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.
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 future 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.
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.

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.
Business Outline

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 cutting-edge treatments with the potential for global rollout and innovative new drugs.

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

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
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 prostate 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.

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.

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

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

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Nippon Shinyaku will improve people’s health by supplying unique and high-quality products.

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 ¥185,315 million, up 21.3% 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 saleselig (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 ¥198,781 million, up 17.3% year-on-year.

In terms of profit, operating income was ¥15,280 million, up 27.7% year-on-year and ordinary income was ¥16,244 million, up 17.3% year-on-year.

Nonetheless, consolidated net sales were ¥98,781 million, up 21.0% year-on-year. Increases in sales of Zalutia, Vidaza and Shinyaku Group in the current period were ¥85,315 million, up 21.0% year-on-year. Increases in sales of Zalutia, Vidaza and Shinyaku Group in the current period were ¥85,315 million, up 21.0% year-on-year. Increases in sales of Zalutia, Vidaza and Shinyaku Group in the current period were ¥85,315 million, up 21.0% year-on-year.

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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 greater stability.

July 2017
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.

Management Policy

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

Society: Earn the Trust of Society
We will achieve regulatory compliance and adherence to internal rules, and always remember our corporate social responsibility and behave according to high ethical standards.

Employees: Develop Each Employee
We will develop each employee through goal-setting and positive challenges in work.

Guidelines for Action

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

Speed: Speedy Action
We will always take speedy action to make certain to seize opportunities.

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

Corporate Vision

To be a company that plays a meaningful role in society in the healthcare sector
—To be a unique organization, trusted and valued by the community—

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

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

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

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

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

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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.

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For Business Partners
We will implement unfettered competition that is fair and transparent by maintaining a healthy and appropriate relationship with politicians, governments, and business partners.

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

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Charter of Business Conduct

I. We will act with high ethical standards and in accordance with our business philosophy and management policy while always being conscious of our social responsibilities. We will also achieve regulatory compliance and adhere to internal rules and other regulations in fostering a relationship of trust with society.

II. We will carefully operate our business, as companies that deal with products that affect life, will strive to enhance our qualifications and quality of our work and act creatively.

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

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

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

VI. We will implement unfettered competition that is fair and transparent by maintaining a healthy and appropriate relationship with politicians, governments, and business partners.

VII. We will fully recognize the value of our corporate assets including information assets, and will manage these appropriately.

VIII. We will not comply with inappropriate or unlawful requests from antisocial forces or organizations who threaten the safety and order of civil society.

IX. As a member of society, we will take a proactive approach in social contribution activities.

X. We will comply with international rules and local regulations, as well as respect local culture and customs in our global business activities.
For the Sake of Patients Struggling with Diseases with No Effective Treatment

We are engaged in open innovation with academia (academic research institutes, such as universities) focusing mainly on drug target discovery, for diseases for which it is difficult to develop treatments, and also pro-actively grappling with the task of developing new technologies to create effective therapeutic agents including nucleic acid drugs. Furthermore, we are also making maximum use of commercialization support programs, such as the SAKIGAKE designation system in Japan, and fast track designation in the U.S., with the aim of early practical application of our innovative drugs.

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 (NCPN) 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 the dystrophin gene (exon skip), 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 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.

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, which is called splenoctasia) 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 III clinical trial conducted in the U.S., the safety and efficacy of NS-018 was examined in patients with intolerance (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 starting NS-018 for use in clinical settings as soon as possible.

Course of Development of NS-065/NCNP-01

2009 Nippon Shinya 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
2017 Granted orphan drug designation and rare pediatric disease designation

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 Shinya, 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.

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 abnormality 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, therefore 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.

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 (primary 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 was completed at the Odawara Central Factory in July 2017 to 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.

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 overwriting 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 these 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.

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.
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: Upraline; generic name: selonsapag). The company received approval in the U.S. in December 2015 and marketing authorization in Europe in May 2016. Nippon Shinyaku received manufacturing and marketing approval in Japan in September 2016. Alongside Otsuka and Adcirca already on the market, the addition of Upraline 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 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 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 PGF2 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 Pharmaceuticals 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.

Main steps of new drug development

**Basic research**

Discovery and creation of a candidate compound that will form the basis for a new drug.

A candidate compound is found by searching through chemically synthesized compounds or natural ingredients.

**Nonclinical studies**

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

**Clinical trials**

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

**Application and approval**

After the efficacy and safety of a candidate compound are verified through clinical trials, an application for drug approval is submitted to the Pharmaceuticals and Medical Devices Agency. Once the compound is approved through an expert review process, it can be marketed and marketed as a new drug.
Market penetration is deepening as more people come to understand the features of our main product suites

We offer Zaluta for urinary disorders, Vidaza for hematological use, and Adcirca and Osumit for pulmonary arterial hypertension (PAH); in November 2016 we launched Uptravi in Japan. Our sales efforts revolve around these key products. Zaluta, 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 Zaluta is positioned as a first-line therapy, we believe it will further permeate the market.

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 corporate 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 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 therapies for PAH; in November 2016 we launched Uptravi in Japan. We are aiming to boost mobility as we strive to supply more detailed information.

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

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.

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

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

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 lower manufacturing costs. We, 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 all Logistic Centers and realizing major cost reductions.

At the Odawara Central Factory, making use of a dormant formulation was constructed on the premises of the Odawara 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 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 all Logistic Centers and realizing major cost reductions.

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

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 × 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.

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 blood vessels affects their pliancy. The human body is always at risk of glycation, and 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.
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 “Disclosures 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 ensuring proper financial reporting, and, through the Internal Audit Department positioned directly under the President, evaluate the state of internal controls for financial reporting.

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

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

General Meeting of Shareholders

Corporate Governance Report

Message from External Directors

Yukio Sugiura

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 evaluates new products and launches them worldwide, relying on cost 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 the 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 undergo future endeavors.

On the brink of a new era, I believe my role as an external director is 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 even greater benefits for shareholders.

