fat into an energy source.

\*High-molecular substance of polysaccharide chain

#### AGE-SHUT Glycation Care Supplement

Glycation is the non-enzymatic browning of sugars and proteins, also called the Maillard reaction. Inside the human body, this reaction occurs when proteins, which compose 20-30% of the body, react with sugars from food that could not be metabolized. Glycation may occur in any tissue where proteins exist, which is roughly everywhere in the body, and the change is most visible on the skin. When the glycation of collagen—a protein that is present in high quantities in the skin—takes place, the skin loses its elasticity and suppleness. In other cases, glycation of the bones affects their quality, and glycation of blood vessels affects their pliancy.

The human body is always at risk of glycation, and as the body's metabolism slows with age, glycation advances. The risk also increases due to lifestyle choices such as lack of exercise, lack of sleep, eating too many sweets, and drinking too much alcohol, or from everyday stress or exposure to UV rays. To lower that risk requires regular glycation care.

We developed the glycation care supplement AGE-SHUT to meet people's need for keeping themselves looking beautiful and feeling healthy even as



they age. AGE-SHUT contains rhodanthenone B, a water-soluble polyphenol derived from mangosteen, known as "the queen of fruits". Nippon Shinyaku was the first in the world to discover the functional ingredient rhodanthenone B in mangosteen. It has a useful function in glycation care.

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### 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 was instituted on December 15, 2015, and sets forth our basic concepts of corporate governance. The Policy has been revised as of June 29, 2016.

#### **Overview of Corporate Governance Organization**

Nippon Shinyaku is a company with auditors, ten directors (of whom three 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 three 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 in November 2016 carries out "Disclosure Based on the Principles" and, where necessary, discloses "Reasons for Non-compliance with the Principles" at the present time.

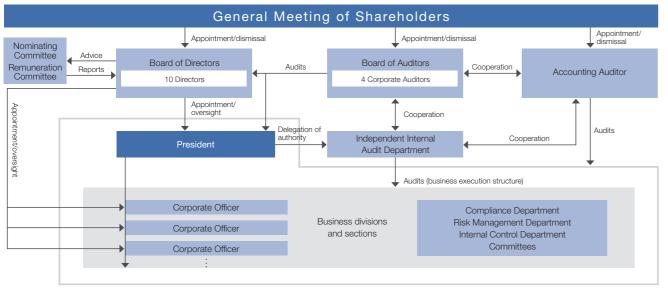
#### **Internal Control System**

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

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

In cooperation with the Board of Auditors and the accounting auditor, the Internal Audit Department examines the effectiveness of risk management, control, and governance.

#### Organization for Corporate Governance



## The following items are posted on our website (Japanese only). http://www.nippon-shinyaku.co.jp/company\_profile/governance.html Corporate Governance Report Corporate Governance Basic Policy

### Message from External Directors



## Providing expert guidance as a globally-minded pharmacologist

Japan's recent efforts to revise the drug price system, illustrated most vividly by the priority afforded to generic products, will likely make things even harder for new drug manufacturers. As a new drug manufacturer, Nippon Shinyaku inevitably researches and develops new products and launches them worldwide, relying on deft leverage of unique strengths. As a pharmacologist with professional knowledge and some global experience, I offer a range of advice that may be useful in that quest.

A company's framework for long-term growth in corporate value must not only focus on obvious points like preventing corruption before it arises, but it must also take a holistic approach to boosting competitiveness and profitability. What is the company's attitude towards disclosure of information? What is the board's role? These issues must be thoroughly debated and settled. I believe external directors are vital to business administration, not only for their advice and oversight, but also for their ability to weigh in on issues like developing next-generation executives to ensure smooth continuity.



## Making a contribution to corporate governance and increased corporate value

Nippon Shinyaku has tackled some hefty challenges of late, including the discovery of new drugs and stepping into a larger role as a global corporation. However, with the company's centenary approaching in 2019, it is important to lay further foundations to underpin future endeavors. On the brink of a new era, I believe my roles as an external director are to steer Nippon Shinyaku toward more robust corporate governance and team up with the corporate officers to help the company stay abreast of changes over the long term.

Board meetings in fiscal 2016 were indeed substantial, with debate on various issues incorporating a range of perspectives. I will continue to encourage such open discussion as a means of seeking solutions to major challenges the company may face.



## Bringing more diverse perspectives and encouraging vigorous debate as a stimulus

External directors are, by definition, required to stand apart from the company's execution of business. Aiming to maximize profitability and corporate value (including the company's standing in society), we have a responsibility to effectively monitor the performance without getting caught up in the common practices of the industry or the company itself. With three external directors, one of whom is a woman, Nippon Shinyaku gets a diverse range of perspectives and I look forward to contributing more than ever to debates. Ensuring opportunities for female employees to play a role in the workplace is not just about diversity, though; I believe it invigorates the company's activities and leads to greater corporate value. I would like to be a stimulus to that end, and I look forward to improving my own skills so that I might help the company deliver ever greater benefits for shareholders.

### Board of Directors, Corporate Officers and Corporate Auditors

#### President



#### Shigenobu Maekawa

- 1976 Joined Nippon Shinyaku Co., Ltd. 1992 Temporarily transferred to Japan Federation of
- 2002 Department Manager, Corporate Planning Dept., Corporate Strategy Office
- 2004 Corporate Officer 2005 Director
- 2005 General Manager, Corporate Planning, Finance & Accounting, and Information System; Department Manager, Corporate Planning Dept. 2006 Managing Director
- 2007 General Manager, Corporate Planning, Finance & Accounting, and Information System
- 2007 President (current position)
- Attendance at board meetings (FY2016): 14/14

#### Managing Directors



#### Tsugio Tanaka

#### General Manager, Business Management

- 1980 Joined Nippon Shinyaku Co., Ltd.
- 2006 Department Manager, Business Development & Planning Dept. 2007 Department Manager, International Business Dept.
- 2008 Department Manager, Manufacturing Management & Material Procurement Center; Department Manager, International Business Dept.
- 2008 Department Manager, Manufacturing Management & Material Procurement Center 2008 Director
- 2008 General Manager, Resource Procurement, Production & Assurance
- 2014 Managing Director (current position)
- 2014 General Manager, Business Management (current position) Attendance at board meetings (FY2016): 14/14



#### Akira Matsuura

#### General Manager, R&D

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

Attendance at board meetings (FY2016): 14/14

#### Corporate Auditors



#### Tomoyuki Oota

#### Standing Corporate Auditor

- 1980 Joined Nippon Shinyaku Co., Ltd. 2007 Department Manager, Fukuoka Business Office, Sales and Marketing
- 2010 Department Manager, Yokohama Business Office, Sales Promotion Div., Sales and Marketing
- 2012 Corporate Officer; Department Manager, Tokyo Business Office, Sales and Marketing 2013 Corporate Officer; Head of Kitanihon Div., Sales
- 2015 Deputy Head of Sales and Marketing
- 2015 Standing Corporate Auditor (current position)

Attendance at board meetings (FY2016): 14/14



#### Kazuhiro Imai

#### Outside Auditor

- 1970 Assigned to Co-ordination Div., Management & Co-ordination Dept., Osaka Regional Taxation Bureau
- 2001 Professor, Second Education Dept., National Tax
- 2003 District Director, Tanabe Tax Office
- 2006 Director, Corporate Taxation Div., Second Taxation Dept., Osaka Regional Taxation Bureau 2009 Deputy Assistant Regional Commissioner, Second
- ixation Dept., Osaka Regional Taxation Bureau 2011 Assistant Regional Commissioner, Collection Dept., Osaka Regional Taxation Bureau
- 2012 Registered as licensed tax account
- 2015 Company Auditor (current position)



#### Hideya Mukai

#### Standing Corporate Auditor

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

Attendance at board meetings (FY2016): 12/12 (Since assuming position in June 2016)



#### Tsuyoshi Kondo

Outside Auditor

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

Attendance at board meetings (FY2016): 12/12 (Since assuming position in June 2016)

#### Directors



#### Yoshiro Yura

#### General Manager, Administration

- 1977 Joined Nippon Shinyaku Co., Ltd. 1994 Temporarily transferred to Japan Federation of Employers' Associations
- 2003 Department Manager, Corporate Communications Dept.
- 2007 Denartment Manager Personnel Dent
- 2008 Director (current position)
- 2008 General Manager, Administration (current position)

Attendance at board meetings (FY2016): 14/14



#### Kenro Kobayashi

#### General Manager, Functional Food

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

Attendance at board meetings (FY2016): 14/14



#### Yukio Sugiura

#### External Director

- 1988 Professor, Institute for Chemical Research, Kyoto University
- 1998 Guest professor, Pharmaceutical Dept., The University of Manchester
- 1998 Director, Institute for Chemical Research, Kyoto University
- 2005 Emeritus professor, Kyoto University (current position) 2005 President, The Pharmaceutical Society of Japan 2007 Specially appointed professor, Faculty of
- Pharmaceutical Sciences, Doshisha Women's College of Liberal Arts 2013 Director (current position)
- 2016 Retired from specially appointed professor, Faculty of Pharmaceutical Sciences, Doshisha Women's College of Liberal Arts

Attendance at board meetings (FY2016): 14/14



#### Miyuki Sakurai

#### External Director

- 1992 Completed legal training at The Legal Training and Research Institute of Janan
- 1992 Registered with Osaka Bar Association
- 1992 Joined Nishimura Law and Accounting Office
- 2003 Joint Owner, Hanamizuki Law Office (current
- 2015 Auditor, Nippon Life Inst. Foundation (current
- 2016 Auditor, Osaka University (current position) 2017 Director (current position)



#### Hitoshi Saito

General Manager, Resource Procurement, Production & Assurance

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

Attendance at board meetings (FY2016): 14/14



#### Shouzou Sano

#### General Manager, Sales and Marketing

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

Attendance at board meetings (FY2016): 14/14



#### Hitoshi Sakata External Director

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

Attendance at board meetings (FY2016): 14/14

#### Corporate Officers

Taro Sakurai Department Manager, Finance & Accounting Dept.

Marketing Planning Div.

Takashi Takaya Takanori Edamitsu Head of Sales and

Hisashi Suehara Koji Honma

Head of Regulatory Affairs Supervision and Assurance Div. Department Manager, Personnel Dept.

Hiromu Nakajima Kazuya Mori Chief Medical Officer and Head of R&D Administration Head of Medical Supervisory Div.

Head of Clinical

Development Div

Department Manager,

Corporate Planning Dept.

#### Hirokata Harada Seiichiro Morimura Head of Licensing & Alliance Div.

Yuji Kamiyoshi Department Manager, Nagova Business Office. Sales and Marketing

Hideki Sasaki Department Manager, Odawara Central Factory

Kazuchika Takagaki Department Manager, Discovery Research Labs.. R&D

Current as of July 2017

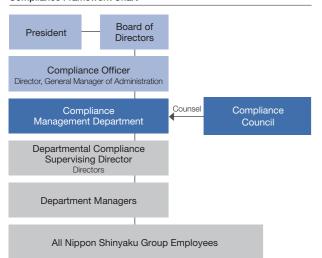
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### Compliance

#### Framework for Compliance

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

#### Compliance Framework Chart



#### **Compliance Initiatives**

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

In fiscal 2016, the President and the compliance officer issued messages to employees in April and October to encourage an even higher level of compliance execution and raise awareness of its importance, and we implemented the training and educational activities outlined below throughout the year.

#### Compliance Training in Fiscal 2016

| Type of Training                                                                     | Description                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Departmental compliance training (monthly)                                           | Departmental training incorporating company-wide content and department-specific content.                                                                                                                                |
| Training for<br>new employees<br>(April)                                             | Training that focuses on teaching new employees about compliance concepts and approaches, and stressing the importance of compliance.                                                                                    |
| Training for newly promoted managers (March, October)                                | Training that focuses on teaching compliance to newly promoted managers.                                                                                                                                                 |
| Enhanced Training<br>(July-August)                                                   | Departmental compliance training in July followed-up by supplemental training through e-learning in August; the theme for fiscal 2016 was "Information Management Centering on Measures against Targeted Email Attacks." |
| Training on the Charter of Business Conduct for new employees (as and when required) | Enhancing understanding of and compliance with the Charter of Business Conduct.                                                                                                                                          |

#### Education Initiatives

- Conducted e-learning education for compliance for employees in their second 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, with regard to "Compliance Reporting System" we communicate information on a regular basis in order to further spread awareness throughout our group companies.

#### Responsible Procurement

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

At Nippon Shinyaku, those responsibilities are enshrined in our Responsible Procurement Guidelines, which govern our day-to-day supplying of unique and high-quality products (as is set forth in our management policy).

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



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

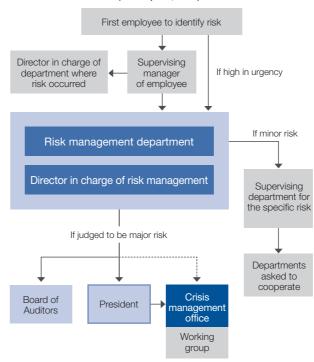
## Risk Management

#### Framework for Risk Management

Nippon Shinyaku Group investigates various risks and departments managing risks formulate preventive policies and methods for responding to them. This is done based on the Basic Risk Management Rules. Additionally, each year we identify highly critical risks. In fiscal 2016, these were "computer viruses," "information leakage," "disasters," and "harassment," which led us to beef up our management framework and raise awareness. Furthermore, every year we conduct a self-check survey of all group employees for the purpose of verifying each individual's risk awareness.

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

Path of Risk Notification (as of April 1, 2017)



#### **Initiatives for Information Security**

Nippon Shinyaku implements a basic policy and rules to guide our initiatives for information security. We operate and implement an Information Security Management System (ISMS) Committee that implements specific rules for information security, guided by the basic policy and rules.

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

In fiscal 2016 we focused our activities on computer viruses, cyberterrorism, and the corruption, disappearance, fabrication, and leakage of electronic data, and engaged in employee education, awareness-raising, and disclosure of information.

Furthermore, to counter the troubling recent development of targeted email attacks (ransomware, etc.), we are improving our internal measures through the strengthening of our system, and thorough education and training for all employees.

