



The cover illustration is from Kotoba Nimpo Onomatope ("Kotoha the Onomatopoeia Ninja"), a picture book published through the 9th Nippon Shinyaku Children's Literary Awards contest. For more information about the contest, please refer to page 39 of this report.









The thrill of delivering new medicines to those who need them

The work of pharmaceutical discovery is never done, and even today, many diseases still have no effective medicine for treatment. Development in these areas can be slow because patients are few, which discourages companies from making the large R&D investments required. At Nippon Shinyaku, we relish the challenge of delivering relief to those who suffer from diseases considered intractable. To that end, we strive to develop medicines that work to bring the joy of relief and recovery to patients and their families.

When others can't, we can When others won't, we will

New drugs brought to market by Nippon Shinyaku

At least one item per year

Average over the past 10 years

1 25,956

Potential for drug discovery

in Japan

Japan Pharmaceutical Manufacturers Association Databook 2018

A candidate compound has one chance in 25,956 of becoming a new drug. In the cut-throat world of drug development, all but the most promising projects are abandoned so most candidate compounds never see the light of day.

At Nippon Shinyaku, our in-house drug discovery, in-licensing, product life cycle management and irrepressible determination to help people struggling with health issues, has seen us bring an average of at least one new drug to market every year for the past ten years.

Nippon Shinyaku is working to develop treatments for intractable diseases that as yet have no known effective cure. As long as there are people struggling with illness, no matter how many or few, we will continue to develop new medicines.





Helping People Lead Healthier, Happier Lives

In the nearly 100 years since its establishment in 1919, Nippon Shinyaku has committed itself, as an R&D-based producer of new medication, to a distinctive kind of drug discovery.

We have fulfilled the wishes of patients and medical professionals by listening to their voices, thereby

We have fulfilled the wishes of patients and medical professionals by listening to their voices, thereby developing and selling therapeutic medication aimed at diseases for which no effective treatment methodologies have been established.

Furthermore, since 1961, utilizing our technology and knowhow from the pharmaceuticals business, we have been branching out into the functional food business. We believe that medicine and food share the same importance in maintaining good health, and through providing society with functional foods, as well as pharmaceuticals, we aim to help people lead healthier, happier lives.

What has supported the Company since it was established, and helped Nippon Shinyaku grow into what it is today, is none other than the determination of all employees to be involved hands-on in the production of innovative products for which there is a pressing necessity.

We will continue our quest to meet as yet unfulfilled medical needs, to put a smile on the faces of patients and their families, and to seek a better future for all.

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
- Speed: Speedy Action
- ■Investigation: Spirit of Investigation

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Editorial Policy

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

Period Covered

Fiscal 2017 (April 1, 2017–March 31, 2018). Some sections of the report also discuss initiatives from April 2018 onwards.

Companies Covered

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

Forward-Looking Statements

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

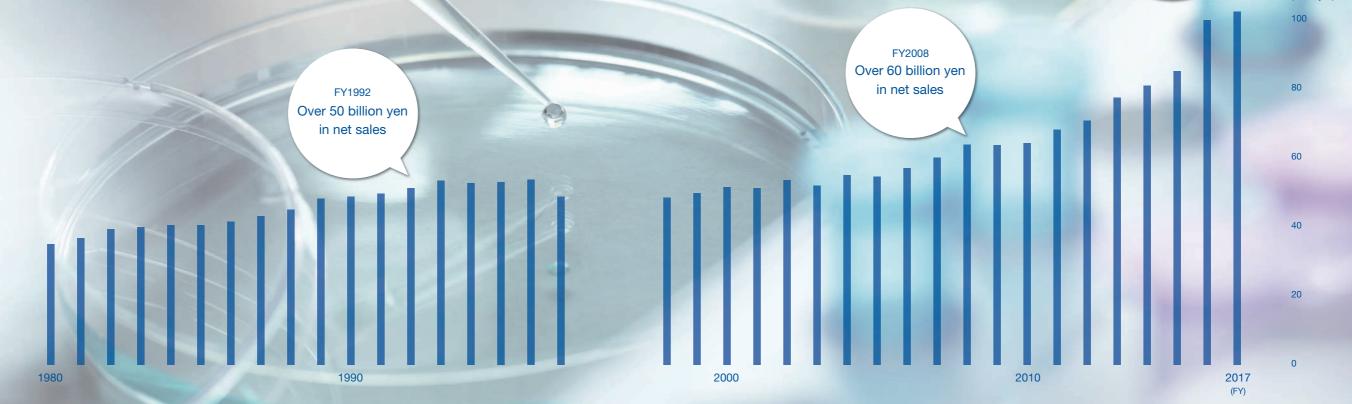
*Information in this report, including comments, has all been obtained in an appropriate manner.