Hitoshi Sakata

Miyuki Sakurai

[http://www.nippon-shinyaku.co.jp/company_profile/governance.html]

[Corporate Governance Report] [Corporate Governance Basic Policy]
Promotion of Corporate Governance

Board of Directors, Corporate Officers and Corporate Auditors

President

Shigenobu Maekawa
1975: Joined Nippon Shinyaku Co., Ltd.
1993: Temporarily transferred to Japan Federation of
Employers’ Associations.
2007: President of R&D and Planning Dept., Corporate Planning Office
2008: Corporate Officer
2011: Director
2016: General Manager, Corporate Planning, Finance &
Accounting, and Information System, Department Manager
2014: Director
2017: General Manager, Corporate Planning, Finance &
Accounting, and Information System
2021: President (current position)
Attendance at board meetings (FY2016): 14/14

Managing Directors

Tsugio Tanaka
General Manager, Business Management
1980: Joined Nippon Shinyaku Co., Ltd.
2009: Department Manager, Strategic Management Office
2011: Chief Manager, Manufacturing Management &
Material Procurement Center
2015: Director
2017: General Manager, Finance Procurement, Procurement &
Management
2019: Managing Director (current position)
2019: General Manager, Business Management (current position)
Attendance at board meetings (FY2016): 14/14

Corporate Auditors

Tomyuki Ota
Standing Corporate Auditor
1980: Joined Nippon Shinyaku Co., Ltd.
2007: Department Manager, Finance Business Office,
Consumer Business Group
2009: Department Manager, Sales Business Office, Consumer Business Group
2012: Corporate Officer, Department Manager, Tokyo Business Office, Sales and Marketing
2015: Corporate Officer, head of Osaka Business Office, Sales and Marketing
2017: Director (current position)
2018: General Manager, Resource Procurement, Procurement &
Management
Attendance at board meetings (FY2016): 14/14

Kazuhiro Imai
Outside Auditor
1970: Admitted to the Bar of Osaka, Minato-ku District
1972: Admitted to the Bar of Osaka, Chuo-ku District
1974: Director, Nippon Shinyaku Co., Ltd.
1976: Director, Nippon Shinyaku Co., Ltd.
2007: Auditor, Nippon Shinyaku Co., Ltd.
2010: Auditor, Nippon Shinyaku Co., Ltd.
2013: Auditor, Nippon Shinyaku Co., Ltd.
2014: Auditor, Nippon Shinyaku Co., Ltd.
2016: Auditor, Nippon Shinyaku Co., Ltd.
2017: Auditor, Nippon Shinyaku Co., Ltd.
2018: Auditor, Nippon Shinyaku Co., Ltd.
2019: Auditor, Nippon Shinyaku Co., Ltd.
2021: Auditor, Nippon Shinyaku Co., Ltd.
Attendance at board meetings (FY2016): 14/14

Hiroyuki Kondo
Outside Auditor
1980: Cooperated legal training at The Legal Training and
Research Institute of Japan
1982: Admitted to the Bar of Osaka
1984: Admitted to the Bar of Tokyo
2001: Auditor (current position)
2003: Auditor (current position)
2005: Auditor (current position)
2007: Auditor (current position)
2009: Auditor (current position)
2011: Auditor (current position)
2013: Auditor (current position)
2015: Auditor (current position)
2017: Auditor (current position)
2019: Auditor (current position)
2021: Auditor (current position)
Attendance at board meetings (FY2016): 14/14

Akira Matsuoka
General Manager, R&D
1980: Jointed Nippon Shinyaku Co., Ltd.
2001: Department Manager, Chemical Research Dept.,
Drug Research Center
2004: Department Manager, Discovery Research Labs.,
R&D
2006: Corporate Officer, Department Manager, Discovery
Research Labs., R&D
2013: Director
2014: General Manager, R&D, Head of RD
2016: Managing Director (current position)
2016: General Manager, R&D (current position)
Attendance at board meetings (FY2016): 14/14

Hideya Mukai
Standing Corporate Auditor
1979: Jointed Nippon Shinyaku Co., Ltd.
2009: Department Manager, Pharmaceuticals &
Medical Research, R&D
2015: Corporate Officer, Department Manager, Discovery
Research Labs, R&D
2017: Director
2018: Standing Corporate Auditor (current position)
2019: Deputy Head of Sales and Marketing
2019: Managing Director (current position)
Attendance at board meetings (FY2016): 14/14

Yoshihito Saito
General Manager, Resource Procurement, Production &
Assurance
1975: Jointed Nippon Shinyaku Co., Ltd.
2002: Department Manager, Quality & Procurement
Support, Head of Manufacturing Management
2006: Department Manager, Disposal Administration Dept.,
Managing Director (current position)
2010: Corporate Officer, Head of R&D Administration
Dept., Managing Director (current position)
2012: Managing Director (current position)
2015: General Manager, Resource Procurement, Production &
Assurance (current position)
Attendance at board meetings (FY2016): 14/14

Kenro Kobayashi
General Manager, Functional Food
1992: Jointed Nippon Shinyaku Co., Ltd.
2007: Department Manager, Corporate Office, Sales and
Marketing
2012: Director, General Manager, Sales Promotion Div., Sales
Promotion Dept., General Manager (current position)
2013: Director
2015: Director
2017: Director (current position)
2019: Standing Corporate Auditor (current position)
Attendance at board meetings (FY2016): 14/14

Shouzou Sano
General Manager, Sales and Marketing
1985: Jointed Nippon Shinyaku Co., Ltd.
2013: Department Manager, Sales and Marketing Dept.,
Head of Osaka Business Office, Sales and Marketing
2015: Corporate Officer, Director, General Manager, Sales and
Marketing
2018: Managing Director (current position)
2019: General Manager, Sales and Marketing, Head of Sales
and Marketing (current position)
Attendance at board meetings (FY2016): 14/14

Yukio Sugiyura
External Director
1966: Professor, Institute of Chemical Research, Kyoto
University
1986: Guest professor, Pharmaceutical Dept.,
The University of Melbourne
1993: Director for Chemical Research, Kyoto University
1997: Professor, Kyoto University (current position)
2001: Professor, University of Manchester
2005: Professor, Université de Versailles, France (current position)
2013: Director (current position)
2017: Jointed from professor, Université de Versailles, France
2019: General Manager, Sales and Marketing (current position)
Attendance at board meetings (FY2016): 14/14