In the future we will continue to strengthen our information security

#### Anti-Harassment Action

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

#### Disaster Countermeasures (Formulating the BCP)

To ensure the supply of medicines to patients is not disrupted in emergency situations such as earthquakes and other disasters, we have established a Business Continuity Plan aimed at keeping the Odawara Central Factory up and running in major earthquakes (up to level upper six on the Japanese *shindo* scale). Meanwhile, we continue to bolster readiness in other areas, such as inventory storage facilities and support for partner companies, and are prepared to invoke the Business Continuity Plan whenever required.

## Respect for and Protection of Intellectual Property Rights

In recognizing the importance of intellectual properties, the Nippon Shinyaku Group's Patent Strategy Committee formulates global patent application strategies as well as examines and determines measures to address various issues associated with intellectual properties created during various stages, from early R&D to post-marketing. To ensure the freedom of our business activities, we properly secure intellectual property rights, including patents and trademarks, related to our proprietary drugs and functional foods.

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



### Patients and Medical Professionals

## For patients to use medicines with peace of mind

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 patients truly want. Furthermore, our job as a drug manufacturer goes beyond stably supplying high-quality medicines—it includes proactively 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

#### **Educating Patients through Websites and Smartphone Applications**

At Nippon Shinyaku, we distribute information helpful for resolving health concerns through a number of websites. On our "Pulmonary Hypertension Treatment Support" website (Japanese only; http://pah-support.jp/), we provide information such as on the disease itself, treatment explanations, medical expenses, and medical systems. We also post videos from medical specialists to allow further understanding of pulmonary hypertension through the information we provide.

#### **Examples of Websites Used to Educate Patients**

| "Talking about Menstrual Cramps" (Japanese only; http://seiritsu.jp/)            | We provide information to patients concerned about menstrual cramps.         |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| "Support Site for Alcohol Dependence" (Japanese only; http://alcoholic-navi.jp/) | We provide information on alcohol dependence and abstinence success stories. |
|                                                                                  | A website which introduces medical                                           |

dispel misunderstandings about the condition to relieve any psychological resistance to seeking out help. We have also launched smartphone apps-Lunabell Diary and

record symptoms, and communicate with medical professionals. Furthermore, we have launched a new website in fiscal 2017, "Otokojishin.com" (Japanese only; http://otoko-jishin.com/), to assist men with urinary issues. Aimed at encouraging people to seek advice from a doctor, the site contains information on the causes of urinary

PAH Care Notebook—that patients can use to track their medication,



"ED Care Support"

サルティアは

institutions where individuals can receive

consultation on erectile dysfunction and

"PAH Care Notebook"

"7alutia Product Information" website

#### **Providing Product Information**

Nippon Shinyaku operates a Customer Call Center which receives inquiries from physicians and pharmacists, and replies with advice on the proper usage of our products. In addition, we respond to a broad range of inquiries from patients and the general public with accurate, easily understood information.

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

For those seeking reference material, the Nippon Shinyaku corporate website carries information for medical professionals and patients. Medical professionals can find pharmaceutical information including drug information sheets\*2, interview forms, package inserts, and updated usage warnings. Patients and general readers can find pharmaceuticals guides and information aimed at improving wellness.

- \*1 Computer telephony integration system: A system linking telephones and computers that routes calls to customer service representatives and provides information management and analysis functionality
- \*2 Explanation sheets (in Japanese, English, and other languages) intended for patients

#### **Educating People about Illnesses**

We have hosted public lectures by doctors since 1998. Most recently, we held two symposiums in February 2017-"The Link Between Lifestyle Diseases and Urinary Disorders" and "Good Health and Drinking"—and both were well attended.

Elsewhere, we endeavor to spread correct, up-to-date information on illnesses and medicine. Activities include sponsorship of Rare Disease Day 2017, wherein we placed newspaper ads to educate people on rare and intractable diseases.



#### Quality Assurance and Supply Stability

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

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

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

After receiving manufacture and marketing approval, we fulfill our responsibilities to the market by assuring the quality of the product being manufactured and sold, and affirming its safety. We also work to maintain and manage the aforementioned approval, marketing authorization, and manufacturing authorization.

#### Pharmaceutical Products Reliability Assurance

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

| Post-manufacture and marketing                                                 |                                                                        |                                                                                                    |  |  |  |  |  |
|--------------------------------------------------------------------------------|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--|--|--|--|--|
| Manufacturing                                                                  | Marketing                                                              | Maintenance and management of approval and authorization                                           |  |  |  |  |  |
| Post-manufacture and<br>marketing quality<br>assurance based on<br>GMP and GQP | Post-manufacture<br>and marketing safety<br>management based<br>on GVP | Maintenance and management of manufacture and marketing approval and marketing authorization, etc. |  |  |  |  |  |

#### Stable Supply of Products

At the Odawara Central Factory, we introduced an original qualification certification system in fiscal 2014 and are working to enhance the versatility of employees' skills. Under a vision to be a factory that is competitive in terms of cost and quality, we have implemented the balanced scorecard (BSC\*3) 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\*4 to manage our progress toward achievement of this strategy and vision. Our distribution framework is configured not only to help maintain quality, for instance through temperature control during transit and storage, but also incorporates ideas such as use of multiple storage sites to minimize loss risks in contingencies such as disasters.

In fiscal 2016, with our continued focus on avoiding shortage risks, we have increased the inventory on hand of anti-cancer drugs and other products with great importance in society.

- \*3 Balanced Scorecard: A method for comprehensively measuring the extent to which
- the corporate strategy has been implemented
  \*4 Key performance indicators: Particularly important indicators among the business process monitoring indicators set under the BSC to achieve corporate goals

## Framework for Supplying Products

We 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 regularly evaluating our suppliers to encourage improvement.

#### Framework for Supplying Products

SCM

Management

Supply Chain

Sourcing and Purchasing Department Manufacturing Planning Department Odawara Central Factory Logistic Control

Regulatory Affairs Supervision and Assurance Division

#### Measures Against Counterfeit Drugs

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

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



### Doctors and pharmaceutical companies: Fighting intractable diseases together

For many years now, I have treated patients with pulmonary hypertension, a rare and intractable disease. I believe that providing feedback from the clinical settings to the corporate community and working together to advance treatments is part of specialist physicians' mission. After all, the patients who suffer every day from these diseases for which there is no established method of treatment are desperate for someone to develop new and effective drugs. Their plight has been compounded by the long-standing reluctance of pharmaceutical companies to try to develop drugs for rare diseases because of the many difficulties involved. In contrast, Nippon Shinyaku's steadfast dedication to developing drugs to treat rare diseases has led to numerous breakthroughs, and I, for one, am grateful for these ongoing efforts which have given hope to pulmonary hypertension sufferers everywhere.



Dr. Shingo Kyotani Director, Kyotani Clinic

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### **Employees**

## Creating a workplace where employees can grow and work with peace of mind

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 diversity in the workplace, and creating environments where people can work with peace of mind.

#### Promoting Work-Life Balance

As part of work-life balance promotion efforts that we describe as "Achieving a virtuous cycle that harmonizes fulfilling work (Motivation) with a rewarding lifestyle (Daily sense of fulfillment)," Nippon Shinyaku conducts the "Good Job Initiative." We envision the goals of the Good Job Initiative as: working productively, resting regularly, and leading a fruitful lifestyle that increases one's satisfaction and zest for life.

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

#### Challenge 100 to Improve Productivity

Launched to commemorate the company's centenary in 2019, Challenge 100 is a movement aimed at improving productivity. Our hope is to leverage Nippon Shinyaku's unique strengths to set ourselves apart from our rivals and boost corporate power.

#### 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

Nippon Shinyaku has acted early to promote increased activity by women as the company's mission. We are working to prepare an environment and create opportunities for growth so that women who, due to various circumstances, are hesitant about their next actions can step boldly forward.

Following the feedback from the opinion exchange meeting with medical reps in fiscal 2016, we revised some of our in-house systems to improve the environment for female employees with children. We also held an informal meeting for women in production engineering positions to discuss their experience and achievements, promote deeper understanding, consider career advancements, and seek ideas to make the workplace more rewarding and enjoyable, all with a view to enabling these talented

women to play a core role in tomorrow's leadership. Moreover, starting in fiscal 2014, we launched a series of career advancement seminars for different age groups including one for those in their twenties and thirties to reevaluate their careers.





Opinion exchange meeting with medical reps

Informal meeting for those in production engineering

#### Hiring Employees with Disabilities

Operating on the belief that proactively hiring employees with disabilities is one of the social responsibilities incumbent upon us as a corporation, Nippon Shinyaku is working toward expanding employment and creating new job opportunities based on the principle of inclusion. 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 allows for those with disabilities to acclimatize to work and the working environment, and to ease into social life. A number of consultants are stationed in the workplace to help promote an environment where those with disabilities will be able to productively work side by side with others. This is one example of how we are working to create comfortable work environments. In fiscal 2016, we expanded our initiatives in employment of those with disabilities in Kyoto, where our head office is located, and began practical training for those with disabilities in our Tokyo Business Office.

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





Workers posting internal mail

Linen work (laundering)

#### **Reemployment of Retired Workers**

Nippon Shinyaku has adopted a continuing employment system (i.e., reemployment system) allowing continued work until age 65. This system takes in workers again after they have left the company, to leverage their experience, techniques, and skills on behalf of the company. The system offers both full-time and part-time employment, in accordance with employees' wishes. At present, 55 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.

As our business becomes more international in scope, developing a globally-capable workforce has become increasingly important. We believe that a globally-capable workforce has a broader perspective and is better equipped to identify and overcome the challenges of modern business. To that end, we

established an Overseas Training Program for R&D staff in fiscal 2015 and, the following year, held two English training courses, one for elite employees and one for those who attended of their own accord.



Elite employees undergoing English training

#### Career Support System: "Developing Each Employee"

Nippon Shinyaku has established a Career Support Academy (CASA) to supply employees with opportunities for development. This system is structured on the twin aspects of level-based education and training, and elite education and training. We revamped our level-based education and training in fiscal 2016 to enable participants to select their own subjects. By making it elective, we sought to align training more closely with each individual's efforts to improve their skills because we believe that encouraging employees to think about their own growth will lead them to consider their career trajectory as a whole. 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.

#### Shaping the Work Environment

#### Occupational Health and Safety

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

We conduct risk assessment and risk prediction activities, and we are practicing the "5S activities" by implementing a three-year plan, to identify potential risks and hazards in our workplaces and establish measures to prevent them. The research laboratories also put an emphasis on conducting risk assessments for chemical substances, which is another effort toward preventing occupational accidents.





Health and safety meeting

#### Mental Healthcare

Nippon Shinyaku effectively promotes the four types of care noted in the guidelines for mental healthcare released by the Ministry of Health, Labour and Welfare in 2000. With the goal of undertaking prevention, early detection, early response, treatment, and prevention of recurrence with regard to mental disorders, in fiscal 2003 we implemented the EAP (Employee Assistance Program) of an external organization and are engaged in ongoing and planned mental healthcare. This program corresponds to the new "stress check" legislation passed in December 2015.



## Harnessing the unique potential of colleagues with disabilities

In fiscal 2016, for the first time we began accepting trainees with intellectual handicaps at sales offices with a view to hiring them. Part of this involved identifying tasks that each trainee could feasibly perform, and I believe that examining the constituent tasks of the work flow actually helped improve efficiency and productivity. Providing employment opportunities for differently abled people is not charity, but it is our responsibility to society and I look forward to expanding this scheme into our network nationwide. The trainees have had a positive influence on the workplace with their cheerful natures and dedication to their work. Indeed, they have earned the trust of other departments and the scope of work entrusted to them is growing. Furthermore, with the launch in fiscal 2017 of Challenge 100 to improve productivity, I welcome our new, uniquely abled colleagues to the quest of working together to meet targets, and I expect that together we will create a better workplace environment.



Takako Yamamoto Tokyo Area General Affairs Department, Tokyo Business Office, Sales and Marketing



### Society and Regional Communities



## Contributing to society and communities as a corporate citizen

In addition to supplying high-quality drugs as a pharmaceuticals manufacturer, our other role is contributing to the development of communities as a member of society. We are working hard to ensure that the children who will lead our society in the future grow up healthy and strong. The ways we do this include sponsoring and hosting sporting and cultural events, and carrying out cultural preservation activities in our hometown of Kyoto.

#### Nippon Shinyaku Children's Literary Awards

We hope to nurture the spirited growth and future dreams of the children who will inherit our world through picture books. With this hope in mind, we created the Nippon Shinyaku Children's Literary Awards to commemorate our 90th anniversary in 2009 with the support of the Japan Juvenile Writers Association. The Nippon Shinyaku Children's Literary Awards call for compositions as either stories or illustrations and winning submissions are selected in each category and a picture book is made based on the best compositions. This book is then distributed to children nationwide in medical institutions such as children's hospitals and public facilities. Also, visitors to our special website (Japanese only; http://kodomo-bungaku.jp/) are able to see electronic versions of past and present books and hear them read aloud as they browse the pages.

At the awards ceremony held in October 2016, tying into the 8th children's book. Boku Shiranaiyo ("It's not me"), a workshop in which characters were made using Japanese confectioneries was held for local children.



Picture book Boku Shiranaiyo



Group photograph from the awards ceremony

#### The Yamashina Botanical Research Institute

The Yamashina Rotanical Research Institute was established in 1934 as the Yamashina Pilot Farm. Since then, we have amassed a collection of some 3,000 varieties of medicinal and therapeutic plants from around the world, including mibuyomogi (Artemisia maritima) in Santonin, the vermicide that has played such a large part in our corporate development.

The institute's collection contains many rare plants, including 160 names as ingredients of the natural remedies listed in the Japanese Pharmacopoeia, as well as many plants on the Japanese Ministry of the Environment's endangered plants list, and even tree tumbo (Welwitschia mirabilis), which is recognized the world over as endangered. Indeed, the institute's research is a vital part of today's efforts to preserve biodiversity. Moreover, the institute is a proud participant in local activities in Kyoto to preserve rare plants, helping to protect and propagate Asarum caulescens Maxim. and chrysanthemum seticuspe.

Starting in fiscal 2016, the institute has held guided tours in spring and

autumn to provide the public with a view of these priceless plants. The institute also held tours and summer holiday indigo dyeing workshops for local elementary school children, which attracted approximately 1,600 participants.