^{*}Figures presented in this report are taken from Nippon Shinyaku's Financial Report for the year ended March 31, 2018. As figures have been rounded, totals may not exactly equal the sum of their composite statistics.

^{*}Product names featured in this report are registered trademarks of Nippon Shinyaku or affiliated companies



1940s to 1950s

Incorporation 1919

Japan's first domestically produced vermicide for roundworms, Santonin, helps to improve public health

Since ancient times, roundworms have afflicted the people of Japan. Santonin is a specific medicine for eliminating the intestinal parasites. Originally it was imported to Japan from Russia, but Nippon Shinyaku worked hard to create its own production process. During the pre- and post-war years, Santonin greatly contributed to the improvement of public health in Japan.

Main Products Launched

1940 Santonin, Japan's first domestically produced vermicide for roundworms

1950 Isomytal, hypnotic and sedative

1958 Azunol, antiinflammatory remedy for skin disorders



1960s to 1980s

Distinctive drugs primarily for urology and otorhinolaryngology

Nippon Shinyaku has a key presence in these fields, selling a number of products including the following.

In otorhinolaryngology: Leftose, an anti-inflammatory enzyme; and Cephadol to treat vertigo

In urology: Eviprostat to treat benign prostatic hypertrophy; Bladderon, a remedy for pollakisuria; and Estracyt to treat prostate cancer

Main Products Launched

1967 Eviprostat, remedy for benign prostatic hypertrophy

1974 Cephadol, remedy for vertigo

Bladderon, remedy for pollakisuria

1984 Estracyt, remedy for prostate cancer

1989 Gaslon N, remedy for gastric ulcers and gastritis







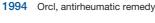
1990s to 2000s

Many new products are released; new products take on a greater share of total sales

Nippon Shinyaku discovered, developed and released Gaslon N, a remedy for gastric ulcers and gastritis. This was followed by such new products as Selectol, a remedy for hypertension and angina pectoris; Orcl, an antirheumatic drug; Hypen, an anti-inflammatory drug; and Cialis, a remedy for erectile dysfunction. With the release of many new products, the share of new products in total net sales expanded.

Main Products Launched

1992 Selectol, remedy for hypertension and angina pectoris



1994 Hypen, anti-inflammator remedy

2009 Cialis, remedy for erectile dvsfunction





2010s

Development speeds up, world-first new drugs are released

Over 100 billion yen in net sales

Nippon Shinyaku released Vidaza, a remedy for myelodysplastic syndrome, Zalutia, a drug for urinary disorders caused by benign prostatic hypertrophy, and other new products. The company discovered and developed Uptravi, the world's first IP receptor agonist for pulmonary arterial hypertension that can be taken orally, which went on sale in 2016.

Main Products Launched

2011 Vidaza, remedy for myelodysplastic syndrome



2013 Regtect, aid for maintaining alcohol abstinence

2014 Zalutia, remedy for urinary disorders caused by benigr prostatic hypertrophy

2016 Uptravi, remedy for pulmonal



We are providing society with distinctive products

in two major areas.

Pharmaceuticals

Drugs for Urological Diseases



- Zalutia Eviprostat Bladderon
- Cialis

Zalutia improves urinary disorders (frequent urination, the urge to urinate, etc.) and difficulty urinating (weak stream, etc.), thereby improving quality of life for individuals with benign prostatic hypertrophy. In the Clinical Guidelines for Male Lower Urinary Tract Symptoms and Benign Prostatic Hyperplasia, Zalutia was named as a first-choice drug, which should help to extend market penetration.

Drugs for Hematology



- Vidaza Cylocide
- Amnolake

Vidaza is the world's first drug to have shown extended survival time for patients with myelodysplastic syndrome. It serves to reduce the frequency of blood transfusions and raise patient QOL

Drugs for Intractable and Rare Diseases



Uptravi

- Adcirca Opsumit

For the treatment of pulmonary arterial hypertension, an intractable disease with an unfavorable prognosis, Nippon Shinyaku offers three types of oral drugs with different mechanisms of action-Adcirca, Opsumit (licensed from Actelion and co-promoted with Actelion Japan), and Uptravi. There is a substantial body of evidence for the three agents, which offer greater choice for treatment.

Drugs for Gynecology



Lunabell Tablets LD Lunabell Tablets ULD

Lunabell Tablets LD are a low-dose estrogen and progesterone compounded agent, the first such medicinal agent for the remedy of dysmenorrhea associated with endometriosis to be covered by health insurance in Japan. Lunabell Tablets ULD offer a further reduced amount of estrogenic hormone to reduce the risk of thrombosis. Together, the remedies will help improve the quality of life of many women who suffer from menstrual cramps.