Miyuki Sakurai
External Director
1990: Cooperated legal training at The Legal Training and
Research Institute of Japan
1990: Admitted to the Bar of Osaka
1992: Admitted to the Bar of Tokyo
2001: Consulting lawyer, International Law Office (current position)
2010: Auditor, Nippon Shinyaku Co., Ltd.
2013: Auditor, Nippon Shinyaku Co., Ltd.
2015: Auditor, Nippon Shinyaku Co., Ltd.
2017: Auditor, Nippon Shinyaku Co., Ltd.
2019: Auditor, Nippon Shinyaku Co., Ltd.
2021: Auditor, Nippon Shinyaku Co., Ltd.
Attendance at board meetings (FY2016): 14/14

Corporate Officers

Taro Sakurai
Department Manager, Finance & Accounting Dept.
2004: General Manager, Finance & Accounting Dept.
2006: Auditor, Nippon Life Insurance Co., Ltd.
2009: Auditor, Nippon Life Insurance Co., Ltd.
2011: Auditor, Nippon Life Insurance Co., Ltd.
2013: Auditor, Nippon Life Insurance Co., Ltd.
2014: Auditor, Nippon Life Insurance Co., Ltd.
2016: Auditor, Nippon Life Insurance Co., Ltd.
2017: Auditor (current position)
2019: Deputy Manager, Nippon Life Insurance Co., Ltd.
Attendance at board meetings (FY2016): 14/14

Hitoshi Harada
Head of Business Development Div.
2016: Jointed Nippon Shinyaku Co., Ltd.
2018: Jointed Nippon Shinyaku Co., Ltd.
2021: Managing Director (current position)
Attendance at board meetings (FY2016): 14/14

Takanori Edamitsu
Department Manager, Engineering & Manufacturing Dept.
2002: Jointed Nippon Shinyaku Co., Ltd.
2004: Jointed Nippon Shinyaku Co., Ltd.
2006: Jointed Nippon Shinyaku Co., Ltd.
2008: Jointed Nippon Shinyaku Co., Ltd.
2010: Jointed Nippon Shinyaku Co., Ltd.
2012: Jointed Nippon Shinyaku Co., Ltd.
2014: Jointed Nippon Shinyaku Co., Ltd.
2016: Jointed Nippon Shinyaku Co., Ltd.
2018: Jointed Nippon Shinyaku Co., Ltd.
2021: Jointed Nippon Shinyaku Co., Ltd.
Attendance at board meetings (FY2016): 14/14

Hiyoshi Suehara
Head of Manufacturing Div.
2010: Jointed Nippon Shinyaku Co., Ltd.
2012: Jointed Nippon Shinyaku Co., Ltd.
2014: Jointed Nippon Shinyaku Co., Ltd.
2016: Jointed Nippon Shinyaku Co., Ltd.
2018: Jointed Nippon Shinyaku Co., Ltd.
2020: Jointed Nippon Shinyaku Co., Ltd.
Attendance at board meetings (FY2016): 14/14

Hiroki Nakajima
Chief Medical Officer and Head of Medical Supplies Div.
2017: Jointed Nippon Shinyaku Co., Ltd.
2019: Jointed Nippon Shinyaku Co., Ltd.
2021: Jointed Nippon Shinyaku Co., Ltd.
Attendance at board meetings (FY2016): 14/14

Kazuhito Morita
Head of R&D Administration Div.
2016: Jointed Nippon Shinyaku Co., Ltd.
2018: Jointed Nippon Shinyaku Co., Ltd.
2020: Jointed Nippon Shinyaku Co., Ltd.
2021: Jointed Nippon Shinyaku Co., Ltd.
Attendance at board meetings (FY2016): 14/14

Current as of July 2017
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 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

<table>
<thead>
<tr>
<th>Type of Training</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Departmental compliance training (monthly)</td>
<td>Departmental training incorporating company-wide content and department-specific content.</td>
</tr>
<tr>
<td>Training for newly promoted managers (March–October)</td>
<td>Training that focuses on teaching new managers about compliance concepts and approaches, and stressing the importance of compliance.</td>
</tr>
<tr>
<td>Enhanced Training (July–August)</td>
<td>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.”</td>
</tr>
</tbody>
</table>

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.

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Responsible Procurement
Companies have much greater responsibilities than simply providing products to consumers. Corporate social responsibility requires that a company, in the conduct of its business, comply with laws and regulations, and protect the environment thorough 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 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/ja/ir

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.

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

First employee to identify risk
Risk management department
Supervising manager of employee
Director in charge of risk management
Supervising department for the specific risk
Departments asked to cooperate

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 Odaibara 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.

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.
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. With a desire to improve quality of life, Nippon Shinyaku is passionately committed to making unique medicines that patients truly want.

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Providing Information

Evaluating 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://paht-support.jp/), we provide information such as on the disease itself, treatment explanations, medical expenses, and 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://tochokjin.com/)

“Support Site for Alcohol Dependence” (Japanese only; http://seiritsu.jp/)

“ED Care Support” (Japanese only; http://www.ed-care-support.jp/)

We have also launched smartphone apps—Lunabell Diary and PAH-Care Notebook—that patients can use to track their medication, record symptoms, and communicate with medical professionals.

Furthermore, we have launched a new website in fiscal 2017, “Otokochin.com” (Japanese only; http://otokochin.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 problems as well as a simple check sheet for consultation.

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 information to 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 contains information for medical professionals and patients. Medical professionals can find pharmaceutical information including drug information sheets*2, interview forms, package inserts, and updated usage warnings. Patients and general readers can find pharmaceutical guides and information aimed at improving wellness.

Educating People about Illnesses

We have hosted public lectures by doctors since 1998. Most recently, we hosted two symposiums in February 2017—“The Urgent Battle of Lifestyle Diseases and Urinary Disorders” and “Good Health and Drinking”—and both were well attended.