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

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





Calendar and the quarterly

A washcloth featuring a motif of

#### Supporting Education through Sports

The Nippon Shinyaku amateur baseball team provides practical coaching guidance to elementary and senior high school students to promote sports in the local community. In November 2016, the Kyoto High School Baseball Federation winter training was held at Wakasa Stadium Kyoto. There we provided coaching for about 300 team members from 73 high school teams in Kyoto Prefecture. In Odawara City, Kanagawa Prefecture, where our Odawara Central Factory is located, we held our 8th Youth Baseball Workshop for 6 teams and about 100 youngsters in January 2017. These workshops contributed to enhancing the skill levels of elementary and high school players.



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

#### Youth Baseball Workshop

## Business practices in harmony with the earth's environment

In order to pass on nature's bounty to future generations, Nippon Shinyaku is fully aware that its pursuits are closely tied with nature and recognizes the importance of practicing business activities that are in harmony with the environment. Drawing upon this concept, in 1998 we established the Nippon Shinyaku Basic Environmental Policy, our guidelines for environmental preservation activities. In fiscal 2017, we have revised this policy and work to further reduce our impact on the environment under the new policy.

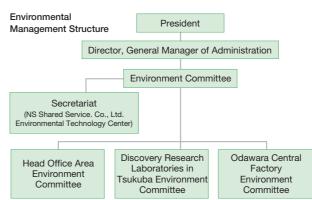
#### Nippon Shinyaku Basic Environmental Policy

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

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

#### **Environmental Management System**

Nippon Shinyaku formulated the Nippon Shinyaku Basic Environmental Policy as the guideline for our environmental conservation activities. The Environment Committee, chaired by Director, General Manager of Administration, was established to put this policy into practice and deliberates on the direction and targets of our environmental preservation activities. The 4th Nippon Shinyaku Environmental Targets Plan, started in fiscal 2014, successfully achieved its targets and finished in fiscal 2016. Presently, the Environment Committee has established the 5th Nippon Shinyaku Environmental Targets Plan (from fiscal 2017 to 2019), and is engaging in activities while checking its progress.



#### **Putting Environmental Management System** Certification into Action

At our Odawara Central Factory production site, Nippon Shinyaku acquired ISO 14001 for international environmental management in August 2004 as a mechanism for promoting continuous environmental improvements, and is engaged in ongoing environmental management activities.

At the head office area, our site for research and development we acquired KES Environmental Management System Standard Step 2 (hereinafter KES Step 2) certification in June 2012 and are engaged in environmental management activities.

#### **Environmental Accounting**

The following is an accounting of the environmental costs and benefits in fiscal 2016.

Environmental conservation costs Costs Costs within our business areas 74,903 Pollution prevention costs

Global environmental conservation costs 5,328 113,994 Resource recycling costs 0 161,123 Upstream & downstream costs 6.124 0 Management activity costs 7.873 91,172 R&D costs 0 4,763 Social activity costs Environmental remediation costs Λ Λ 405.813

28.637

#### Environmental conservation benefits

| Benefit verification                                       | Units               | FY2016<br>results | Year-on-year<br>change |
|------------------------------------------------------------|---------------------|-------------------|------------------------|
| CO <sub>2</sub> emissions                                  | Tons                | 12,937            | 181                    |
| Electricity usage                                          | Thousand kWh        | 14,013            | 404                    |
| Heavy oil & kerosene usage                                 | kl                  | 3                 | 0                      |
| City gas & LPG usage                                       | 1000 m <sup>3</sup> | 1,589             | 52                     |
| Gasoline & diesel usage                                    | kl                  | 971               | 25                     |
| Water consumption (main business locations)                | Thousand kWh        | 266               | 20                     |
| Waste substances generated (main business locations)       | Tons                | 424               | 9                      |
| Final amount of landfilled waste (main business locations) | Tons                | 2.7               | 0.6                    |

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#### The Global Environment

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

Nippon Shinyaku has drawn up a Basic Environmental Policy to serve as a set of guidelines for its environmental conservation activities. Voluntary environmental targets have been established to help guide the entire company toward reducing environmental impacts and making contributions to society. In fiscal 2014, we began initiatives under the 4th Nippon Shinyaku Environmental Targets Plan. In fiscal 2016, its final year, the plan achieved its targets with a reduction of 13.7% in total energy consumption compared with fiscal 1990, and a reduction of 81.5% in final amount of landfilled waste compared with fiscal 2005. In fiscal 2017, we have revised our Basic Environmental Policy and established the 5th Nippon Shinyaku Environmental Targets Plan (from fiscal 2017 to fiscal 2019) and will further engage in environmental preservation activities.

| Objective                                                                     | Targets                                                                                                                                                                                                                                                                                               | Results in FY2016                                                                                                                                                                                                           |  |  |  |
|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| Promotion of Energy<br>Conservation and Global<br>Warming Countermeasures     | <ul> <li>Reduce total energy consumption (GJ) in FY2016 to below FY1990 levels.*1</li> <li>Medium- to long-term target: The target for reducing CO<sub>2</sub> emissions shall be the same as that of the Japan Pharmaceutical Manufacturers Association.</li> </ul>                                  | <ul> <li>■Total energy consumption*² in FY2016 was 13.7% lower than in FY1990.</li> <li>■CO₂ emissions*³ were 3.8% lower than in FY1990.</li> </ul>                                                                         |  |  |  |
| Reduction of Waste                                                            | <ul> <li>Actively pursue the 3Rs (Reduce, Reuse, Recycle) and work to increase our usage ratio of recycled materials.</li> <li>Reduce the final amount of landfilled waste in FY2016 by more than 65% of FY2005 levels.</li> <li>Keep the final landfilled waste ratio below 1% in FY2016.</li> </ul> | In FY2016, final amount of landfilled waste was<br>reduced to 2.7 tons, 81.5% lower than in FY2005,<br>achieving a final landfilled waste ratio of 0.6%.                                                                    |  |  |  |
| Promote Proper<br>Management of Chemical<br>Substances                        | Promote the proper management of chemical<br>substances, including those stipulated under the<br>Pollutant Release and Transfer Register (PRTR) system,<br>and continuously reduce their emission into the natural<br>environment.                                                                    |                                                                                                                                                                                                                             |  |  |  |
| Promote an Environmental<br>Management System<br>(EMS)                        | Effectively improve the results of our environmental<br>performance by maintaining certifications for<br>environmental management systems (ISO 14001 and<br>KES Step 2).                                                                                                                              | •We maintained certification and registration for ISO<br>14001 and KES Step 2.                                                                                                                                              |  |  |  |
| Environmentally<br>Conscious Product<br>Upgrades and Materials<br>Procurement | Reduce product packaging materials as part of pharmaceutical and food product package simplification efforts.  Promote green purchasing and procurement practices.                                                                                                                                    | Trial operation of equipment that removes pills from PTP sheets (aimed at reducing the volume of PTP sheets containing defective pills) was completed. Currently preparing for full operation.  Green purchasing ratio: 93% |  |  |  |
| Communication with<br>Society and Local<br>Neighbors                          | Actively participate in activities to give back to the areas where we do business.      Appropriately disclose information (through our corporate website and Annual Report) to society and to the local areas of our business offices.                                                               | <ul> <li>We participated in regional volunteer cleanup activities.</li> <li>We issued the Annual Report 2016 and updated our website.</li> </ul>                                                                            |  |  |  |

- \*1 Total energy consumption, which is not dependent on CO<sub>2</sub> emission coefficient and directly reflects energy-saving efforts, was chosen as the indicator for the three-year period.
  \*2 Among total energy consumption of 242,104 GJ, the total energy consumption that targets the business locations to which fiscal 1990 emissions are applicable (i.e., our main business locations apart from
- "2 Among total energy consumption of 242,104 GJ, the total energy consumption that targets the business locations to which liscal 1990 emissions are applicable (i.e., our main business locations apart from sales offices, etc.).
- \*3 This figure is for the business locations to which the fiscal 1990 emission amounts are applicable (i.e., our main business locations apart from sales offices, etc.); total emissions were 12,937 tons. Calculations are made using the CO<sub>2</sub> real emission coefficients from the Ministry of Economy. Trade and Industry.

#### Material Balance of Our Business Activities



## Promotion of Energy Conservation and Global Warming Countermeasures

In addition to companywide drives to conserve electricity and promote energy-efficiency, fiscal 2016 saw an upgrade to the air conditioning facilities of the Discovery Research Laboratories in Tsukuba and Food Development Laboratories, and of the absorption refrigeration equipment at the No. 2 wing of the Odawara Central Factory. Meanwhile, the Hokuriku Business Branch and the No. 2 wing of the Discovery Research Laboratories were completely retrofitted with LED lights, while head office, the Hoyu Kaikan hall, and the Discovery Research Laboratories in Tsukuba were partially retrofitted as part of our ongoing plan to gradually switch over to LEDs.

Total energy consumption in fiscal 2016 (198,799 GJ)\*2 was up 2.9% (5,628 GJ) over fiscal 2015 (193,171 GJ). This increase was caused by the start of operations of the manufacturing building for active pharmaceutical ingredients for clinical trials, construction of which was completed at the end of fiscal 2015. Elsewhere,  $CO_2$  emissions\*3 in fiscal 2016 were up 106 tons (1.1%) over fiscal 2015 (10,059 tons) to 10,165 tons, which is 404 tons (3.8%) lower than the base year of fiscal 1990 (10,569 tons).

#### **Reducing Volume of Waste**

The amount of the final landfilled waste in fiscal 2016 was 2.7 tons, an increase of 0.6 tons from fiscal 2015, and the final landfilled waste ratio was 0.6%, an increase of 0.1%. This was down to the proper disposal of unnecessary fixtures and machinery accompanying the repair work on a building in our head office area. The amount of final landfilled waste was 81.5% lower compared to the base year of fiscal 2005, maintaining a final waste ratio of under 1%, and meeting our targets.

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

#### Proper Management of Chemical Substances

We submit reports to the legal authorities on business sites that handle more than 1 ton of Class 1 designated chemical substances

per year based on the PRTR system under the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof.

In fiscal 2016, the amount of acetonitrile handled was up 65.9%, and n-hexane was up 23.0% compared to fiscal 2015. This increase was caused by the start of operations of the manufacturing building for active pharmaceutical ingredients for clinical trials, construction of which was completed at the end of fiscal 2015. The building is equipped with solvent adsorption devices that minimize the release into the atmosphere of chemical substances generated during the manufacturing process of active pharmaceutical ingredients.

#### **Elementary School Workshops**

Starting in 2008, we have sent employees to conduct workshops at elementary schools in Kyoto City as part of their practical environment studies. Here, our staff teach the children not only about the

importance of protecting the environment, but also the dos and don'ts of taking medicine. In fiscal 2016, for instance, we held workshops for fourth year students at Shoho Elementary School and for fifth year students at Kuze Nishi Elementary School. Designed to be interesting for the

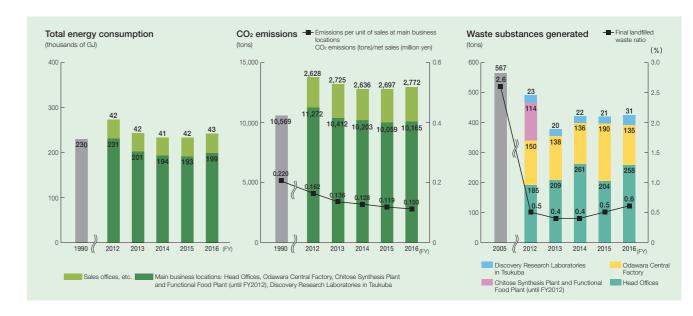


School kids enjoy Nippon Shinyaku workshop

children, the workshops focus on experiments, including measuring how much carbon dioxide plants absorb through photosynthesis, and studying the way pills dissolve (mock pills were used in the workshops).

#### Helping Local Clean-up Initiatives

We are proud sponsors of the Keep the Nishioji Station Precinct Clean action group, and we pitch in and help with the neighborhood cleaning efforts every Friday. Similarly, employees of the Odawara Central Factory help keep the surrounding area clean and tidy, and a total of 340 participated in the local council's Clean Sakawa initiative.



## Summaries and Highlights

### Summary of Consolidated Financial Indicators

|                                                 | 2013/3  | 2014/3  | 2015/3  | 2016/3  | 2017/3          | 2017/3                    |
|-------------------------------------------------|---------|---------|---------|---------|-----------------|---------------------------|
| or the year                                     |         |         |         |         | Millions of Yen | Thousands of U.S. Dollars |
| Net sales                                       | 69,941  | 76,517  | 79,991  | 84,209  | 98,781          | 881,973                   |
| Pharmaceuticals                                 | 58,318  | 63,345  | 66,340  | 70,489  | 85,315          | 761,741                   |
| Functional food                                 | 11,622  | 13,172  | 13,651  | 13,720  | 13,466          | 120,232                   |
| Operating income                                | 6,901   | 8,038   | 8,562   | 8,549   | 15,280          | 136,428                   |
| Net income attributable to owners of the parent | 4,647   | 5,750   | 5,882   | 6,340   | 11,749          | 104,901                   |
| Depreciation and amortization                   | 2,759   | 2,704   | 2,665   | 2,452   | 2,648           | 23,643                    |
| Capital investment                              | 1,332   | 1,072   | 1,239   | 3,554   | 3,949           | 35,258                    |
| R&D expenses                                    | 9,049   | 9,530   | 8,968   | 9,739   | 14,903          | 133,062                   |
| and of the year                                 |         |         |         |         | Millions of Yen | Thousands of U.S. Dollars |
| Total assets                                    | 113,730 | 118,188 | 129,757 | 135,370 | 150,905         | 1,347,366                 |
| Net assets                                      | 89,529  | 93,186  | 101,207 | 102,762 | 114,316         | 1,020,678                 |
|                                                 |         |         |         |         |                 |                           |
| Financial information per share                 |         |         |         |         | Yen             | U.S. Dollars              |
| Earnings per share                              | 68.87   | 85.25   | 87.26   | 94.10   | 174.42          | 1.56                      |
| Dividend per share                              | 21      | 23      | 25      | 28      | 48              | 0.43                      |

## Summary of ESG Indices

Principal financial indicators

Ratio of net worth

Return on equity

Pay-out ratio

| Total energy consumption (thousands of GJ)          | 231    | 201    | 194    | 193    | 199    | - |
|-----------------------------------------------------|--------|--------|--------|--------|--------|---|
| CO <sub>2</sub> emissions (t)                       | 11,272 | 10,412 | 10,203 | 10,059 | 10,165 | - |
| CO <sub>2</sub> per unit of revenue (t/million yen) | 0.162  | 0.136  | 0.128  | 0.119  | 0.103  | - |
| Number of employees (people)                        | 1,895  | 1,899  | 1,939  | 1,950  | 2,011  | - |