Drugs for Otorhinolaryngology



- Erizas Baynas Livostin
- Cephadol Isobide Azunol Gargle Liquid

In otorhinolaryngology, Nippon Shinyaku offers a large number of remedies, including Erizas, Baynas, and Livostin to treat allergic rhinitis, Cephadol and Isobide to treat vertigo, as well as Azunol Gargle Liquid.

Others



- Tramal OD

Nippon Shinyaku sells Tramal OD, an immediate-release analgesic for cancer pain and chronic pain administered four times a day, and Onetram, an oral long-lasting formulation based on Japan's first release technologies, as well as Regtect, an aid for alcoholics to maintain abstinence from drinking that works by reducing the craving for alcohol.

Functional Food

Health Food for Consumers



- WINZONE ENERGY × ENERGY AGE-SHUT
- We want to help people lead healthier, happier lives through diet. We communicate this directly to consumers by supplying original health foods for the sports market and aging care market that we develop in-house as a research-based maker of new pharmaceuti-

Health Food Ingredients

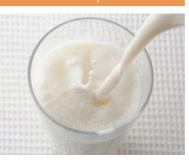


- Mangosteen Aqua Hyaluronic Acid 3000 Garcinia Powder J NS Amla Extract Powder
- We leverage expertise in safety and quality control practices developed in our pharmaceuticals business to provide health food ingredients beneficial to maintaining and improving human health based on assured quality and evidence of efficacy.



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

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



- Milka MPI Lactocrystal plus PROGEL800
 - Enlacto HG Fitness S

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

Spices and Condiments



- Kenda chili pepper extract New Onion Concentrate Haskap Concentrate H
- Hokkaido Cantaloupe Melon Extract
- We utilize our extraction and formulation

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

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



Shigenobu Maekawa

Corporate Vision

We aspire to be a company that plays a meaningful role in the healthcare sector

Nippon Shinyaku is committed to bringing people better health through its pharmaceuticals and functional food segments, providing distinctive products of high quality to society. In addition to supplying high-quality medicines, an important function of a pharmaceutical company, we feel it is our duty as a corporate citizen to assist in the development of society and the regions in which we do business, at the same time as we strive to improve corporate value from the standpoint of stakeholders. With an indispensable role to play in the healthcare field, we aspire to be a unique, trusted, and respected company that plays a meaningful role in society.

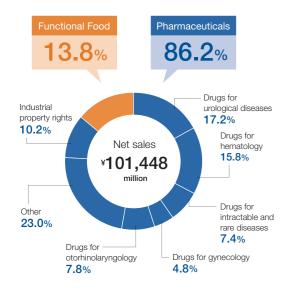
Situation in FY2017

Both sales and profits are higher than last year, reaching record highs

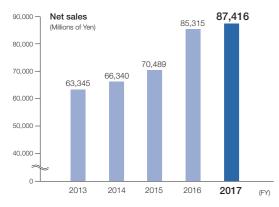
In fiscal 2017, in the Pharmaceuticals business, although no revenue was recorded for the active pharmaceutical ingredient of Uptravi (a treatment for pulmonary arterial hypertension that was released in Japan in November 2016), payments for which were calculated in the previous fiscal year, there has been growth in our new product suites-such as Zalutia, a drug for urinary disorders caused by benign prostatic hypertrophy, and Vidaza, a myelodysplastic syndrome treatment. There has been a rise in income from co-promotion, and growth in domestic sales of Uptravi along with rising royalty income from its overseas sales. These developments led to net sales of ¥87,416 million (a year-on-year increase of 2.5%). In the Functional Food business, net sales increased year-on-year by 4.2% to ¥14,031 million, due to increased sales of protein preparations, preservatives, and health food ingredients. As a result, the Nippon Shinyaku Group's net sales increased 2.7% year-on-year to ¥101,448 million.

In terms of profit, operating income increased year-on-year by 11.8% to ¥17,079 million. Ordinary income was ¥17,451 million (a year-on-year increase of 7.4%). Net income attributable to owners of the parent was ¥12,953 million (a 10.2% year-on-year increase). In all cases profits rose by a large margin to all-time highs.

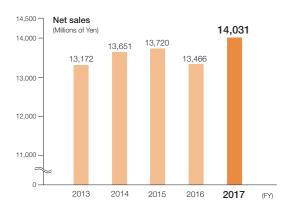
	FY2016 Business Performance	FY2017 Business Performance	Rate of Change
Net sales	¥ 98,781 million	¥ 101,448 million	2.7%
Operating income	¥ 15,280 million	¥ 17,079 million	11.8%
Ordinary income	¥ 16,244 million	¥ 17,451 million	7.4%
Net income attributable to owners of the parent	¥ 11,749 million	¥ 12,953 million	10.2%



Pharmaceuticals



Functional Food



Basic Policy on Management

Implementing our business philosophy at the core of all business activities

Nippon Shinyaku carries out business in pharmaceuticals and functional foods by steadily applying our business philosophy of helping people lead healthier, happier lives. Based on our guidelines for action—challenge, speed, and investigation—we encourage every one of our employees to work to achieve their targets with promptness and a strong sense of ethics. In this way we are able to build relationships of trust with patients and our many other stakeholders and carry out business activities with full integrity. Based on that trust, we aim to differentiate our products from those of other companies and grow by launching new products and improving profitability.