Elsewhere, we endeavor to spread awareness and understanding about the condition to reduce any psychological resistance to seeking out help.

Post-manufacture and marketing

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 financial, customers, business processes, human resources, innovation, and more. We set KPIs*4 to manage the 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 logistics 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.

Quality Assurance and Supply Stability

Quality Assurance and Supplying Stability

Under the leadership of the Assurance Division, Nippon Shinyaku strives to maintain our 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 those 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.

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.

SCM

Supply Chain Management

Measures Against Counterfeit Drugs

Nippon Shinyaku recognizes that improved counterfeit 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 counterfeit of our products to enact appropriate countermeasures, cooperate with our license and industry organizations, and provide information to government and other related parties.
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 times 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 work with peace of mind.

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.

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 P&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.


Nippon Shinyaku has established a Career Support Academy (CSA) 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 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 reduction 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.

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 these trainees 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 nature 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.

*Training system that combines corporate internship with education at a special-needs support school.
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.

Nicotiana caulescens and Nicotiana chrysanthemum seticuspe, which are recognized the world over as endangered. Indeed, the Welwitschia vermicide that has played such a large part in our corporate development.

The Yamashina Botanical Research Institute was established in 1934 as Santonin, the Yamashina Pilot Farm. Since then, we have amassed a collection of 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.

We hope to nurture the spirited growth and future dreams of the children, both in Kyoto and the whole country. We also support 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, “Nihon no Hito (My People),” a workshop in which characters were made using Japanese confectioneries was held for local children.

The Yamashina Botanical Research Institute

The research institute was established in 1934 as the Yamahama Pilot Farm. Since then, we have amassed a collection of some 3,000 varieties of medicinal and therapeutic plants from around the world, including mitsuboshi (Artemisia maritima) in Santonin, the Yamashina Pilot Farm. Since then, we have amassed a collection of 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.

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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 Hakusai 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 youth’s baseball skills and physical strength, while increasing our interaction with local communities.

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.

Environmental Accounting

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

Environmental conservation benefits

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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.

1. We will effectively operate an internal organization responsible for environmental issues and establish clear targets for our collective pursuit of environmental conservation initiatives.
2. We will comply with laws, regulations, and internal rules pertaining to the environment, and work at environmental conservation cognizant of our responsibility to society at large.
3. We will maintain an accurate awareness of the impact of our business activities on the environment (e.g., global warming, depletion of resources, environmental pollution) and seek to continuously improve our environmental preservation activities and prevent pollution.

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.

Environmental Accounting

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

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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.

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Raising Corporate Value in the Eyes of Stakeholders

Society and Regional Communities

The Global Environment

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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 the final amount of landfill 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.

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

- Total energy consumption*2 in FY2016 was 13.7% lower than in FY1990. CO2 emissions*3 were 3.8% lower than in FY1990.
- By FY2016, final amount of landfill waste was reduced to 2.7 tons, 81.5% lower than in FY2005, achieving a final landfill waste ratio of 0.6%.
- Promote the proper management of chemical substances, including those stipulated under the Pollutant Release and Transfer Register (PRTR) system, and continuously reduce their emission into the natural environment.
- Effectively improve the results of our environmental performance by maintaining certifications for environmental management systems (ISO 14001 and KES Step 2).
- Trial operation of equipment that removes pellets 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%.
- Reduce product packaging materials as part of pharmaceutical and food product package simplification efforts.
- Promote green purchasing and procurement practices.
- 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.

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 Hokusui Business Branch and the No. 2 wing of the Discovery Research Laboratories were completely retrofitted with LED lights, while head office, the Hyou Kakan hall, and the Discovery Research Laboratories in Tsukuba were partially retrofitted as part of our ongoing plan to gradually switch over to LED lighting.

Total energy consumption in fiscal 2016 (198,789 GJ)*2 was up 2.9% (5,626 GJ) over fiscal 2015 (196,173 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, CO2 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 landfill waste in fiscal 2016 was 2.7 tons, an increase of 0.6 tons from fiscal 2015, and the final landfill waste ratio was 0.6%, which was maintained from the previous year. This means that we have achieved a final landfill 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. For waste with high PCB concentrations, we are properly preparing 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 acetic acid handled was up 65.9%, and in 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.

Material Balance of Our Business Activities

Raising Corporate Value in the Eyes of Stakeholders

The Global Environment
Non-Financial Highlights

Summary of ESG Indices

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total energy consumption (thousands of GJ)</td>
<td>231</td>
<td>201</td>
<td>194</td>
<td>193</td>
<td>199</td>
<td>-</td>
</tr>
<tr>
<td>CO₂ emissions (t)</td>
<td>11,272</td>
<td>10,412</td>
<td>10,203</td>
<td>10,059</td>
<td>10,165</td>
<td>-</td>
</tr>
<tr>
<td>CO₂ per unit of revenue (million yen)</td>
<td>0.162</td>
<td>0.136</td>
<td>0.128</td>
<td>0.119</td>
<td>0.103</td>
<td>-</td>
</tr>
<tr>
<td>Number of employees (people)</td>
<td>1,895</td>
<td>1,899</td>
<td>1,939</td>
<td>1,950</td>
<td>2,011</td>
<td>-</td>
</tr>
</tbody>
</table>
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, to ¥36,589 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 ¥5,172 million.

Net cash used in investing activities amounted to ¥5,750 million. The main cash outflows were for the acquisition of marketable securities of ¥557 million, and an acquisition of long-term prepaid expenses of ¥864 million, and an increase in other current assets of ¥3,084 million and an increase in accounts receivable of ¥1,742 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.

Operating Results

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 ¥170,677 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%.

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 Zulala, a drug for urinary disorders caused by benign prostatic hypertrophy, Vidaza, a myelodysplastic syndrome treatment, Tarimal and Otsenram for cancer pain and chronic pain, and Adorca 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.

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 the 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.