78.7

6.3

27.0

77.8

6.1

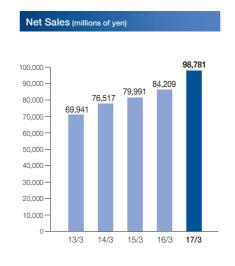
28.7

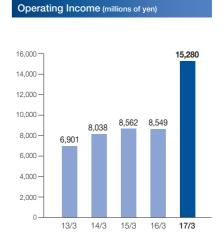
78.5

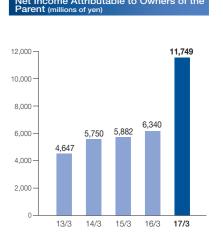
5.4

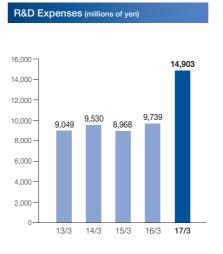
30.5

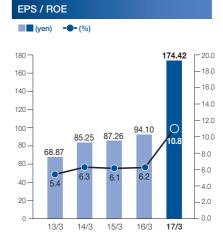
### Financial Highlights





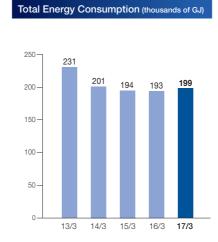


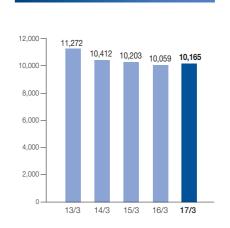




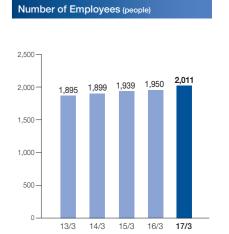


#### Non-Financial Highlights





CO<sub>2</sub> Emissions (t)



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75.6

10.8

27.5

75.8

6.2

29.8

### Financial Section

#### **Operating Results**

#### 1. Fundamental Policy Regarding Profit Sharing

Under our strategy to maximize corporate value, we strive to strengthen our business foundations by bolstering R&D to expand the pipeline for product development, and considering a balance of the investment and return of profits to enable us to maintain a corporate position to withstand increasingly competitive conditions.

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

For the year ended March 31, 2017, we issued an annual cash dividend of ¥48 per share, comprising an interim dividend of ¥18 per share and year-end dividend of ¥30 per share.

For the year ending March 31, 2018, we are projecting an annual dividend of ¥50 per share, comprising an interim dividend of ¥25 per share and year-end dividend of ¥25 per share.

#### 2. Financial Condition

Decreases in inventory assets, and increases in cash and deposits, notes receivable and accounts receivable compared to the previous fiscal year end caused current assets to rise by ¥13,386 million.

Fixed assets increased by  $\frac{42,149}{100}$  million due to an increase in tangible fixed assets despite decreases in long-term prepared expenses, etc. compared to the previous fiscal year end.

As a result, total assets increased by ¥15,535 million compared to the previous fiscal year end to ¥150,905 million.

Current liabilities increased by ¥6,431 million compared to the previous fiscal year end, due to an increase in accrued liabilities, despite decreases in notes and accounts payables–trade and consumption taxes payable, etc.

Fixed liabilities decreased by ¥2,450 million compared to the previous fiscal year end, due to decreases in retirement benefits, etc. As a result, total liabilities increased by ¥3,981 million compared to the previous fiscal year end to ¥36,589 million.

Equity increased by \$10,203\$ million compared to the previous fiscal year end to \$107,067\$ million. Accumulated other comprehensive income increased by \$1,337\$ million to \$7,022\$ million.

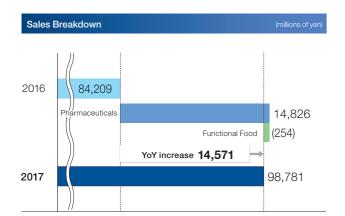
As a result, net assets increased by ¥11,554 million to ¥114,316 million. The equity ratio was 75.6%.

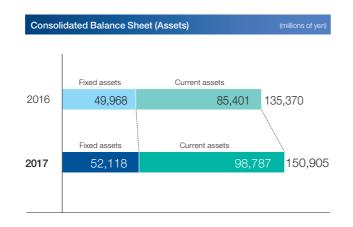
Net cash provided by operating activities amounted to ¥18,916 million. The main cash inflows were income before income taxes of ¥15,477 million, depreciation costs of ¥2,648 million, and an increase in other current liabilities of ¥5,782 million, while the main outflows were income tax, etc. paid of ¥3,084 million and an increase in accounts receivable of ¥1,742 million.

Net cash used in investing activities amounted to ¥5,750 million. The main cash outflows were expenditures for the acquisition of tangible fixed assets of ¥4,131 million, for the acquisition of long-term prepaid expenses of ¥864 million, and for the acquisition of marketable securities of ¥557 million.

Net cash used in financing activities amounted to ¥2,193 million, primarily comprising cash payment of dividends.

As a result, cash and cash equivalents as of March 31, 2017 increased by ¥11,166 million compared to the previous fiscal year end, to ¥35,914 million.





#### 3. Summary of Consolidated Business Results

#### (1) Pharmaceuticals

In the pharmaceuticals segment, sales for long-listed products declined, while sales of new product suites increased, including Zalutia, a drug for urinary disorders caused by benign prostatic hypertrophy, Vidaza, a myelodysplastic syndrome treatment, Tramal and Onetram for cancer pain and chronic pain, and Adcirca for pulmonary arterial hypertension (PAH). In November 2016 we began selling our original product Uptravi for PAH, which was co-developed with Actelion Pharmaceuticals Japan Ltd. in Japan, and which also contributed to the increased sales.

We also had one-time income, royalty income and active pharmaceutical ingredient sales. The result was net sales of ¥85,315 million, up 21.0% year-on-year.

#### (2) Functional Food

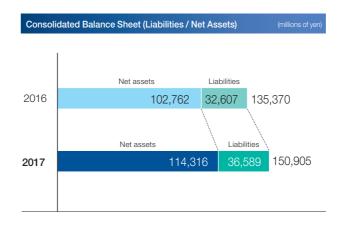
In the functional food segment, sales increased in preservatives and health food ingredients, but fell in protein preparations and other areas. As a result, net sales decreased by 1.9% year-on-year to ¥13,466 million.

#### **Business Risks**

Following are some of the risks that could impact the financial position and business results of the Nippon Shinyaku Group. Forward-looking statements contained below are based on judgments made at the end of the current fiscal year.

#### 1. Regulatory Control Risks

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



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

#### 2. R&D Risks

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

#### 3. Side Effect Risks

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

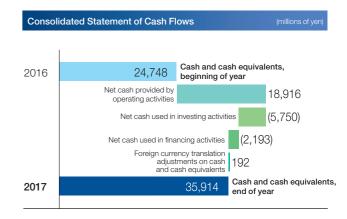
#### 4. Drug Price Revision Risks

Selling prices of drugs used for medical care are 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 natural disasters or other circumstances, they 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 Financial Statements

| Consolidated Balance Sheet                                             |           |           |                                    |
|------------------------------------------------------------------------|-----------|-----------|------------------------------------|
| opon Shinyaku Co., Ltd. and Consolidated Subsidiaries<br>arch 31, 2017 | Millions  | of Yen    | Thousands of U.S. Dollars (Note 1) |
| SSETS                                                                  | 2017      | 2016      | 2017                               |
| CURRENT ASSETS:                                                        |           |           |                                    |
| Cash and cash equivalents (Note 11)                                    | ¥ 35,914  | ¥ 24,748  | \$ 320,660                         |
| Time deposits (Note 11)                                                | 867       | 387       | 7,741                              |
| Marketable securities (Notes 3 and 11)                                 | 2,657     | 2,926     | 23,723                             |
| Notes and accounts receivables (Note 11):                              |           |           |                                    |
| Trade notes                                                            | 556       | 412       | 4,964                              |
| Trade accounts                                                         | 36,322    | 34,723    | 324,303                            |
| Other                                                                  | 347       | 242       | 3,098                              |
| Total notes and accounts receivables                                   | 37,226    | 35,378    | 332,375                            |
| Inventories (Note 4)                                                   | 18,577    | 18,929    | 165,866                            |
| Deferred tax assets (Note 10)                                          | 2,408     | 1,861     | 21,500                             |
| Other current assets                                                   | 1,135     | 1,168     | 10,133                             |
|                                                                        |           |           |                                    |
| Total current assets                                                   | 98,787    | 85,401    | 882,026                            |
| PROPERTY, PLANT AND EQUIPMENT:                                         |           |           |                                    |
| Land                                                                   | 7,463     | 7,509     | 66,633                             |
| Buildings and structures                                               | 25,187    | 24,210    | 224,883                            |
| Machinery, equipment, and vehicles                                     | 10,834    | 10,783    | 96,732                             |
| Tools, furniture, and fixtures                                         | 8,577     | 8,559     | 76,580                             |
| Construction in progress                                               | 2,153     | 130       | 19,223                             |
| Total                                                                  | 54,216    | 51,193    | 484,071                            |
| Accumulated depreciation                                               | (34,173)  | (33,569)  | (305,116)                          |
|                                                                        | 00.040    | 17.004    | 450.055                            |
| Net property, plant and equipment                                      | 20,043    | 17,624    | 178,955                            |
|                                                                        |           |           |                                    |
| INVESTMENTS AND OTHER ASSETS:                                          |           |           |                                    |
| Investment securities (Notes 3 and 11)                                 | 21,681    | 21,497    | 193,580                            |
| Long-term prepaid expenses                                             | 7,085     | 7,521     | 63,258                             |
| Deferred tax assets (Note 10)                                          | 55        | 55        | 491                                |
| Other assets                                                           | 3,252     | 3,269     | 29,035                             |
|                                                                        |           |           |                                    |
| Total investments and other assets                                     | 32,074    | 32,344    | 286,375                            |
| TOTAL                                                                  | ¥ 150,905 | ¥ 135,370 | \$ 1,347,366                       |
| ee notes to consolidated financial statements.                         | 1 300,000 |           | .,,                                |

| Notes and accounts payables (Note 11):                 |   |         |   |         |              |
|--------------------------------------------------------|---|---------|---|---------|--------------|
| Trade notes                                            | ¥ | 1,966   | ¥ | 1,761   | \$ 17,553    |
| Trade accounts                                         |   | 4,265   |   | 4,998   | 38,080       |
| Other                                                  |   | 9,285   |   | 4,793   | 82,901       |
| Total notes and accounts payables                      |   | 15,517  |   | 11,553  | 138,544      |
| Income taxes payable (Note 11)                         |   | 3,892   |   | 1,929   | 34,750       |
| Accrued expenses                                       |   | 3,942   |   | 3,721   | 35,196       |
| Deposits from customers                                |   | 263     |   | 295     | 2,348        |
| Other current liabilities                              |   | 3,384   |   | 3,069   | 30,214       |
| Total current liabilities                              |   | 27,001  |   | 20,569  | 241,080      |
| LONG-TERM LIABILITIES:                                 |   |         |   |         |              |
| Liability for retirement benefits (Note 5)             |   | 8,064   |   | 10,410  | 72,000       |
| Deferred tax liabilities (Note 10)                     |   | 1,121   |   | 1,192   | 10,008       |
| Other long-term liabilities                            |   | 401     |   | 434     | 3,580        |
| Total long-term liabilities                            |   | 9,587   |   | 12,037  | 85,598       |
| EQUITY (Notes 6 and 14):                               |   |         |   |         |              |
| Common stock, authorized, 200,000,000 shares;          |   |         |   |         |              |
| issued 70,251,484 shares                               |   | 5,174   |   | 5,174   | 46,196       |
| Capital surplus                                        |   | 4,445   |   | 4,445   | 39,687       |
| Retained earnings                                      |   | 99,897  |   | 89,658  | 891,937      |
| Treasury stock - at cost, 2,894,408 shares in 2017 and |   |         |   |         |              |
| 2,888,330 shares in 2016                               |   | (2,450) |   | (2,413) | (21,875)     |
| Accumulated other comprehensive income (loss):         |   |         |   |         |              |
| Unrealized gain on available-for-sale securities       |   | 9,235   |   | 9,091   | 82,455       |
| Deferred loss on derivatives under hedge accounting    |   | (5)     |   | (2)     | (44)         |
| Foreign currency translation adjustments               |   | 11      |   | 17      | 98           |
| Defined retirement benefit plans                       |   | (2,217) |   | (3,421) | (19,794)     |
| Total                                                  |   | 114,089 |   | 102,549 | 1,018,651    |
| Noncontrolling interests                               |   | 226     |   | 213     | 2,017        |
| Total equity                                           |   | 114,316 |   | 102,762 | 1,020,678    |
| TOTAL                                                  | ¥ | 150,905 | ¥ | 135,370 | \$ 1,347,366 |
|                                                        |   | ,       |   | ,       | , .,,        |

Thousands of U.S. Dollars (Note 1)

2017

Millions of Yen

2016

2017

See notes to consolidated financial statements.