Growth Strategy for the Future

We are accelerating R&D and expanding internationally to achieve sustainable growth

Pharmaceutical companies throughout the industry were hit hard by NHI drug price revisions pursuant to 2018 medical treatment fee revisions. Drug prices were reduced by 1.65% on a medical cost basis (7.5% on the basis of drug costs). The government's drastic reform of the drug pricing system sharply constricts the definition of new drugs eligible for innovation premiums, and a new system was introduced to lower the drug prices of certain long-listed items to the level of generic drugs. We expect change to escalate and intensify in the pharmaceutical industry. That includes a number of measures, as those above, being taken by the Japanese government to curb medical costs. Technological innovation is also advancing rapidly, and restructuring is taking place throughout the industry. In the food industry, consumers remain highly price-conscious and market competition is expected to intensify. To respond to such changes in the business environment and continue to grow in the future, we believe it is all the more necessary to maximize our business value through such measures as speeding up R&D and expanding our international business.

Overall Strategy



In research and development, we will boldly strive to promote open innovation and the latest drug discovery methods, create highly original drugs, and carry out highly reliable clinical trials. 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 (PLCM), through which we are improving our development pipeline. Our aim is to launch one or more products per year on average and to expand market share by fostering each drug after its release into the market.

Outside of Japan, we anticipate future growth as a result of expanding the number of countries in which Uptravi is sold, combined with further market penetration. We are in the process of strengthening management at both our U.S. subsidiary, NS Pharma, Inc., and our Beijing

Business Strategies

Pharmaceuticals

We concentrate our management resources on five fields of focus, with the aim of expanding our share of sales in these areas and to 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.

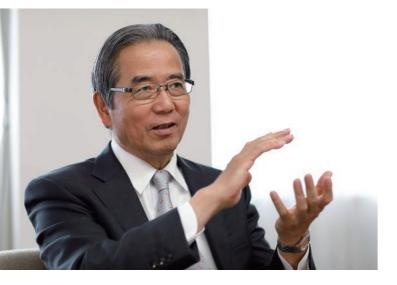


Functional Food

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. Such business efforts will help us to achieve a stable earnings structure.

Representative Office, aiming to commercialize such products as NS-065/NCNP-01, our treatment for Duchenne muscular dystrophy. We plan to increase international sales by promoting international business using measures tailored to suit the conditions of each target country.

In terms of capital investment, at the manufacturing building completed in March 2016 for active pharmaceutical ingredients (APIs) for clinical trials, we are pursuing the manufacture of APIs of investigational drugs such as nucleic acid drugs and NS-580 for endometriosis, which will lead to lower costs for APIs and speed up their research and development. Also, we completed a new facility at the Odawara Central Factory in July 2017 to manufacture highly active solid formulations in-house for our own pharmaceutical products, as well as to perform contract manufacturing. The facility is expected to reach full operating capacity in late fiscal 2018.



ESG Initiatives

Fulfilling our responsibility to society by contributing through our business activities

The purpose of our business is to protect the lives and health of people, and we believe that our business activities themselves build both corporate value and social value. We are concentrating particularly on the development of therapeutic agents for patients with intractable diseases and rare diseases, through which we offer unique value. Furthermore, we plan to not only fulfill our mission toward patients and medical professionals, but also contribute to the achievement of SDGs (the sustainable development goals of the United Nations) and enhance efforts toward ESG (Environment, Society, Governance). By so doing we aim to earn the trust of all our stakeholders and become indispensable to society.

SDGs (Sustainable Development Goals)

SUSTAINABLE GEALS DEVELOPMENT GEALS 17 GOALS TO TRANSFORM OUR WORLD



Regarding governance, at Nippon Shinyaku we recognize that it is a critical management priority to fulfill our accountability to all stakeholders by ensuring the transparency of management. We will continue striving to enhance corporate governance in line with our Corporate Governance Basic Policy, which sets forth our fundamental approach. In addition, Nippon Shinyaku conducts compliance training on a monthly basis and holds training and educational activities to raise awareness among all of our employees as part of our corporate integrity in business.