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

#### Consolidated Balance Sheet

**Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries**  
March 31, 2017

<table>
<thead>
<tr>
<th>ASSETS</th>
<th>2017</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>CURRENT ASSETS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents (Note 11)</td>
<td>¥ 35,914</td>
<td>¥ 24,748</td>
<td>$ 320,660</td>
</tr>
<tr>
<td>Time deposits (Note 11)</td>
<td>867</td>
<td>387</td>
<td>7,741</td>
</tr>
<tr>
<td>Marketable securities (Notes 3 and 11)</td>
<td>2,657</td>
<td>2,906</td>
<td>23,723</td>
</tr>
<tr>
<td>Notes and accounts receivables (Note 11):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade notes</td>
<td>556</td>
<td>412</td>
<td>4,964</td>
</tr>
<tr>
<td>Trade accounts</td>
<td>36,322</td>
<td>34,723</td>
<td>324,303</td>
</tr>
<tr>
<td>Other</td>
<td>347</td>
<td>242</td>
<td>3,098</td>
</tr>
<tr>
<td>Total notes and accounts receivables</td>
<td>37,226</td>
<td>35,378</td>
<td>332,375</td>
</tr>
<tr>
<td>Inventories (Note 4)</td>
<td>18,577</td>
<td>18,929</td>
<td>165,866</td>
</tr>
<tr>
<td>Deferred tax assets (Note 10)</td>
<td>2,408</td>
<td>1,861</td>
<td>21,500</td>
</tr>
<tr>
<td>Other current assets</td>
<td>1,135</td>
<td>1,168</td>
<td>10,133</td>
</tr>
<tr>
<td>Total current assets</td>
<td>98,787</td>
<td>85,401</td>
<td>882,026</td>
</tr>
</tbody>
</table>

| 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 | 76,980 |
| Construction in progress | 2,163 | 130 | 19,223 |
| Total | 54,216 | 51,193 | 494,071 |
| Accumulated depreciation | (34,173) | (33,569) | (305,116) |
| 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 | 63,358 |
| 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

See notes to consolidated financial statements.

#### LIABILITIES AND EQUITY

**Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries**  
March 31, 2017

<table>
<thead>
<tr>
<th>LIABILITIES AND EQUITY</th>
<th>2017</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>CURRENT LIABILITIES:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes and accounts payables (Note 11):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade notes</td>
<td>¥ 1,966</td>
<td>¥ 1,761</td>
<td>$ 17,553</td>
</tr>
<tr>
<td>Trade accounts</td>
<td>4,265</td>
<td>4,998</td>
<td>38,080</td>
</tr>
<tr>
<td>Other</td>
<td>9,285</td>
<td>4,793</td>
<td>82,901</td>
</tr>
<tr>
<td>Total notes and accounts payables</td>
<td>15,517</td>
<td>11,553</td>
<td>138,544</td>
</tr>
<tr>
<td>Income taxes payable (Note 11)</td>
<td>3,892</td>
<td>1,929</td>
<td>34,750</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>3,942</td>
<td>3,721</td>
<td>35,196</td>
</tr>
<tr>
<td>Deposits from customers</td>
<td>263</td>
<td>295</td>
<td>2,348</td>
</tr>
<tr>
<td>Other current liabilities</td>
<td>3,384</td>
<td>3,069</td>
<td>30,214</td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>27,001</td>
<td>20,569</td>
<td>241,080</td>
</tr>
</tbody>
</table>

| LONG-TERM LIABILITIES: | | | |
| Liability for retirement benefit (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 |
| Total | 109,516 | 109,207 | 1,051,820 |
| Treasury stock – at cost, 2,394,408 shares in 2017 and | (2,450) | (2,413) | (21,875) |
| 2,898,330 shares in 2016 | | | |
| Accumulated other comprehensive income (loss): | | | |
| Unrealized gain on available-for-sale securities | 9,235 | 9,091 | 82,455 |
| Defined loss on derivatives under hedge accounting | (9) | (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

See notes to consolidated financial statements.
### Consolidated Financial Statements

#### Consolidated Statement of Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2017

<table>
<thead>
<tr>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2017</strong></td>
<td><strong>2016</strong></td>
</tr>
<tr>
<td><strong>NET SALES</strong> (Note 15)</td>
<td>¥ 98,781</td>
</tr>
<tr>
<td><strong>COST AND EXPENSES:</strong></td>
<td></td>
</tr>
<tr>
<td>Cost of sales</td>
<td>44,835</td>
</tr>
<tr>
<td>Selling, general, and administrative expenses (Notes 7 and 8)</td>
<td>38,666</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>83,501</td>
</tr>
<tr>
<td>Operating income (Note 15)</td>
<td>15,280</td>
</tr>
<tr>
<td><strong>OTHER INCOME (EXPENSES):</strong></td>
<td></td>
</tr>
<tr>
<td>Interest and dividend income</td>
<td>434</td>
</tr>
<tr>
<td>Impairment loss (Note 9)</td>
<td>(766)</td>
</tr>
<tr>
<td>Other – net</td>
<td>533</td>
</tr>
<tr>
<td><strong>Other income – net</strong></td>
<td>197</td>
</tr>
<tr>
<td><strong>INCOME BEFORE INCOME TAXES</strong></td>
<td>15,477</td>
</tr>
<tr>
<td><strong>INCOME TAXES</strong> (Note 10)</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>15,280</td>
</tr>
<tr>
<td>Deferred</td>
<td>197</td>
</tr>
<tr>
<td><strong>Total income taxes</strong></td>
<td>15,477</td>
</tr>
<tr>
<td><strong>NET INCOME</strong></td>
<td>11,749</td>
</tr>
<tr>
<td><strong>NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTERESTS</strong></td>
<td>15</td>
</tr>
<tr>
<td><strong>NET INCOME ATTRIBUTABLE TO OWNERS OF THE PARENT</strong></td>
<td>¥ 11,765</td>
</tr>
</tbody>
</table>