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LIABILITIES AND EQUITY

**CURRENT LIABILITIES:** 

## Consolidated Financial Statements

| Consolidated Statement of Income                                                   |          |          |                                    |
|------------------------------------------------------------------------------------|----------|----------|------------------------------------|
| Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  'ear Ended March 31, 2017 | Millions | s of Yen | Thousands of U.S. Dollars (Note 1) |
|                                                                                    | 2017     | 2016     | 2017                               |
| NET SALES (Note 15)                                                                | ¥ 98,781 | ¥ 84,209 | \$881,973                          |
| COST AND EXPENSES:                                                                 |          |          |                                    |
| Cost of sales                                                                      | 44,835   | 44,016   | 400,312                            |
| Selling, general, and administrative expenses (Notes 7 and 8)                      | 38,666   | 31,643   | 345,232                            |
| Total                                                                              | 83,501   | 75,660   | 745,544                            |
| Operating income (Note 15)                                                         | 15,280   | 8,549    | 136,428                            |
| OTHER INCOME (EXPENSES):                                                           |          |          |                                    |
| Interest and dividend income                                                       | 434      | 416      | 3,875                              |
| Interest expense                                                                   | (3)      | (3)      | (26)                               |
| Impairment loss (Note 9)                                                           | (766)    | (5)      | (6,839)                            |
| Other – net                                                                        | 533      | (9)      | 4,758                              |
| Other income – net                                                                 | 197      | 403      | 1,758                              |
| INCOME BEFORE INCOME TAXES                                                         | 15,477   | 8,952    | 138,187                            |
| INCOME TAXES (Note 10):                                                            |          |          |                                    |
| Current                                                                            | 4,864    | 2,398    | 43,428                             |
| Deferred                                                                           | (1,152)  | 207      | (10,285)                           |
| Total income taxes                                                                 | 3,712    | 2,605    | 33,142                             |
| NET INCOME                                                                         | 11,765   | 6,346    | 105,044                            |
| NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTEREST                                 | S 15     | 6        | 133                                |
| NET INCOME ATTRIBUTABLE TO OWNERS OF THE PARENT                                    | ¥ 11,749 | ¥ 6,340  | \$ 104,901                         |
|                                                                                    | ,        |          | •                                  |

|                                             | Yen      |         | U.S. Dollars |  |  |
|---------------------------------------------|----------|---------|--------------|--|--|
|                                             |          |         |              |  |  |
| PER SHARE OF COMMON STOCK (Notes 2 and 13): |          |         |              |  |  |
| Basic net income                            | ¥ 174.42 | ¥ 94.10 | \$ 1.56      |  |  |
| Cash dividends applicable to the year       | 48.00    | 28.00   | 0.43         |  |  |
| caon annachae applicable to the jour        | 10.00    | 20.00   | 57.15        |  |  |

See notes to consolidated financial statements.

| pon Shinyaku Co., Ltd. and Consolidated Subsidiaries       |          |         | The control of LLC Dellem          |
|------------------------------------------------------------|----------|---------|------------------------------------|
| r Ended March 31, 2017                                     | Millions | of Yen  | Thousands of U.S. Dollars (Note 1) |
|                                                            | 2017     | 2016    | 2017                               |
| NET INCOME                                                 | ¥ 11,765 | ¥ 6,346 | \$105,044                          |
|                                                            |          |         |                                    |
| OTHER COMPREHENSIVE INCOME (LOSS) (Note 12):               |          |         |                                    |
| Unrealized gain (loss) on available-for-sale securities    | 143      | (509)   | 1,276                              |
| Deferred (loss) gain on derivatives under hedge accounting | (3)      | 8       | (26)                               |
| Foreign currency translation adjustments                   | (6)      |         | (53)                               |
| Defined retirement benefit plans                           | 1,203    | (2,384) | 10,741                             |
| Total other comprehensive income (loss)                    | 1,337    | (2,884) | 11,937                             |
| COMPREHENSIVE INCOME                                       | ¥ 13,102 | ¥ 3,462 | \$116,982                          |
| TOTAL COMPREHENSIVE INCOME ATTRIBUTARI E TO                |          |         |                                    |
| TOTAL COMPREHENSIVE INCOME ATTRIBUTABLE TO:                |          |         |                                    |
| Owners of the parent                                       | ¥ 13,087 | ¥ 3,455 | \$116,848                          |
| Noncontrolling interests                                   | 15       | 6       | 133                                |

See notes to consolidated financial statements.

| Consolidated Statement of Changes in Equity |  |
|---------------------------------------------|--|
|                                             |  |

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

| _ The                            | nousands                                               |                 |                    |                      |                   |                                                               |                                                                        |                                                   |                                           |           |                             |                   |
|----------------------------------|--------------------------------------------------------|-----------------|--------------------|----------------------|-------------------|---------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------|-------------------------------------------|-----------|-----------------------------|-------------------|
|                                  |                                                        |                 |                    |                      |                   |                                                               | Millions of Yen                                                        |                                                   |                                           |           |                             |                   |
|                                  |                                                        |                 |                    |                      |                   | Accum                                                         | ulated Other Co                                                        | omprehensive                                      | Income                                    |           |                             |                   |
| Nu<br>Si<br>Ci                   | utstanding<br>umber of<br>chares of<br>common<br>Stock | Common<br>Stock | Capital<br>Surplus | Retained<br>Earnings | Treasury<br>Stock | Unrealized<br>Gain on<br>Available<br>-for-sale<br>Securities | Deferred<br>Gain (Loss)<br>on Derivatives<br>under Hedge<br>Accounting | Foreign<br>Currency<br>Translation<br>Adjustments | Defined<br>Retirement<br>Benefit<br>Plans | Total     | Noncontrolling<br>Interests | g Total<br>Equity |
| BALANCE, APRIL 1, 2015           | 67,382                                                 | ¥ 5,174         | ¥ 4,445            | ¥ 85,137             | ¥ (2,327)         | ¥ 9,600                                                       | ¥ (11)                                                                 | ¥ 17                                              | ¥ (1,037)                                 | ¥ 100,998 | ¥ 208                       | ¥ 101,207         |
| Net income attributable to       |                                                        |                 |                    |                      |                   |                                                               |                                                                        |                                                   |                                           |           |                             |                   |
| owners of the parent             |                                                        |                 |                    | 6,340                |                   |                                                               |                                                                        |                                                   |                                           | 6,340     |                             | 6,340             |
| Cash dividends, ¥27.00 per share |                                                        |                 |                    | (1,819)              |                   |                                                               |                                                                        |                                                   |                                           | (1,819)   |                             | (1,819)           |
| Purchase of treasury stock       | (19)                                                   |                 |                    |                      | (85)              |                                                               |                                                                        |                                                   |                                           | (85)      |                             | (85)              |
| Net change during the year       |                                                        |                 |                    |                      |                   | (509)                                                         | 8                                                                      |                                                   | (2,384)                                   | (2,884)   | 4                           | (2,880)           |
| BALANCE, MARCH 31, 2016          | 67,363                                                 | 5,174           | 4,445              | 89,658               | (2,413)           | 9,091                                                         | (2)                                                                    | 17                                                | (3,421)                                   | 102,549   | 213                         | 102,762           |
| Net income attributable to       |                                                        |                 |                    |                      |                   |                                                               |                                                                        |                                                   |                                           |           |                             |                   |
| owners of the parent             |                                                        |                 |                    | 11,749               |                   |                                                               |                                                                        |                                                   |                                           | 11,749    |                             | 11,749            |
| Cash dividends, ¥32.00 per share |                                                        |                 |                    | (2,155)              |                   |                                                               |                                                                        |                                                   |                                           | (2,155)   |                             | (2,155)           |
| Purchase of treasury stock       | (6)                                                    |                 |                    |                      | (36)              |                                                               |                                                                        |                                                   |                                           | (36)      |                             | (36)              |
| Change of scope of consolidation |                                                        |                 |                    | 645                  |                   |                                                               |                                                                        |                                                   |                                           | 645       |                             | 645               |
| Net change during the year       |                                                        |                 |                    |                      |                   | 143                                                           | (3)                                                                    | (6)                                               | 1,203                                     | 1,337     | 13                          | 1,351             |
| BALANCE, MARCH 31, 2017          | 67,357                                                 | ¥ 5,174         | ¥ 4,445            | ¥ 99,897             | ¥ (2,450)         | ¥ 9,235                                                       | ¥ (5)                                                                  | ¥ 11                                              | ¥ (2,217)                                 | ¥ 114,089 | ¥ 226                       | ¥ 114,316         |

|                                   | Thousands of U.S. Dollars (Note 1) |                    |                      |                   |                                                               |                                                                 |              |                                           |            |                             |                 |
|-----------------------------------|------------------------------------|--------------------|----------------------|-------------------|---------------------------------------------------------------|-----------------------------------------------------------------|--------------|-------------------------------------------|------------|-----------------------------|-----------------|
|                                   |                                    |                    |                      |                   | Accum                                                         | ulated Other C                                                  | omprehensive | Income                                    |            |                             |                 |
|                                   | Common<br>Stock                    | Capital<br>Surplus | Retained<br>Earnings | Treasury<br>Stock | Unrealized<br>Gain on<br>Available<br>-for-sale<br>Securities | Deferred<br>Loss<br>on Derivatives<br>under Hedge<br>Accounting |              | Defined<br>Retirement<br>Benefit<br>Plans | N<br>Total | Noncontrolling<br>Interests | Total<br>Equity |
| BALANCE, MARCH 31, 2016           | \$ 46,196                          | \$ 39,687          | \$ 800,517           | \$ (21,544)       | \$ 81,169                                                     | \$ (17)                                                         | \$ 151       | \$ (30,544)                               | \$ 915,616 | \$ 1,901                    | \$ 917,517      |
| Net income attributable to owners |                                    |                    |                      |                   |                                                               |                                                                 |              |                                           |            |                             |                 |
| of the parent                     |                                    |                    | 104,901              |                   |                                                               |                                                                 |              |                                           | 104,901    |                             | 104,901         |
| Cash dividends, \$0.29 per share  |                                    |                    | (19,241)             |                   |                                                               |                                                                 |              |                                           | (19,241)   |                             | (19,241)        |
| Purchase of treasury stock        |                                    |                    |                      | (321)             |                                                               |                                                                 |              |                                           | (321)      |                             | (321)           |
| Change of scope of consolidation  |                                    |                    | 5,758                |                   |                                                               |                                                                 |              |                                           | 5,758      |                             | 5,758           |
| Net change during the year        |                                    |                    |                      |                   | 1,276                                                         | (26)                                                            | (53)         | 10,741                                    | 11,937     | 116                         | 12,062          |
| BALANCE, MARCH 31, 2017           | \$ 46,196                          | \$ 39,687          | \$ 891,937           | \$ (21,875)       | \$ 82,455                                                     | \$ (44)                                                         | \$ 98        | \$ (19,794)\$                             | 1,018,651  | \$ 2,017                    | \$1,020,678     |

See notes to consolidated financial statements.

#### Consolidated Financial Statements

| onsolidated Statement of Cash Flows                                                 |          |                 |            |  |  |  |
|-------------------------------------------------------------------------------------|----------|-----------------|------------|--|--|--|
| on Shinyaku Co., Ltd. and Consolidated Subsidiaries<br>Ended March 31, 2017         | Millior  | Millions of Yen |            |  |  |  |
| -                                                                                   | 2017     | 2016            | 2017       |  |  |  |
| OPERATING ACTIVITIES:                                                               |          |                 |            |  |  |  |
| Income before income taxes                                                          | ¥ 15,477 | ¥ 8,952         | \$ 138,188 |  |  |  |
| Adjustments for:                                                                    |          |                 |            |  |  |  |
| Income taxes – paid                                                                 | (3,084)  | (2,657)         | (27,536)   |  |  |  |
| Depreciation and amortization                                                       | 2,648    | 2,452           | 23,643     |  |  |  |
| Impairment loss                                                                     | 766      |                 | 6,839      |  |  |  |
| Changes in assets and liabilities:                                                  |          |                 |            |  |  |  |
| Increase in trade notes and trade accounts receivables                              | (1,742)  | (125)           | (15,554)   |  |  |  |
| Decrease in inventories                                                             | 352      | 728             | (3,143)    |  |  |  |
| Decrease in other current assets                                                    | 32       | 96              | 286        |  |  |  |
| Decrease in trade notes and trade accounts payables                                 | (533)    | (358)           | (4,759)    |  |  |  |
| Decrease in other current liabilities                                               | (311)    | (793)           | (2,777)    |  |  |  |
| Decrease in liability for retirement benefits                                       | (589)    | (1,021)         | (5,259)    |  |  |  |
| Other – net                                                                         | 5,901    | 1,641           | 52,688     |  |  |  |
| Total adjustments                                                                   | 3,439    | (37)            | 30,705     |  |  |  |
| Net cash provided by operating activities                                           | 18,916   | 8,915           | 168,893    |  |  |  |
|                                                                                     |          |                 |            |  |  |  |
| INVESTING ACTIVITIES:                                                               |          |                 |            |  |  |  |
| Purchases of property, plant and equipment                                          | (4,131)  | (1,517)         | (36,884)   |  |  |  |
| Purchases of investment securities                                                  | (1)      | (501)           | (9)        |  |  |  |
| Purchases of software                                                               | (221)    | (187)           | (1,973)    |  |  |  |
| Acquisition of long-term prepaid expenses                                           | (864)    | (650)           | (7,714)    |  |  |  |
| Other – net                                                                         | (532)    | (1,121)         | (4,750)    |  |  |  |
| Net cash used in investing activities                                               | (5,750)  | (3,978)         | (51,339)   |  |  |  |
|                                                                                     |          |                 |            |  |  |  |
| FINANCING ACTIVITIES:                                                               |          |                 |            |  |  |  |
| Cash dividends paid                                                                 | (2,154)  | (1,819)         | (19,232)   |  |  |  |
| Repurchase of treasury stock                                                        | (36)     | (85)            | (321)      |  |  |  |
| Other – net                                                                         | (1)      | (2)             | (9)        |  |  |  |
| Net cash used in financing activities                                               | (2,193)  | (1,907)         | (19,580)   |  |  |  |
| FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON                                         |          |                 |            |  |  |  |
| CASH AND CASH EQUIVALENTS                                                           | 125      | (194)           | 1,116      |  |  |  |
|                                                                                     |          | ` ,             |            |  |  |  |
| NET INCREASE IN CASH AND CASH EQUIVALENTS                                           | 11,098   | 2,833           | 99,089     |  |  |  |
| CASH AND CASH EQUIVALENTS OF NEWLY-<br>CONSOLIDATED SUBSIDIARIES, BEGINNING OF YEAR | 67       |                 | 598        |  |  |  |
| CUNSULIDA I ED SUDSIDIARIES. BEGINNING UT YEAK                                      | 0/       |                 | 598        |  |  |  |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR                                        | 24,748   | 21,914          | 221,571    |  |  |  |

See notes to consolidated financial statements.

#### Notes to Consolidated Financial Statements

## 1. BASIS OF PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

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

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form that is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2016 consolidated financial statements to conform to the classifications used in 2017.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Nippon Shinyaku Co., Ltd. (the "Company") is incorporated and operates. Japanese yen figures less than one million yen are rounded down to the nearest million, except for per share data. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥112 to \$1, the approximate rate of exchange at March 31, 2017. U.S. dollar figures less than one thousand dollars are rounded down to the nearest thousand, except for per share data. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. Consolidation - The consolidated financial statement as of March 31, 2017 includes the accounts of the Company and its three domestic subsidiaries and one overseas subsidiary (collectively, the "Companies"). NS Shared-Service Co., Ltd. is included in the scope of consolidation due to increased importance within the Companies.