Efforts for Our Employees

The personal growth of each employee supports the continued growth of the company

A company's growth is built on the individuals within it, making the personal growth of each employee indispensable. With respect to human resources, we employ various training systems to carry out personnel training and recruitment in order to develop the talents of employees who can always think critically and take necessary action on their own. We are working to actively recruit women and hire retired employees, and encourage the development of individuals of differing personalities and strengths. Plus, we are implementing motivation-boosting

Main Initiatives Based on Our HR Strategy

- The hiring of outside experts (mid-career recruitment), foreign students and others, in addition to recruiting new graduates
- The cultivation of talented people with global sensibilities to take responsibility for the company's core business
- The provision of training to cultivate business leadership and enhance English language skills to produce talent estimated both inside and outside the company
- The employment of people based on diversity, regardless of gender, age or disability
- The establishment of an environment in which every employee can work with pride and motivation to achieve goals, while growing as individuals

measures to enable employees to fulfill their potential and elicit their full capabilities. In January 2018, we introduced a flextime system for MRs for the first time in the pharmaceutical industry. We will continue to create an environment that is easy for employees to work in and encourage more efficient ways of working.

Forecast for FY2018

A continued rise in income for Pharmaceuticals and Functional Food

In the Pharmaceuticals business in fiscal 2018, we anticipate an increase in sales of 7.1% year on year to ¥93.6 billion due to growth in new product suites such as Uptravi and Zalutia, and growth in royalty income from Uptravi's overseas sales. In the Functional Food business, we will focus further on developing and introducing new products, and by strengthening our efforts for priority items, we expect sales to be ¥14.4 billion (a year-on-year increase of 2.6%).

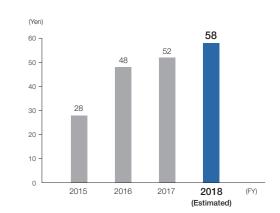
In terms of profits, we expect operating income to increase 8.3% year-on-year to ¥18.5 billion, ordinary income to increase 8.9% year-on-year to ¥19 billion, and net income attributable to owners of the parent to reach ¥14 billion (an 8.1% year-on-year increase). In all cases, profits are expected to increase year on year, and we aim to set record highs in earnings as we expand sales.

To Our Shareholders

An estimated increase of ¥6 per share year on year over FY2017

In order for the company to grow sustainably and provide value to shareholders, we need to raise profits above the cost of operations. One indicator of business efficiency is return on equity. In fiscal 2017, our ROE was 10.8%, indicating how far we exceeded our capital costs. We will continue working to create high value.

Dividend Per Share



Our policy on returning profits to shareholders is to issue dividends linked to earnings and maintain a consolidated payout ratio of around 30%. For fiscal 2017, we issued an interim dividend of ¥26 per share and a year-end dividend of ¥26 per share for an annual cash dividend of ¥52 per share. For fiscal 2018, we are projecting an annual dividend of ¥58 per share, comprising an interim dividend of ¥29 per share and a year-end dividend of ¥29 per share.

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 achievement of which will lead to sustainable growth.

August 2018

S. machawa

higenobu Maekawa

Disorders



Blood cancers, which are also called hematopoietic tumors, include leukemia, in which white blood cells replicate uncontrollably, malignant lymphoma, which originates in lymphoid tissue, and multiple myeloma, in which plasma cells become cancerous and cause tumor proliferation in the bone marrow. Nippon Shinyaku has been committed to R&D, and marketing of blood cancer drugs ever since developing and marketing Cylocide (generic name: cytarabine), our first foray into the field.

Nippon Shinyaku's Initiatives in Hematological Disorders

Our first drug for blood cancer, the leukemia drug Cylocide Injection, was approved in 1971. We later launched Cylocide N Injection, a high-dose formulation for relapsed/refractory acute leukemia resistant to treatment, and for malignant lymphoma as an additional indication. It remains an essential first-line drug in the treatment of acute myeloid leukemia (AML).

The widespread popularity of Cylocide encouraged us to further commit to development and marketing of blood cancer drugs to meet the many unmet medical needs still remaining in the field. We launched Trisenox in 2004 and Amnolake in 2005 as highly effective drugs for relapsed/refractory acute promyelocytic leukemia (APL), a very rare disease. We then released Vidaza, Japan's first drug for myelodysplastic syndrome (MDS), in 2011. Vidaza has contributed greatly to treatment of MDS not only as a first-line drug but also through its important role in the development pipeline for our priority field of blood cancer.

Gazyva (generic name: obinutuzumab), a drug we developed jointly with Chugai Pharmaceutical Co., Ltd., was approved in July of this year. Clinical trials of Gazyva in CD20-positive follicular lymphoma showed that it had greater efficacy than previous treatments, making it a promising new treatment option.

Current projects in our blood cancer development pipeline are a drug for hepatic veno-occlusive disease after hematopoietic cell transplantation (NS-73), a drug

for myelofibrosis (NS-018), addition of AML to the indication of Vidaza, a drug for relapsed/refractory AML (NS-917), and a drug for secondary AML (NS-87). We are working on developing these products so that we can deliver new drugs to patients suffering from blood cancers as quickly as possible.