#### Consolidated Statement of Comprehensive Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2017

<table>
<thead>
<tr>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2017</strong></td>
<td><strong>2016</strong></td>
</tr>
<tr>
<td><strong>NET INCOME</strong></td>
<td>¥ 11,765</td>
</tr>
<tr>
<td><strong>OTHER COMPREHENSIVE INCOME (LOSS)</strong> (Note 12):</td>
<td></td>
</tr>
<tr>
<td>Unrealized gain (loss) on available-for-sale securities</td>
<td>143</td>
</tr>
<tr>
<td>Deferred (loss) gain on derivatives under hedge accounting</td>
<td>(6)</td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>(33)</td>
</tr>
<tr>
<td>Defined retirement benefit plans</td>
<td>1,203</td>
</tr>
<tr>
<td><strong>Total other comprehensive income (loss)</strong></td>
<td>1,227</td>
</tr>
<tr>
<td><strong>COMPREHENSIVE INCOME</strong></td>
<td>¥ 13,192</td>
</tr>
<tr>
<td><strong>TOTAL COMPREHENSIVE INCOME ATTRIBUTABLE TO:</strong></td>
<td></td>
</tr>
<tr>
<td>Owners of the parent</td>
<td>¥ 13,067</td>
</tr>
<tr>
<td>Noncontrolling interests</td>
<td>15</td>
</tr>
</tbody>
</table>

See notes to consolidated financial statements.

#### Consolidated Statement of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Year Ended March 31, 2017

<table>
<thead>
<tr>
<th>Thousands of Yen</th>
<th>Accumulated Other Comprehensive Income</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2017</strong></td>
<td><strong>2016</strong></td>
</tr>
<tr>
<td><strong>OUTSTANDING NUMBER OF SHARES OF COMMON STOCK</strong></td>
<td></td>
</tr>
<tr>
<td>Outstanding</td>
<td>89,658</td>
</tr>
<tr>
<td><strong>CAPITAL SURPLUS</strong></td>
<td></td>
</tr>
<tr>
<td>Common stock</td>
<td>82,455</td>
</tr>
<tr>
<td>Capital stock</td>
<td>1,276</td>
</tr>
<tr>
<td><strong>RETAINED EARNINGS</strong></td>
<td></td>
</tr>
<tr>
<td>Treasury stock</td>
<td>151</td>
</tr>
<tr>
<td><strong>UNREALIZED GAIN (LOSS) ON AVAILABLE-FOR-SALE SECURITIES</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(26)</td>
</tr>
<tr>
<td><strong>DEFERRED GAIN (LOSS) UNDER HEDGE ACCOUNTING</strong></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>(2,884)</td>
</tr>
<tr>
<td><strong>DEFINED BENEFIT PLANS TOTAL</strong></td>
<td></td>
</tr>
<tr>
<td>Net change during the year</td>
<td>114,316</td>
</tr>
<tr>
<td><strong>AMORTIZATION (REVERSION)</strong></td>
<td></td>
</tr>
<tr>
<td>Defined retirement benefit plans</td>
<td>(17)</td>
</tr>
<tr>
<td>Net change during the year</td>
<td>114,316</td>
</tr>
<tr>
<td><strong>BALANCE, MARCH 31, 2017</strong></td>
<td>¥ 114,316</td>
</tr>
<tr>
<td><strong>BALANCE, MARCH 31, 2016</strong></td>
<td>¥ 105,044</td>
</tr>
<tr>
<td><strong>BALANCE, MARCH 31, 2017</strong></td>
<td>¥ 114,316</td>
</tr>
</tbody>
</table>

See notes to consolidated financial statements.

### Consolidated Balance Sheet

#### Balance Sheet at March 31, 2017

<table>
<thead>
<tr>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2017</strong></td>
<td><strong>2016</strong></td>
</tr>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
</tr>
<tr>
<td>Current assets</td>
<td>¥ 99,897</td>
</tr>
<tr>
<td>Noncurrent assets</td>
<td>¥ 114,429</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>¥ 214,326</td>
</tr>
<tr>
<td><strong>LIABILITIES</strong></td>
<td></td>
</tr>
<tr>
<td>Current liabilities</td>
<td>¥ 3,455</td>
</tr>
<tr>
<td>Noncurrent liabilities</td>
<td>¥ 9,600</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES</strong></td>
<td>¥ 13,065</td>
</tr>
<tr>
<td><strong>OWNERS’ EQUITY</strong></td>
<td></td>
</tr>
<tr>
<td>Capital stock</td>
<td>82,455</td>
</tr>
<tr>
<td>Retained earnings</td>
<td>114,316</td>
</tr>
<tr>
<td><strong>TOTAL OWNERS’ EQUITY</strong></td>
<td>¥ 196,771</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES AND OWNERS’ EQUITY</strong></td>
<td>¥ 214,326</td>
</tr>
</tbody>
</table>

See notes to consolidated financial statements.
Consolidated Financial Statements

CONSOLIDATED SUBSIDIARIES, BEGINNING OF YEAR

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>¥ 35,914</td>
<td>¥ 24,748</td>
<td>$ 320,661</td>
</tr>
</tbody>
</table>
| 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 included 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 Company has 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 disposal 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 disposal 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 calculating 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 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 pre-tax 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.

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

m. Foreign Currency Financial Statements - The 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.

o. Per Share Information - Basic net income per share (EPS) is computed by dividing net income attributable to common shareholders by the weighted-average number of common shares outstanding for the period. Cash dividends per share presented in the accompanying consolidated statement of income are dividends applicable to the respective fiscal years, including dividends to be paid after the end of the year.