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

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

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

- b. Cash Equivalents Cash equivalents are short-term investments that are readily convertible into cash and exposed to insignificant risk of changes in value. Cash equivalents include time deposits, certificates of deposit, and commercial paper, all of which mature or become due within three months of the date of acquisition.
- c. Marketable and Investment Securities Marketable and investment securities are classified and accounted for, depending on management's intent, as follows: i) held-to-maturity debt securities, which management has the positive intent and ability to hold to maturity, are reported at amortized cost; and ii) available-for-sale securities that are not classified as held-to-maturity securities and are reported, except for nonmarketable available-for-sale securities, at fair value, with unrealized gains and losses, net of applicable taxes, are reported as a separate component of equity. Realized gains and losses on available-for-sale securities are included in earnings and are calculated by using the moving-average method to determine the cost of securities sold. Nonmarketable available-for-sale securities are stated at cost, cost being determined principally by the moving-average method. Write-downs are recorded in earnings for securities with a significant decline in value that is considered to be other than temporary.
- d. Inventories Inventories held for sale in the ordinary course of business are measured at the lower of cost, determined mainly by the average cost method, or net selling value, which is defined as the selling price, less additional estimated manufacturing costs and estimated direct selling expenses. The replacement cost may be used in place of the net selling value, if appropriate.
- e. Property, Plant and Equipment Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment of the Companies is computed by the straight-line method based on the estimated useful lives of the assets. The range of useful lives is principally from 10 to 50 years for buildings and structures, from 8 to 10 years for machinery, equipment, and vehicles, and from 4 to 6 years for tools, furniture, and fixtures.
- f. Long-Lived Assets The Companies review their long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss would be measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from the continued use and eventual disposition of the asset or the net selling price at disposition.
- g. Retirement and Pension Plans The Company has contributory funded defined benefit pension plans, unfunded retirement benefit plans and a defined

contribution pension plan for employees. Certain subsidiaries use a simplified method of calculated pension liabilities.

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

- h. Allowance for Doubtful Accounts The allowance for doubtful accounts is stated at an amount considered to be appropriate based on the Companies' past credit loss experience and an evaluation of potential losses in receivables outstanding.
- i. Leases Finance lease transactions are capitalized by recognizing lease assets and lease obligations in the consolidated balance sheet. All other leases are accounted for as operating leases.
- j. Allowance for Bonuses To prepare for the payment of employee bonuses, an amount corresponding to the current portion of estimated bonus payments to employees is recorded.
- k. Income Taxes The provision for income taxes is computed based on the pretax income included in the consolidated statement of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted income tax rates to the temporary differences.

The Company applied the Accounting Standards Board of Japan (the ASBJ) Guidance No. 26, "Guidance on Recoverability of Deferred Tax Assets," effective April 1, 2016. There was no impact from this for the year ended March 31, 2017.

- I. Foreign Currency Transactions All short- and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statement of income to the extent that they are not hedged by forward exchange contracts.
- m. Foreign Currency Financial Statements The consolidated balance sheet accounts of the consolidated foreign subsidiaries are translated into Japanese yen at the current exchange rate as of the consolidated balance sheet date except for equity, which is translated at the

historical rate. Differences arising from such translation are shown as "Foreign currency translation adjustments" under accumulated other comprehensive income in a separate component of equity. Revenue and expense accounts of consolidated foreign subsidiaries are translated into yen at the average exchange rate.

- n. Derivative Financial Instruments The Company uses foreign currency forward contracts as a means of hedging exposure to foreign currency exchange risks related to the procurement of merchandise from overseas suppliers. The Company does not enter into derivatives for trading or speculative purposes. Derivative financial instruments and foreign currency transactions are classified and accounted for as follows: a) all derivatives are recognized as either assets or liabilities and measured at fair value, and gains or losses on derivative transactions are recognized in the consolidated statement of income and b) for derivatives used for hedging purposes, if such derivatives qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are deferred until maturity of the hedged transactions. Trade payables denominated in foreign currencies are translated at the contracted rates if the forward contracts qualify for hedge accounting.
- Per Share Information Basic net income per share (EPS) is computed by dividing net income attributable to common shareholders by the weighted-average number of common shares outstanding for the period.

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

p. Accounting Changes and Error Corrections - Under ASBJ Statement No. 24, "Accounting Standard for Accounting Changes and Error Corrections," and ASBJ Guidance No. 24, "Guidance on Accounting Standard for Accounting Changes and Error Corrections," accounting treatments are required as follows: (1) Changes in Accounting Policies—When a new accounting policy is applied following revision of an accounting standard, the new policy is applied retrospectively unless the revised accounting standard includes specific transitional provisions, in which case the entity shall comply with the specific transitional provisions. (2) Changes in Presentation—When the presentation of financial statements is changed, prior-period financial statements are reclassified in accordance with the new presentation. (3) Changes in Accounting Estimates—A change in an accounting estimate is accounted for in the period of the change if the change affects that period only, and is accounted for prospectively if the change affects both the period of the change and future periods. (4) Corrections of Prior-Period Errors—When an error in prior-period financial statements is discovered, those statements are

#### 3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2017 and 2016, consisted of the following:

|                          |   | Millio | Thousands of<br>U.S. Dollars |        |            |   |
|--------------------------|---|--------|------------------------------|--------|------------|---|
|                          | _ | 2017   |                              | 2016   | 2017       | _ |
| Current:                 |   |        |                              |        |            | _ |
| Government and corporate |   |        |                              |        |            |   |
| bonds                    | ¥ | 2,657  | ¥                            | 1,800  | \$ 23,723  | 3 |
| Other                    |   |        |                              | 1,126  |            |   |
| Total                    | ¥ | 2,657  | ¥                            | 2,926  | \$ 23,723  | 3 |
| Noncurrent:              |   |        |                              |        |            | _ |
| Equity securities        | ¥ | 21,611 | ¥                            | 21,497 | \$ 192,95  | 5 |
| Government and corporate |   |        |                              |        |            |   |
| bonds                    |   | 70     |                              |        | 62         | 5 |
| Total                    | ¥ | 21,681 | ¥                            | 21,497 | \$ 193,580 | 0 |

The costs and aggregate fair values of marketable and investment securities at March 31, 2017 and 2016, were as follows:

|                           | Millions of Yen |        |     |                     |          |        |            |
|---------------------------|-----------------|--------|-----|---------------------|----------|--------|------------|
| Manuel 04 0047            |                 | 0      | U   | Inrealized<br>Gains |          | alized | E-in Makes |
| March 31, 2017            |                 | Cost   |     | Gains               | Losses   |        | Fair Value |
| Securities classified as: |                 |        |     |                     |          |        |            |
| Available-for-sale:       |                 |        |     |                     |          |        |            |
| Equity securities         | ¥               | 8,306  | ¥   | 12,976              |          |        | ¥ 21,282   |
| Held-to-maturity          |                 | 2,728  |     |                     | ¥        | 6      | 2,721      |
|                           |                 |        |     | Millions            | s of Yen |        |            |
|                           |                 |        | - 1 | Inrealized          |          | alized |            |
| March 31, 2016            |                 | Cost   |     | Gains               |          | ses    | Fair Value |
| Securities classified as: |                 |        |     |                     |          |        |            |
| Available-for-sale:       |                 |        |     |                     |          |        |            |
| Equity securities         | ¥               | 8,310  | ¥   | 12,856              |          |        | ¥ 21,166   |
| Held-to-maturity          |                 | 2,926  |     |                     | ¥        | 8      | 2,917      |
|                           |                 |        | Ti  | housands o          | f U.S. Γ | ollars |            |
|                           |                 |        |     | Inrealized          |          | alized |            |
| March 31, 2017            |                 | Cost   |     | Gains               | Los      | ses    | Fair Value |
| Securities classified as: |                 |        |     |                     |          |        |            |
| Available-for-sale:       |                 |        |     |                     |          |        |            |
| Equity securities         | \$              | 74,164 | \$  | 115,854             |          |        | \$190,018  |

#### 4. INVENTORIES

Held-to-maturity

Inventories at March 31, 2017 and 2016, consisted of the following:

60 24,295

|                            |   | Millions of Yen |   |        | Thousands of<br>U.S. Dollars |
|----------------------------|---|-----------------|---|--------|------------------------------|
|                            |   | 2017            |   | 2016   | 2017                         |
| Finished products and      |   |                 |   |        |                              |
| merchandise                | ¥ | 12,291          | ¥ | 12,730 | \$109,741                    |
| Work in process            |   | 2,155           |   | 1,519  | 19,241                       |
| Raw materials and supplies |   | 4,129           |   | 4,679  | 36,866                       |
| Total                      | ¥ | 18,577          | ¥ | 18,929 | \$ 165,866                   |

#### 5. RETIREMENT AND PENSION PLANS

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

- 1. Defined Benefit Pension Plan
- (1) The changes in defined benefit obligation for the years ended March 31, 2017 and 2016 were as follows:

|                              |   | Millions of Yen |   |         | Thousands of<br>U.S. Dollars |
|------------------------------|---|-----------------|---|---------|------------------------------|
|                              | _ | 2017            |   | 2016    | 2017                         |
| Balance at beginning of year | ¥ | 30,019          | ¥ | 27,589  | \$268,026                    |
| Current service cost         |   | 1,090           |   | 963     | 9,732                        |
| Interest cost                |   | 193             |   | 326     | 1,723                        |
| Actuarial (gains) losses     |   | (1,090)         |   | 2,969   | (9,732)                      |
| Benefits paid                |   | (1,551)         |   | (1,830) | (13,848)                     |
| Balance at end of year       | ¥ | 28,662          | ¥ | 30,019  | \$255,910                    |

(2) The changes in plan assets for the years ended March 31, 2017 and 2016 were as follows:

|                                 | Million | Thousands of<br>U.S. Dollars |           |
|---------------------------------|---------|------------------------------|-----------|
|                                 | 2017    | 2016                         | 2017      |
| Balance at beginning of year ¥  | 19,609  | ¥ 19,592                     | \$175,080 |
| Expected return on plan assets  | 781     | 780                          | 6,973     |
| Actuarial losses                | (84)    | (1,024)                      | (750)     |
| Contributions from the employer | 1,825   | 1,422                        | 16,294    |
| Benefits paid                   | (1,456) | (1,161)                      | (13,000)  |
| Others                          | (78)    |                              | (696)     |
| Balance at end of year ¥        | 20,597  | ¥ 19,609                     | \$183,901 |
|                                 |         |                              |           |

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

|                                    |   | Millio   | ns of | f Yen    |      | ousands of<br>.S. Dollars |
|------------------------------------|---|----------|-------|----------|------|---------------------------|
|                                    | - | 2017     |       | 2016     |      | 2017                      |
| Funded defined benefit             |   |          |       |          |      |                           |
| obligation                         | ¥ | 26,123   | ¥     | 27,573   | \$ 2 | 233,241                   |
| Plan assets                        |   | (20,597) |       | (19,609) | (    | 183,901)                  |
|                                    |   | 5,525    |       | 7,964    |      | 49,330                    |
| Unfunded defined                   |   |          |       |          |      |                           |
| benefit obligation                 |   | 2,538    |       | 2,445    |      | 22,660                    |
| Net liability arising from defined |   |          |       |          |      |                           |
| benefit obligation                 | ¥ | 8,064    | ¥     | 10,410   | \$   | 72,000                    |
|                                    |   | Millio   | ns of | f Yen    |      | ousands of<br>.S. Dollars |
|                                    |   | 2017     |       | 2016     |      | 2017                      |
| Liability for retirement benefits  | ¥ | 8,064    | ¥     | 10,410   | \$   | 72,000                    |
| Net liability arising from         |   |          |       |          |      |                           |
| defined benefit obligation         | ¥ | 8,064    | ¥     | 10,410   | \$   | 72,000                    |

(4) The components of net periodic benefit costs for the years ended March 31, 2017 and 2016 were as follows:

|                                    | Millions of Yen |   |       | Thousands of<br>U.S. Dollars |         |
|------------------------------------|-----------------|---|-------|------------------------------|---------|
|                                    | 2017            |   | 2016  |                              | 2017    |
| Service cost ¥                     | 1,090           | ¥ | 963   | \$                           | 9,732   |
| Interest cost                      | 193             |   | 326   |                              | 1,723   |
| Expected return on plan assets     | (781)           |   | (780) |                              | (6,973) |
| Amortization of prior service cost | 716             |   | 515   |                              | 6,392   |
| Recognized actuarial losses        | 45              |   | 45    |                              | 401     |
| Others                             | 30              |   | 19    |                              | 267     |
| Net periodic benefit costs ¥       | 1,294           | ¥ | 1,089 | \$                           | 11,553  |

(5) Amounts recognized in other comprehensive income (before income tax effect) in respect of defined retirement benefit plans for the years ended March 31, 2017 and 2016 were as follows:

|                          |   | Millions of Yen |   |       | Thousands of<br>U.S. Dollars |          |
|--------------------------|---|-----------------|---|-------|------------------------------|----------|
|                          |   | 2017            |   | 2016  |                              | 2017     |
| Prior service cost       | ¥ | (45)            | ¥ | (45)  | \$                           | (401)    |
| Actuarial losses (gains) |   | (1,722)         |   | 3,478 |                              | (15,375) |
| Total                    | ¥ | (1,768)         | ¥ | 3,433 | \$                           | (15,785) |

(6) Amounts recognized in accumulated other comprehensive income (before income tax effect) in respect of defined retirement benefit plans as of March 31, 2017 and 2016 were as follows:

|                                   | Millions of Yen |      |       | Thousands of<br>U.S. Dollars |        |
|-----------------------------------|-----------------|------|-------|------------------------------|--------|
|                                   | 2017            | 2016 |       | 2017                         |        |
| Unrecognized prior service cost ¥ | 65              | ¥    | 110   | \$                           | 580    |
| Unrecognized actuarial losses     | 3,125           |      | 4,848 |                              | 27,901 |
| Total ¥                           | 3,191           | ¥    | 4,959 | \$                           | 28,491 |

- (7) Plan assets
- a. Components of plan assets
   Plan assets as of March 31, 2017 and 2016
   consisted of the following:

|                  | 2017   | 2016   |  |
|------------------|--------|--------|--|
| Domestic bonds   | 18.3%  | 18.5%  |  |
| Domestic stocks  | 16.1   | 15.6   |  |
| Foreign bonds    | 12.7   | 13.7   |  |
| Foreign stocks   | 11.1   | 11.5   |  |
| General accounts | 29.1   | 26.6   |  |
| Alternative      | 9.5    | 9.9    |  |
| Others           | 3.2    | 4.2    |  |
| Total            | 100.0% | 100.0% |  |

 Method of determining the expected rate of return on plan assets

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

(8) Assumptions used for the years ended March 31, 2017 and 2016 are set forth as follows:

|                            | 2017       | 2016       |  |
|----------------------------|------------|------------|--|
| Discount rate              | 0.1 - 0.9% | 0.1 - 0.7% |  |
| Expected rate of return on |            |            |  |
| plan assets                | 4.0%       | 4.0%       |  |

Defined Contribution Pension Plan
 Premiums for defined contribution pension plan were ¥66 million (\$589 thousand) and ¥55 million for the years ended March 31, 2017 and 2016, respectively.