Nippon Shinyaku's Initiatives in Hematological Disorders Released Cylocide Injection for Leukemia Released Cylocide N Injection for Relapsed/ Refractory Acute Leukemia Added Malignant Lymphoma to the Indication of Cylocide N Injection Released Trisenox for APL Released Amnolake for API Released Vidaza, Japan's First MDS Drug Gazyva (generic name: obinutuzumab) 2018 for CD20-positive Follicular Lymphoma NS-73 for hepatic veno-occlusive disease NS-018 for myelofibrosis Addition of AML to the indication of Vidaza NS-917 for relapsed/refractory AML NS-87 for secondary AML

Vidaza for Myelodysplastic Syndrome (MDS)

The Only Drug That Has Extended the Survival Time for MDS Patients, Now Expanded to AML

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 80 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. Although hematopoietic cell transplantation is available as a complete cure, as MDS is a disease that is prevalent in the elderly, active treatment such as transplantation is not an option for many MDS patients, thereby making MDS a disease with an extremely poor prognosis.

Vidaza exhibits the effect of inhibiting the proliferation of abnormal blood cells. 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 one. 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.

MDS is known to transform into AML, and Vidaza is also used as a standard therapeutic drug for AML overseas. We are currently conducting a clinical trial of Vidaza for AML in Japan as well, and hope that Vidaza will bring hope to many patients in future.



Main Products in Development

NS-73 for Hepatic Veno-occlusive Disease

Hepatic veno-occlusive disease (VOD; also called hepatic sinusoidal obstruction syndrome) is a complication that occurs after hematopoietic cell transplantation performed to treat blood cancers and other such diseases. It is caused by epithelial injury and inflammation of liver sinusoids associated with conditioning procedures such as myeloablative chemotherapy (administration of high-dose chemotherapy drugs) and systemic radiotherapy. These issues ultimately result in development of VOD three to four weeks after transplantation. This complication affects about 10% of patients who undergo allogeneic transplantation, and progression to severe disease with multiple organ failure is associated with a poor prognosis (with a mortality rate of over 80%). NS-73 is a single-stranded DNA purified from the intestinal mucosa of pigs. It is believed to be effective against VOD due to its protective effect on vascular endothelium and the coagulation-fibrinolysis system. It is the only drug recommended for VOD in Western guidelines. We anticipate that it will be approved soon in Japan due to the lack of any other available drug for the indication of VOD.

NS-917 for Relapsed/Refractory Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is a disease in which genetic mutations in myeloblasts, immature blood cells that are part of the process of making blood, result in abnormal proliferation. It can cause anemia, fever due to infection, or bleeding, resulting from suppression of normal hematopoiesis. Typical treatment for AML consists of intensive chemotherapy called the "7+3" regimen (treatment with seven days of cytarabine and three days of daunorubicin). However, this treatment is not suitable for elderly patients with relapsed/refractory AML, which has created demand for a drug with excellent safety and efficacy in this patient group. NS-917 is a new drug that kills cancer cells by being incorporated into cancer cell DNA and cleaving its DNA strands. It is also very safe when administered continuously at a low dose and shows promise as a drug for relapsed/refractory AML that is also suitable for elderly patients.

NS-018 for Myelofibrosis

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

NS-87 for Secondary Acute Myeloid Leukemia

Secondary AML is a general term for AML caused by treatment for another disease or AML that has transformed from myelodysplastic syndrome. It affects about 6,000 people in Japan. Like primary AML, it is treated with the "7+3" regimen. However, this regimen is not very effective against secondary AML, and is said to have a poor prognosis. NS-87 is a liposomal formulation engineered with a special technique to ensure it contains the most effective ratio of cytarabine to daunorubicin, and it has properties that cause it to accumulate in bone marrow. In overseas clinical trials in secondary AML, it was demonstrated to be the first treatment in the world to extend survival time beyond the conventional "7+3" regimen. It has already been approved in the U.S. and will hopefully become the first drug for secondary AML in Japan as well.

TOPICS

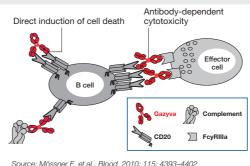
Obtained Manufacture and Marketing Approval for Gazyva (Generic Name: obinutuzumab) for CD20-positive Follicular Lymphoma in July 2018

What is follicular lymphoma?

Malignant lymphoma is classified by characteristics such as the type of lymphocyte that becomes cancerous and its progression speed. Follicular lymphoma (FL), a kind of indolent malignant lymphoma that affects B cells, has been increasing in prevalence in Japan in recent years. It manifests as lumps in lymph nodes in areas such as the neck, armpit, and groin that gradually increase in size over a period of several months. Once the disease spreads across the body, general symptoms such as fever, weight loss, and night sweats appear as well.