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

4. INVENTORIES

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

<table>
<thead>
<tr>
<th></th>
<th>Thousands of U.S. Dollars</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished products and merchandise</td>
<td>$12,291</td>
<td>$12,730</td>
<td>$10,741</td>
</tr>
<tr>
<td>Work in process</td>
<td>$2,155</td>
<td>$1,519</td>
<td>$1,241</td>
</tr>
<tr>
<td>Raw materials and supplies</td>
<td>$4,129</td>
<td>$4,679</td>
<td>$3,894</td>
</tr>
<tr>
<td>Total</td>
<td>$18,575</td>
<td>$18,930</td>
<td>$15,886</td>
</tr>
</tbody>
</table>

3. MARKETABLE AND INVESTMENT SECURITIES

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

<table>
<thead>
<tr>
<th></th>
<th>Million of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available-for-sale:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equity securities</td>
<td>$8,306</td>
<td>$12,976</td>
</tr>
<tr>
<td>Held-to-maturity</td>
<td>$2,728</td>
<td>$6</td>
</tr>
<tr>
<td>Total</td>
<td>$11,034</td>
<td>$13,034</td>
</tr>
<tr>
<td>Held-to-maturity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equity securities</td>
<td>$6,380</td>
<td>$11,666</td>
</tr>
<tr>
<td>Held-to-maturity</td>
<td>$964</td>
<td>$24</td>
</tr>
<tr>
<td>Total</td>
<td>$7,344</td>
<td>$11,910</td>
</tr>
<tr>
<td>Held-to-maturity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equity securities</td>
<td>$1,920</td>
<td>$3,310</td>
</tr>
<tr>
<td>Held-to-maturity</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Total</td>
<td>$1,920</td>
<td>$3,310</td>
</tr>
</tbody>
</table>

4. INVENTORIES

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

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<tr>
<td>Total</td>
<td>$18,575</td>
<td>$18,930</td>
<td>$15,886</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th></th>
<th>Million of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at beginning of year</td>
<td>$20,597</td>
<td>$19,030</td>
</tr>
<tr>
<td>Expected return on plan assets</td>
<td>$781</td>
<td>$780</td>
</tr>
<tr>
<td>Actuarial losses</td>
<td>$(84)</td>
<td>$(52)</td>
</tr>
<tr>
<td>Contributions to the employer</td>
<td>$1,285</td>
<td>$1,422</td>
</tr>
<tr>
<td>Benefits paid</td>
<td>$(1,458)</td>
<td>$(1,161)</td>
</tr>
<tr>
<td>Balance at end of year</td>
<td>$20,597</td>
<td>$19,030</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Million of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at beginning of year</td>
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<td>$19,030</td>
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<td>$1,422</td>
</tr>
<tr>
<td>Benefits paid</td>
<td>$(1,458)</td>
<td>$(1,161)</td>
</tr>
<tr>
<td>Balance at end of year</td>
<td>$20,597</td>
<td>$19,030</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Million of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning balance</td>
<td>$183,591</td>
<td>$183,591</td>
</tr>
<tr>
<td>Contributions to the employer</td>
<td>$1,285</td>
<td>$1,422</td>
</tr>
<tr>
<td>Benefits paid</td>
<td>$(1,458)</td>
<td>$(1,161)</td>
</tr>
<tr>
<td>Ending balance</td>
<td>$183,591</td>
<td>$183,591</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Million of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning balance</td>
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<td>$183,591</td>
</tr>
<tr>
<td>Contributions to the employer</td>
<td>$1,285</td>
<td>$1,422</td>
</tr>
<tr>
<td>Benefits paid</td>
<td>$(1,458)</td>
<td>$(1,161)</td>
</tr>
<tr>
<td>Ending balance</td>
<td>$183,591</td>
<td>$183,591</td>
</tr>
</tbody>
</table>
(4) The components of net periodic benefit costs for the years ended March 31, 2017 and 2016 were as follows:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Service cost</td>
<td>¥1,060</td>
<td>¥963</td>
<td>¥9,732</td>
<td>$850</td>
</tr>
<tr>
<td>Interest cost</td>
<td>193</td>
<td>326</td>
<td>1,723</td>
<td></td>
</tr>
<tr>
<td>Expected return on plan assets</td>
<td>(781)</td>
<td>(786)</td>
<td>(6,973)</td>
<td></td>
</tr>
<tr>
<td>Amortization of prior service cost</td>
<td>716</td>
<td>515</td>
<td>6,392</td>
<td></td>
</tr>
<tr>
<td>Recognized actuarial losses</td>
<td>45</td>
<td>45</td>
<td>401</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>30</td>
<td>19</td>
<td>267</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>¥1,204</td>
<td>¥1,089</td>
<td>¥11,593</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior service cost</td>
<td>(40)</td>
<td>(45)</td>
</tr>
<tr>
<td>Actuarial losses (gain)</td>
<td>(1,722)</td>
<td>3,478</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>(1,762)</td>
<td>(3,421)</td>
</tr>
</tbody>
</table>

(6) The components of net periodic benefit costs for the years ended March 31, 2017 and 2016 are set forth as follows:

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discount rate</td>
<td>0.7%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Expected rate of return on plan assets</td>
<td>4.0%</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

2. Defined Contribution Pension Plan

Premiums for defined contribution pension plan were ¥66 million ($6,392 thousand) and ¥56 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 for 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 of these criteria.

(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, capital 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:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Due within one year</td>
<td>¥4</td>
<td>$35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Due after one year</td>
<td>1</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>¥5</td>
<td>$44</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 ¥76 million ($8,039 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:
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 purchasing 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.

Liability risk management
Liability risk comprises the risk that the Companies cannot meet their contractual obligations in full on maturity dates. The Companies manage their liability 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 national valuation techniques are used instead.

(a) Fair value of financial instruments

<table>
<thead>
<tr>
<th>Description</th>
<th>Fair Value</th>
<th>Unrealized Loss (Gain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$3,914</td>
<td>$875,098</td>
</tr>
<tr>
<td>Time deposits</td>
<td>$875</td>
<td>$2,937</td>
</tr>
<tr>
<td>Notes and accounts receivables</td>
<td>$3,914</td>
<td>$875,098</td>
</tr>
<tr>
<td>Marketable and investment securities</td>
<td>$875,098</td>
<td>$3,914</td>
</tr>
<tr>
<td>Total</td>
<td>$875,098</td>
<td>$3,914</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Due in 1 Year</th>
<th>Due after 1 year through 5 Years</th>
<th>Due after 5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$3,914</td>
<td>$875,098</td>
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<tr>
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<td>$875,098</td>
</tr>
<tr>
<td>Total</td>
<td>$875,098</td>
<td>$3,914</td>
<td>$875,098</td>
</tr>
</tbody>
</table>

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 5.