#### 6. EQUITY

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

#### (a) Dividends

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

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

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

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

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

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

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

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

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

#### 7. RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥14,903 million (\$133,062 thousand) and ¥9,739 million for the years ended March 31, 2017 and 2016, respectively.

#### 8. LEASES

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

Total rental expenses for the years ended March 31, 2017 and 2016 were ¥1,266 million (\$11,306 thousand) and ¥1,263 million, respectively.

Future minimum payments under noncancelable operating leases are as follows:

|                     |          | Operatin | g Leases |                     |
|---------------------|----------|----------|----------|---------------------|
|                     |          | 20       | 17       |                     |
|                     | Millions | s of Yen |          | sands of<br>Dollars |
| Due within one year | ¥        | 4        | \$       | 35                  |
| Due after one year  |          | 1        |          | 8                   |
| Total               | ¥        | 5        | \$       | 44                  |

#### 9. LONG-LIVED ASSETS

The Companies reviewed its long-lived assets for impairment as of March 31, 2017. As a result, the Companies recognized an impairment loss of ¥766 million (\$6,839 thousand) for long-term prepaid expenses. Due to a termination of a pharmaceutical product development program related to the prepaid expenses, the carrying amount was written down to zero.

#### 10. 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 31% and 33% for the years ended March 31, 2017 and 2016, respectively.

The tax effects of significant temporary differences and tax loss carryforwards which resulted in deferred tax assets and liabilities at March 31, 2017 and 2016 are as follows:

|                               | Millions o     | Thousands of U.S. Dollars |           |
|-------------------------------|----------------|---------------------------|-----------|
| _                             | 2017           | 2016                      | 2017      |
| Deferred tax assets:          |                |                           |           |
| Retirement benefits ¥         | <b>2,459</b> ¥ | 3,230                     | \$ 21,955 |
| Accrued expenses              | 1,088          | 963                       | 9,714     |
| Property, plant and equipment | 39             | 36                        | 348       |
| Other                         | 2,805          | 1,592                     | 25,044    |
| Less valuation allowance      | (309)          | (314)                     | (2,758)   |
| Deferred tax assets           | 6,083          | 5,508                     | 54,312    |
| Deferred tax liabilities:     |                |                           |           |
| Unrealized gain on available- |                |                           |           |
| for-sale securities           | 3,740          | 3,769                     | 33,392    |
| Deferred gains on sales of    |                |                           |           |
| property                      | 976            | 997                       | 8,714     |
| Other                         | 23             | 16                        | 205       |
| Deferred tax liabilities      | 4,740          | 4,783                     | 42,321    |
| Net deferred tax assets ¥     | 1,342 ¥        | 724                       | \$ 11,982 |

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 year ended March 31, 2017, with the corresponding figures for 2016, is as follows:

|                                                 | 2017  | 2016  |
|-------------------------------------------------|-------|-------|
| Normal effective statutory tax rate             | 31.0% | 33.0% |
| Expenses not deductible for income tax purposes | 8.0   | 1.4   |
| Income not taxable for income tax purposes      | (0.5) | (8.0) |
| Tax credits for research and development costs  | (7.6) | (5.5) |
| Effect of tax rate reduction                    | 0.2   | 1.0   |
| Inhabitant tax on per capita basis              | 0.4   | 0.7   |
| Other – net                                     | (0.3) | (0.7) |
| Actual effective tax rate                       | 24.0% | 29.1% |

#### 11. FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

#### (1) Group policy for financial instruments

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

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

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

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

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

#### (3) Risk management for financial instruments Credit risk management

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

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

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

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

the purpose of reducing market risks.

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

#### Liquidity risk management

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

#### (4) Fair values of financial instruments

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

#### (a) Fair value of financial instruments

|                                                                                                                                               |     |                                                                 | Mil | ions of Yen                                           |   |                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----|-----------------------------------------------------------------|-----|-------------------------------------------------------|---|-----------------|
|                                                                                                                                               |     | Carrying                                                        |     |                                                       |   | realize         |
| March 31, 2017                                                                                                                                | A   | Amount                                                          | F   | air Value                                             | l | LOSS            |
| Cash and cash equivalents                                                                                                                     | ¥   | 35,914                                                          | ¥   | 35,914                                                |   |                 |
| Time deposits                                                                                                                                 |     | 867                                                             |     | 867                                                   |   |                 |
| Notes and accounts receivables                                                                                                                |     | 37,226                                                          |     | 37,226                                                |   |                 |
| Marketable and investment                                                                                                                     |     |                                                                 |     |                                                       |   |                 |
| securities                                                                                                                                    |     | 24,009                                                          |     | 24,003                                                | ¥ |                 |
| Total                                                                                                                                         | ¥   | 98,018                                                          | ¥   | 98,011                                                | ¥ |                 |
| Notes and accounts payables                                                                                                                   | ¥   | 15,517                                                          | ¥   | 15,517                                                |   |                 |
| Income taxes payable                                                                                                                          |     | 3,892                                                           |     | 3,892                                                 |   |                 |
| Total                                                                                                                                         | ¥   | 19,410                                                          | ¥   | 19,410                                                |   |                 |
|                                                                                                                                               |     |                                                                 | Mil | lions of Yen                                          |   |                 |
| Marsh 04 0040                                                                                                                                 |     | Carrying                                                        |     |                                                       |   |                 |
| March 31, 2016                                                                                                                                | A   | Amount                                                          | F   | air Value                                             |   | realize<br>Loss |
| Cash and cash equivalents                                                                                                                     | A   | Amount 24,748                                                   | F   | air Value                                             |   |                 |
| Cash and cash equivalents<br>Time deposits                                                                                                    | ¥   | 24,748<br>387                                                   | F   | Fair Value<br>24,748<br>387                           |   |                 |
| Cash and cash equivalents<br>Time deposits<br>Notes and accounts receivables                                                                  | ¥   | Amount 24,748                                                   | F   | air Value                                             |   |                 |
| Cash and cash equivalents Time deposits Notes and accounts receivables Marketable and investment                                              | ¥   | 24,748<br>387<br>35,378                                         | F   | 24,748<br>387<br>35,378                               |   | Loss            |
| Cash and cash equivalents Time deposits Notes and accounts receivables Marketable and investment securities                                   | ¥   | 24,748<br>387<br>35,378<br>24,093                               | ¥   | 24,748<br>387<br>35,378<br>24,084                     | ¥ | Loss            |
| Cash and cash equivalents Time deposits Notes and accounts receivables Marketable and investment securities Total                             | ¥   | 24,748<br>387<br>35,378<br>24,093<br>84,607                     | ¥   | 24,748<br>387<br>35,378<br>24,084<br>84,597           |   | Loss            |
| Cash and cash equivalents Time deposits Notes and accounts receivables Marketable and investment securities Total Notes and accounts payables | ¥   | Amount<br>24,748<br>387<br>35,378<br>24,093<br>84,607<br>11,553 | ¥   | 24,748<br>387<br>35,378<br>24,084<br>84,597<br>11,553 | ¥ | realize         |
| Cash and cash equivalents Time deposits Notes and accounts receivables Marketable and investment securities Total                             | ¥¥¥ | 24,748<br>387<br>35,378<br>24,093<br>84,607                     | ¥   | 24,748<br>387<br>35,378<br>24,084<br>84,597           | ¥ | Loss            |

|                                | Thousands of U.S. Dollars |            |    |                 |  |  |  |  |  |
|--------------------------------|---------------------------|------------|----|-----------------|--|--|--|--|--|
| March 31, 2017                 | Carrying<br>Amount        | Fair Value |    | ealized<br>_oss |  |  |  |  |  |
| Cash and cash equivalents      | \$320,660                 | \$320,660  |    |                 |  |  |  |  |  |
| Time deposits                  | 7,741                     | 7,741      |    |                 |  |  |  |  |  |
| Notes and accounts receivables | 332,375                   | 332,375    |    |                 |  |  |  |  |  |
| Marketable and investment      |                           |            |    |                 |  |  |  |  |  |
| securities                     | 214,366                   | 214,313    | \$ | 53              |  |  |  |  |  |
| Total                          | \$875,160                 | \$875,098  | \$ | 53              |  |  |  |  |  |
| Notes and accounts payables    | \$138,544                 | \$138,554  |    |                 |  |  |  |  |  |
| Income taxes payable           | 34,750                    | 34,750     |    |                 |  |  |  |  |  |
| Total                          | \$173,303                 | \$173,303  |    |                 |  |  |  |  |  |

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

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

#### Marketable and investment securities

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

## Notes and accounts payables and income taxes payable

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

#### **Derivatives**

Fair value information for derivatives is omitted because fair values and unrealized gains were immaterial for the years ended March 31, 2017 and 2016.

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

|                                   | Carrying Amount |      |                              |  |  |  |
|-----------------------------------|-----------------|------|------------------------------|--|--|--|
| _                                 | Millions of Yen |      | Thousands of<br>U.S. Dollars |  |  |  |
| _                                 | 2017            | 2016 | 2017                         |  |  |  |
| Investments in equity instruments |                 |      |                              |  |  |  |
| that do not have a quoted marke   | t               |      |                              |  |  |  |
| price in an active market         | ¥329            | ¥331 | \$2,937                      |  |  |  |

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

|                                       |                             | Million                                   | s of Yen                                    |                       |
|---------------------------------------|-----------------------------|-------------------------------------------|---------------------------------------------|-----------------------|
| March 31, 2017                        | Due in<br>1 Year<br>or Less | Due after<br>1 Year<br>through<br>5 Years | Due after<br>5 Years<br>through<br>10 Years | Due after             |
| Cash and cash equivalents             | ¥ 35,914                    |                                           |                                             |                       |
| Time deposits                         | 867                         |                                           |                                             |                       |
| Notes and accounts receivables        | 37,226                      |                                           |                                             |                       |
| Marketable and investment securities: |                             |                                           |                                             |                       |
| Government and corporate bonds        | 2,657                       | ¥ 70                                      |                                             |                       |
| Total                                 | ¥ 76,666                    | ¥ 70                                      |                                             |                       |
|                                       | Due in                      | Due after<br>1 Year                       | Due after<br>5 Years                        |                       |
| March 31, 2016                        | 1 Year<br>or Less           | through<br>5 Years                        | through<br>10 Years                         | Due after<br>10 Years |
| Cash and cash equivalents             | ¥ 24,748                    |                                           |                                             |                       |
| Time deposits                         | 387                         |                                           |                                             |                       |
| Notes and accounts receivables        | 35,378                      |                                           |                                             |                       |
| Marketable and investment securities: |                             |                                           |                                             |                       |
| Government and corporate bonds        | 1,800                       |                                           |                                             |                       |
| Other                                 | 1,150                       |                                           |                                             |                       |

¥ 63,464

Total

|                                       |                             | Thousands (                               | of U.S. Dollar                              | S                     |
|---------------------------------------|-----------------------------|-------------------------------------------|---------------------------------------------|-----------------------|
| March 31, 2017                        | Due in<br>1 Year<br>or Less | Due after<br>1 Year<br>through<br>5 Years | Due after<br>5 Years<br>through<br>10 Years | Due after<br>10 Years |
| Cash and cash equivalents             | \$320,660                   |                                           |                                             |                       |
| Time deposits                         | 7,741                       |                                           |                                             |                       |
| Notes and accounts receivables        | 332,375                     |                                           |                                             |                       |
| Marketable and investment securities: |                             |                                           |                                             |                       |
| Government and corporate bonds        | 23,723                      | \$ 625                                    |                                             |                       |
| Total                                 | \$684,517                   | \$ 625                                    |                                             |                       |

#### 12. OTHER COMPREHENSIVE INCOME (LOSS)

The components of other comprehensive income (loss) for the years ended March 31, 2017 and 2016 were as follows:

|                                                                                                   |         | Millior  | ns of | Yen      |    | ousands of<br>S. Dollars |
|---------------------------------------------------------------------------------------------------|---------|----------|-------|----------|----|--------------------------|
|                                                                                                   | -       | 2017     |       | 2016     |    | 2017                     |
| Unrealized gain (loss) on                                                                         |         |          |       |          |    |                          |
| available-for-sale securities:                                                                    |         |          |       |          |    |                          |
| (Losses) gains arising                                                                            |         |          |       |          |    |                          |
| during the year                                                                                   | ¥       | 114      | ¥     | (667)    | \$ | 1,017                    |
| Reclassification adjustmen                                                                        | ts      |          |       |          |    |                          |
| to profit or loss                                                                                 |         |          |       | (258)    |    |                          |
| Amount before income                                                                              |         |          |       |          |    |                          |
| tax effect                                                                                        |         | 114      |       | (925)    |    | 1,017                    |
| Income tax effect                                                                                 |         | 28       |       | 416      |    | 250                      |
| Total                                                                                             | ¥       | 143      | ¥     | (509)    | \$ | 1,276                    |
| Deferred gain (loss) on derivativ<br>under hedge accounting:<br>Gains (losses) arising            | es      |          |       |          |    |                          |
| , ,                                                                                               | ¥       | (4)      | ¥     | 13       | \$ | (05)                     |
| during the year<br>Income tax effect                                                              | #       | (4)<br>1 | Ŧ     |          | Ф  | (35)                     |
| Total                                                                                             | ¥       |          | ¥     | (4)      | \$ | 8                        |
| างเลเ                                                                                             | Ŧ       | (3)      | Ŧ     | 0        | Ф  | (26)                     |
| Foreign currency translation adjustments:  Adjustments arising                                    |         |          |       |          |    |                          |
| during the year                                                                                   | ¥       | (6)      | ¥     |          | \$ | (53)                     |
| Total                                                                                             | ¥       | (6)      | ¥     |          | \$ | (53)                     |
| Defined retirement benefit plans Adjustments arising during the year Reclassification adjustments | s:<br>¥ | 1,006    | ¥     | (3,994)  | \$ | 8,982                    |
| to profit or loss                                                                                 |         | 761      |       | 560      |    | 6,794                    |
| Amount before income tax ef                                                                       | fect    | 1,768    |       | (3,433)  |    | 15,785                   |
| Income tax effect                                                                                 | 1001    | (564)    |       | 1,049    |    | (5,035)                  |
| Total                                                                                             | ¥       | 1,203    | ¥     | (2,384)  | \$ | 10,741                   |
| Total other comprehensive                                                                         | •       | .,=00    |       | (=,00 +) |    |                          |
| income (loss)                                                                                     | ¥       | 1,337    | ¥     | (2,884)  | \$ | 11,937                   |