Treatment for FL is determined by disease presentation. If the lymphoma is localized and progressing slowly, observation without treatment is

Effect of Gazyva on B cells



selected or radiotherapy is performed. If the disease is progressing and the patient's condition is deteriorating, it is treated with the anti-CD20 antibody rituximab alone or in combination with chemotherapy drugs. Even with this treatment, patients may experience repeated relapses and a complete cure is difficult to attain. To address this issue, there is demand for a new treatment that can extend time to relapse or progression.

Features of Gazyva

Gazyva was first developed globally by Roche Pharmaceuticals and in Japan by Chugai Pharmaceutical Co., Ltd. In 2012, Nippon Shinyaku began joint development of the drug with Chugai Pharmaceutical Co., Ltd. in Japan.

Like rituximab, Gazyva works by acting on CD20 antigens expressed on B cells to destroy B cells. Gazyva exerts a potent antibody-dependent cytotoxic effect because of the modified glycan component of the antibody. It shows strong direct apoptotic activity and superior antitumor activity to rituximab. In the GALLIUM trial in indolent non-Hodgkin's lymphoma, Gazyva showed statistically significant extended progression-free survival compared with rituximab when used in combination with chemotherapy drugs. These results indicate that the Gazyva drug has the potential to become a standard treatment for FL.

A Doctor's Comments

A hematologist and a pharmaceutical company taking on the challenges of blood cancers

At the time I had graduated medical school and was doing my residency, the only treatment available for blood cancers such as leukemia was chemotherapy drugs. One of the patients with acute leukemia in my care, a young woman, suddenly died of cerebral hemorrhage the day after treatment with chemotherapy drugs, and that was a huge shock to me. It was at that point that I decided to pursue hematology to defeat leukemia, and now it has been almost 40 years. During that time, many new molecular targeted therapies tailored to each disease type have been developed as the molecular pathology of blood cancers is uncovered. There have also been advances in supportive care to address complications, and both these developments have greatly improved treatment outcomes for blood cancers. Blood cancers are by no means common, and Nippon Shinyaku is one of the few pharmaceutical companies targeting blood cancers for new drug development. Unlike with solid cancers, there is no surgical option for blood cancers and development of excellent drugs is essential. I feel that seeing academic researchers and companies working side-by-side to defeat incredibly challenging blood cancers gives great hope to patients fighting these diseases and their families.



Masahiro Kizaki
University Vice President and
Graduate School Director,
Saitama Medical University
Professor,
Department of Hematology,
Saitama Medical Center

To Enhance Corporate Value

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 improve our development pipeline by overviewing the state of in-house drug discovery, and by carrying out in-licensing and PLCM.

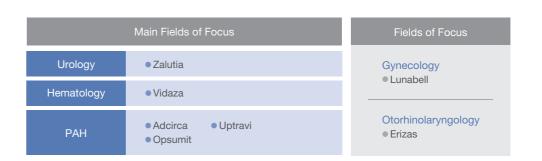


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Pharmaceuticals (Sales)

Bolstering three product suites to be growth drivers

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



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Pharmaceuticals (Production)

Stable product supply and improving productivity

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

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

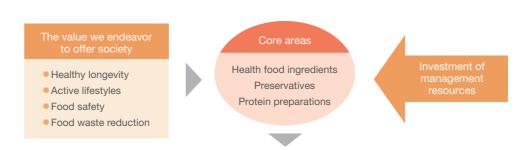


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Functional Food

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.



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

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Pharmaceuticals R&D

We make effective use of both internal and external resources to provide patients with our unique medications even just one day earlier.

Situation in FY2017

Continuing developmental progress in our main fields of focus

Chugai Pharmaceutical Co., Ltd., with whom we have collaborated on the development of GA101 (product name: Gazyva, generic name: obinutuzumab, see page 20), an anti-CD20 monoclonal antibody for CD20-positive follicular lymphoma, applied for domestic manufacturing and marketing approval in August 2017, which was granted in July 2018. We are now working to offer Gazyva as a new treatment option to patients and medical practitioners without delay.

NS-73, a therapeutic agent for hepatic veno-occlusive disease after hematopoietic stem-cell transplantation, became listed as a "drug with high medical need" in August 2017 by the Study Group on Unapproved and Off-label Drugs of High Medical Need. We are currently preparing an application to gain approval for its manufacturing and marketing.