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

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

(6) Fair values of financial instruments

<table>
<thead>
<tr>
<th>Description</th>
<th>Fair Value</th>
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</tr>
</thead>
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<td>Time deposits</td>
<td>$875</td>
<td>$2,937</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$3,914</td>
<td>$875,098</td>
</tr>
<tr>
<td>Total</td>
<td>$875,098</td>
<td>$3,914</td>
</tr>
</tbody>
</table>

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 5.

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.

(7) Risk management

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.

(8) Foreign currency exchange 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.

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

(9) 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 national valuation techniques are used instead.

(a) Fair value of financial instruments

<table>
<thead>
<tr>
<th>Description</th>
<th>Fair Value</th>
<th>Unrealized Loss (Gain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$3,914</td>
<td>$875,098</td>
</tr>
<tr>
<td>Time deposits</td>
<td>$875</td>
<td>$2,937</td>
</tr>
<tr>
<td>Notes and accounts receivables</td>
<td>$3,914</td>
<td>$875,098</td>
</tr>
<tr>
<td>Marketable and investment securities</td>
<td>$875,098</td>
<td>$3,914</td>
</tr>
<tr>
<td>Total</td>
<td>$875,098</td>
<td>$3,914</td>
</tr>
</tbody>
</table>

12. OTHER COMPREHENSIVE INCOME (LOSS)

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unrealized gain (loss) on available-for-sale securities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gains (losses) arising during the year</td>
<td>¥114</td>
<td>$36</td>
</tr>
<tr>
<td>Reclassification adjustments to profit or loss</td>
<td>$114</td>
<td>$114</td>
</tr>
<tr>
<td>Amount before income tax effect</td>
<td>¥114</td>
<td>$114</td>
</tr>
<tr>
<td>Income tax effect</td>
<td>$35</td>
<td>$35</td>
</tr>
<tr>
<td>Total</td>
<td>¥149</td>
<td>$149</td>
</tr>
<tr>
<td>Gains (losses) arising during the year</td>
<td>$(925)</td>
<td>$(925)</td>
</tr>
</tbody>
</table>

Total before income tax effect | ¥1,049 | $1,049 |
Income tax effect | $35 | $35 |
Total | ¥1,014 | $1,014 |

Foreign currency translation adjustments:
Adjustments arising during the year | $(925) | $(925) |

Total | ¥1,014 | $1,014 |

Defined benefit plans:
Adjustments arising during the year | ¥1,006 | $1,006 |
Reclassification adjustments to profit or loss | $1,006 | $1,006 |

Total before income tax effect | ¥2,012 | $2,012 |
Income tax effect | $35 | $35 |
Total | ¥2,047 | $2,047 |

Other comprehensive income (loss) | ¥1,912 | $1,912 |

Total | ¥1,912 | $1,912 |
Under ASUJ Statement No. 17, "Accounting Standard for Segment Information Disclosures," and ASUJ 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:

<table>
<thead>
<tr>
<th>Segment</th>
<th>Millions of Yen</th>
<th>Reportable Segment</th>
<th>Functional Food</th>
<th>Total</th>
<th>Reconciliation</th>
<th>Consolidated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales to external customers</td>
<td>¥ 70,489</td>
<td>¥ 13,720</td>
<td>¥ 84,209</td>
<td>¥ 84,209</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales to external customers</td>
<td>¥ 70,489</td>
<td>¥ 13,720</td>
<td>¥ 84,209</td>
<td>¥ 84,209</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Segment profit</td>
<td>¥ 3,893</td>
<td>¥ 193</td>
<td>¥ 3,549</td>
<td>¥ 3,549</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Segment assets</td>
<td>76,037</td>
<td>10,167</td>
<td>86,205</td>
<td>136,370</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td>2,214</td>
<td>211</td>
<td>2,425</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase in property, plant and equipment and intangible assets</td>
<td>3,439</td>
<td>114</td>
<td>3,554</td>
<td>3,554</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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 ($0.28) per share to holders of record at March 31, 2017, for a total of ¥2,020 million ($18,035 thousand).

13. NET INCOME PER SHARE
Net EPS for the years ended March 31, 2017 and 2016 was as follows:

<table>
<thead>
<tr>
<th>Period</th>
<th>Million of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic EPS</td>
<td>¥ 94.10</td>
<td>$ 1.55</td>
</tr>
<tr>
<td>Diluted EPS</td>
<td>¥ 94.10</td>
<td>$ 1.55</td>
</tr>
</tbody>
</table>

The companies’ shareholders approved the following:

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 ($0.28) per share to holders of record at March 31, 2017, for a total of ¥2,020 million ($18,035 thousand).

15. SEGMENT INFORMATION

<table>
<thead>
<tr>
<th>Segment</th>
<th>Millions of Yen</th>
<th>Reportable Segment</th>
<th>Functional Food</th>
<th>Total</th>
<th>Reconciliation</th>
<th>Consolidated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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</tr>
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</tr>
<tr>
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<td>114</td>
<td>3,554</td>
<td>3,554</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

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.

2. Information about products and services

3. Information about major customers

<table>
<thead>
<tr>
<th>Name of Customers</th>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actelion Pharmaceuticals Ltd.</td>
<td>¥ 16,768</td>
<td>$149,714</td>
</tr>
<tr>
<td>MEDICED CORPORATION</td>
<td>15,934</td>
<td>142,267</td>
</tr>
<tr>
<td>Althea Corporation</td>
<td>14,967</td>
<td>133,633</td>
</tr>
<tr>
<td>Suzuki Co., Ltd.</td>
<td>13,634</td>
<td>121,732</td>
</tr>
<tr>
<td>Toho Pharmaceutical Co., Ltd.</td>
<td>8,777</td>
<td></td>
</tr>
</tbody>
</table>

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

INDEPENDENT AUDITORS’ REPORT

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

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

June 29, 2017

Member of Deloitte Touche Tohmatsu Limited