#### 13. NET INCOME PER SHARE

Net EPS for the years ended March 31, 2017 and 2016 was as follows:

|                      |      | Millions<br>of Yen                                | Thousands of Shares            |   | Yen    | U.S.<br>Dollars |
|----------------------|------|---------------------------------------------------|--------------------------------|---|--------|-----------------|
| _                    | Attr | et Income<br>ibutable to<br>wners of<br>ie Parent | Weighted-<br>Average<br>Shares |   | EP     |                 |
| For the year ended   |      |                                                   |                                |   |        |                 |
| March 31, 2017 -     |      |                                                   |                                |   |        |                 |
| Basic EPS            |      |                                                   |                                |   |        |                 |
| Net income available |      |                                                   |                                |   |        |                 |
| to common            |      |                                                   |                                |   |        |                 |
| shareholders         | ¥    | 11,749                                            | 67,362                         | ¥ | 174.42 | \$ 1.55         |
| For the year ended   |      |                                                   |                                |   |        |                 |
| March 31, 2016 -     |      |                                                   |                                |   |        |                 |
| Basic EPS            |      |                                                   |                                |   |        |                 |
| Net income available |      |                                                   |                                |   |        |                 |
| to common            |      |                                                   |                                |   |        |                 |
| shareholders         | ¥    | 6,340                                             | 67,372                         | ¥ | 94.10  |                 |

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

#### 14. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 29, 2017, the Company's shareholders approved the following:

Payment of year-end cash dividend of ¥30 (\$0.26) per share to holders of record at March 31, 2017, for a total of ¥2,020 million (\$18,035 thousand).

#### 15. 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 decisionmaker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments.

#### 1. Description of Reportable Segments

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

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

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

## 3. Information about Sales, Profit, Assets, and Other Items is as follows:

|                                                                 |                 |                    | Millions of Yen |                 |              |
|-----------------------------------------------------------------|-----------------|--------------------|-----------------|-----------------|--------------|
|                                                                 |                 |                    | 2017            |                 |              |
|                                                                 | -               | Reportable Segment | t               |                 |              |
|                                                                 | Pharmaceuticals | Functional Food    | Total           | Reconciliations | Consolidated |
| Sales:                                                          |                 |                    |                 |                 |              |
| Sales to external customers                                     | ¥ 85,315        | ¥ 13,466           | ¥ 98,781        |                 | ¥ 98,781     |
| Intersegment sales or transfers                                 |                 |                    |                 |                 |              |
| Total                                                           | ¥ 85,315        | ¥ 13,466           | ¥ 98,781        |                 | ¥ 98,781     |
| Segment profit                                                  | ¥ 14,690        | ¥ 589              | ¥ 15,280        |                 | ¥ 15,280     |
| Segment assets                                                  | 79,208          | 10,155             | 89,364          | ¥ 61,541        | 150,905      |
| Other:                                                          |                 |                    |                 |                 |              |
| Depreciation                                                    | 2,370           | 240                | 2,610           | 38              | 2,648        |
| Increase in property, plant and equipment and intangible assets | 3,811           | 135                | 3,947           | 2               | 3,949        |

|                                                                 | Millions of Yen |              |        |              |   |        |                 |              |
|-----------------------------------------------------------------|-----------------|--------------|--------|--------------|---|--------|-----------------|--------------|
|                                                                 |                 |              |        |              |   | 2016   |                 |              |
|                                                                 |                 | F            | Report | table Segmen | t |        | _               |              |
|                                                                 | Phar            | rmaceuticals | Fund   | ctional Food |   | Total  | Reconciliations | Consolidated |
| Sales:                                                          |                 |              |        |              |   |        |                 |              |
| Sales to external customers                                     | ¥               | 70,489       | ¥      | 13,720       | ¥ | 84,209 |                 | ¥ 84,209     |
| Intersegment sales or transfers                                 |                 |              |        |              |   |        |                 |              |
| Total                                                           | ¥               | 70,489       | ¥      | 13,720       | ¥ | 84,209 |                 | ¥ 84,209     |
| Segment profit                                                  | ¥               | 8,389        | ¥      | 159          | ¥ | 8,549  |                 | ¥ 8,549      |
| Segment assets                                                  |                 | 76,037       |        | 10,167       |   | 86,205 | ¥ 49,164        | 135,370      |
| Other:                                                          |                 |              |        |              |   |        |                 |              |
| Depreciation                                                    |                 | 2,214        |        | 211          |   | 2,425  | 26              | 2,452        |
| Increase in property, plant and equipment and intangible assets |                 | 3,439        |        | 114          |   | 3,554  |                 | 3,554        |

|                                                                 | Thousands of U.S. Dollars |                   |            |                 |              |  |  |  |
|-----------------------------------------------------------------|---------------------------|-------------------|------------|-----------------|--------------|--|--|--|
|                                                                 | 2017                      |                   |            |                 |              |  |  |  |
|                                                                 |                           | Reportable Segmen | t          |                 |              |  |  |  |
|                                                                 | Pharmaceuticals           | Functional Food   | Total      | Reconciliations | Consolidated |  |  |  |
| Sales:                                                          |                           |                   |            |                 |              |  |  |  |
| Sales to external customers                                     | \$ 761,741                | \$ 120,232        | \$ 881,973 |                 | \$ 881,973   |  |  |  |
| Intersegment sales or transfers                                 |                           |                   |            |                 |              |  |  |  |
| Total                                                           | \$ 761,741                | \$ 120,232        | \$ 881,973 |                 | \$ 881,973   |  |  |  |
| Segment profit                                                  | \$ 131,160                | \$ 5,258          | \$ 136,428 |                 | \$ 136,428   |  |  |  |
| Segment assets                                                  | 707,214                   | 90,669            | 797,892    | \$549,473       | 1,347,366    |  |  |  |
| Other:                                                          |                           |                   |            |                 |              |  |  |  |
| Depreciation                                                    | 21,160                    | 2,142             | 23,303     | 339             | 23,642       |  |  |  |
| Increase in property, plant and equipment and intangible assets | 34,026                    | 1,205             | 35,241     | 17              | 35,258       |  |  |  |

Note: Unallocated corporate assets included under "Reconciliations" for 2017 and 2016 are ¥61,541 million (\$549,473 thousand) and ¥49,164 million, respectively, and consist primarily of funds, such as cash equivalents, investment securities, assets for administrative functions, and deferred tax assets.

#### **Related Information**

#### 1. Information about products and services

|                             | Millions of Yen |                 |        |                 |     |         |  |  |
|-----------------------------|-----------------|-----------------|--------|-----------------|-----|---------|--|--|
|                             |                 | 2017            |        |                 |     |         |  |  |
|                             | Pha             | rmaceuticals    |        | Total           |     |         |  |  |
| Sales to external customers | ¥               | 85,315          | ¥      | 13,466          | ¥   | 98,781  |  |  |
|                             |                 |                 | Millio | ns of Yen       |     |         |  |  |
|                             |                 |                 |        |                 |     |         |  |  |
|                             | Pha             | Pharmaceuticals |        | Functional Food |     | Total   |  |  |
| Sales to external customers | ¥               | 70,489          | ¥      | 13,720          | ¥   | 84,209  |  |  |
|                             |                 | Thou            | usands | of U.S. Dolla   | ars |         |  |  |
|                             |                 | 2017            |        |                 |     |         |  |  |
|                             | Pha             | rmaceuticals    | Fun    | ctional Food    |     | Total   |  |  |
| Sales to external customers | \$              | 761,741         | \$     | 120,232         | \$  | 881,973 |  |  |

#### 2. Information about geographical areas

(1) Sale

|   | Japan  | Europe    | (              | Other |   | Total |  |
|---|--------|-----------|----------------|-------|---|-------|--|
|   |        |           | 2017           |       |   |       |  |
|   |        | Thousands | s of U.S. Doll | ars   |   |       |  |
| ¥ | 81,134 | ¥ 17,393  | ¥              | 253   | ¥ | 98,78 |  |
|   |        |           |                |       |   |       |  |
|   | Japan  | Europe    | 2017           | Other |   | Total |  |
|   |        |           | ons of Yen     |       |   |       |  |
|   |        | A ATHE    |                |       |   |       |  |

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

Information about geographical area is omitted as sales to external customers located in Japan accounted for more than 90% of net sales presented in the consolidated statement of income for the year ended March 31, 2016.

(2) Property, plant and equipment Information about geographical area is omitted, as property, plant and equipment located in Japan accounted for more than 90% of property, plant and equipment presented in the consolidated balance sheets as of March 31, 2017 and 2016.

#### 3. Information about major customers

|                              | 2017            |                              |                 |  |
|------------------------------|-----------------|------------------------------|-----------------|--|
|                              | S               | Related                      |                 |  |
| Name of Customers            | Millions of Yen | Thousands of<br>U.S. Dollars | Segment<br>Name |  |
| Actelion Pharmaceuticals Ltd | ¥ 16,768        | \$149,714                    | Pharmaceuticals |  |
| MEDICEO CORPORATION          | 15,934          | 142,267                      | Pharmaceuticals |  |
| Alfresa Corporation          | 14,967          | 133,633                      | Pharmaceuticals |  |
| Suzuken Co., Ltd.            | 13,634          | 121,732                      | Pharmaceuticals |  |

|                               |                 | 2016            |  |  |
|-------------------------------|-----------------|-----------------|--|--|
| _                             | Sales           | Related         |  |  |
| Name of Customers             | Millions of Yen | Segment<br>Name |  |  |
| MEDICEO CORPORATION ¥         | 15,485          | Pharmaceuticals |  |  |
| Alfresa Corporation           | 13,966          | Pharmaceuticals |  |  |
| Suzuken Co., Ltd.             | 13,480          | Pharmaceuticals |  |  |
| Toho Pharmaceutical Co., Ltd. | 8,777           | Pharmaceuticals |  |  |

## **Deloitte.**

Deloitte Touche Tohmatsu LLC Shijokarasuma FT Square 20 Naginataboko-cho Karasuma-higashiiru, Shijo-dori Shimogyo-ku, Kyoto 600-8008 Japan

Tel: +81 (75) 222 0181 Fax: +81 (75) 231 2703 www.deloitte.com/in/en

#### INDEPENDENT AUDITOR'S REPORT

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

We have audited the accompanying consolidated balance sheet of Nippon Shinyaku Co., Ltd. (the "Company") and its consolidated subsidiaries as of March 31, 2017, and the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

#### Management's Responsibility for the Consolidated Financial Statements

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

#### Auditor's Responsibility

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

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

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

#### Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its consolidated subsidiaries as of March 31, 2017, and the consolidated results of their operations and their cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

#### **Convenience Translation**

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

Deloitee Touche Tohmaky LLC

June 29, 2017

Member of Deloitte Touche Tohmatsu Limited

#### Corporate Data / Investor Information

As of March 31, 2017

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 ¥5.2 billion (Listed in the First Section of

the Tokyo Stock Exchange)

Representative Director Shigenobu Maekawa, President

Independent andDeloitte Touche TohmatsuCertified PublicShijokarasuma FT SquareAccountants20, Naginataboko-cho,

Karasuma-higashiiru, Shijo-dori, Shimogyo-ku, Kyoto 600-8008, Japan

Issued and Outstanding

**Number of Shares** 70,251,484

Number of Shareholders 4,067

Share Registrar Mitsubishi UFJ

Trust and Banking Corporation
3-6-3, Fushimi-machi, Chuo-ku, Osaka

Price

Trading

Volumes

5-0-5, Fusi ii Tii-Tiaci ii, Criuo

541-8502, Japan

#### Major Shareholders

Meiji Yasuda Life Insurance Company The Master Trust Bank of Japan, Ltd. (trust account) The Bank of Tokyo-Mitsubishi UFJ, Ltd.

Japan Trustee Services Bank, Ltd. (trust account)

The Bank of Kyoto, Ltd.

Nippon Life Insurance Company Goldman, Sachs & Co. Reg

Japan Trustee Services Bank, Ltd. (trust account 9)
JPMC Oppenheimer JASDEC Lending Account

JP Morgan Chase Bank 385147

#### Network

As of April 1, 2017

#### Main Offices

#### Tokyo Office

#### Business Offices

Sapporo, Tohoku, Kitakanto/Koshin-etsu, Tokyo, Saitama, Chiba, Yokohama, Nagoya, Osaka, Keiji/Hokuriku, Kobe, Chushikoku, Kyushu

#### Business Branches

Asahikawa, Kitatohoku, Koriyama, Niigata, Utsunomiya, Ibaraki, Nagano/Yamanashi, Tokyo No. 2, Tokyo No. 3, Tama, Yokohama No. 3, Shizuoka, Hokuriku, Himeji, Okayama, Shikoku, Fukuoka No. 2, Nagasaki/Saga, Kumamoto, Kagoshima, Okinawa, and others

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

#### **Domestic Subsidiaries**

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

#### Overseas Offices and Subsidiary

NS Pharma, Inc. Beijing Representative Office

London Office