For an additional indication of Uptravi, a Phase III trial for chronic thromboembolic pulmonary hypertension is underway with Actelion Pharmaceuticals Japan Ltd. for NS-304 (generic name: selexipag), a product launched in 2016 for pulmonary arterial hypertension. In addition to a late Phase II clinical trial covering arteriosclerosis obliterans that we are conducting independently, in February 2018 we also started an early Phase II study targeting lumbar spinal stenosis.

We are progressing with an early Phase II trial that began in July 2017 for NS-580, an endometriosis treatment that is expected to yield an analgesic effect and lesion improvement effect by blocking the

production of PGE2.

We are conducting a Phase I/II trial in Japan and a Phase II trial in the United States for the Duchenne muscular dystrophy treatment NS-065/NCNP-01. In Japan, this treatment has been listed under the Ministry of Health, Labour and Welfare's "Sakigake" Designation System, set up to accelerate the time to market for innovative drug candidates. In the United States, the FDA has given it fast track designation, orphan drug designation, and rare pediatric disease designation status.

Our Future Growth Strategy

Answering medical needs by strengthening our lineup in the field of blood cancer drugs

Nippon Shinyaku released NS-17 (product name: Vidaza, generic name: azacitidine) in 2011 as a remedy for myelodysplastic syndrome. A Phase II trial began in Japan in January 2018 to assess its efficacy in the treatment of acute myeloid leukemia. Other drugs being prepared for development in Japan are: NS-917 for the treatment of relapsed/refractory acute myeloid leukemia, and NS-87 for the treatment of secondary acute myeloid leukemia. In addition, we are preparing the next clinical trial in the United States for the myelofibrosis therapy NS-018. By adding these therapeutic agents to our product lineup, we are responding to medical needs in the area of blood cancer, through which we wish to do even more to help in the treatment of patients with these conditions.



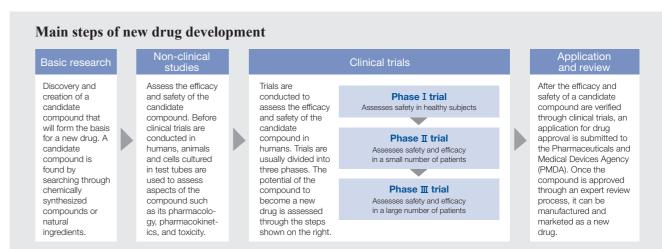
Pipeline

JapanAs of July 2, 2018

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase I	Phase II	Phase Ⅲ	Preparation for NDA	NDA filing	Prepara for launc
GA101 (Obinutuzumab)	Preparation for launching	Hematologic malignancies	CD20-positive follicular lymphoma	Licensed-in from: Chugai Pharmaceutical Co., Ltd.	Co-development: Chugai Pharmaceutical Co., Ltd.						
NS-73	Preparation for NDA	Hematologic malignancies	Veno-occlusive disease (treatment)	Licensed-in from: Jazz Pharmaceuticals PLC	Nippon Shinyaku						
(Defibrotide)	РШ	Hematologic malignancies	Veno-occlusive disease (prevention)	Licensed-in from: Jazz Pharmaceuticals PLC	Co-development: Jazz Pharmaceuticals PLC						
	PⅢ	Intractable disease-orphan disease	Chronic thromboembolic pulmonary hypertension	Nippon Shinyaku	Co-development: Actelion Pharmaceuticals Japan Ltd.						
NS-304 (Selexipag)	PΙΙ	Cardiovascular	Arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku						
	PΙΙ	Orthopedics	Lumbar spinal stenosis	Nippon Shinyaku	Nippon Shinyaku						
NS-580	PΙΙ	Gynecology	Endometriosis	Nippon Shinyaku	Nippon Shinyaku						
NS-17 (Azacitidine)	PΙΙ	Hematologic malignancies	Acute myeloid leukemia	Licensed-in from: Celgene Corporation	Nippon Shinyaku						
NS-065/ NCNP-01	PI/II	Intractable disease-orphan disease	Duchenne muscular dystrophy	Co-development: NCNP*	Nippon Shinyaku						
NS-32	PI	Gynecology	Iron deficiency anemia	Licensed-in from: Pharmacosmos A/S	Nippon Shinyaku						
NS-917	Preparation for development	Hematologic malignancies	Relapsed/refractory acute myeloid leukemia	Licensed-in from: Delta-Fly Pharma, Inc.	Nippon Shinyaku						
NS-87	Preparation for development	Hematologic malignancies	Secondary acute myeloid leukemia	Licensed-in from: Jazz Pharmaceuticals PLC	Nippon Shinyaku						

Overseas

Code No. (generic name)	Development phase	Therapeutic field	Indications	Origin	Development	Phase I	Phase II	Phase	Preparation for NDA	Preparation for launching
NM441 (Prulifloxacin)	NDA filing	Anti-infection	Bacterial infections	Nippon Shinyaku	Licensed-out to: Lee's Pharmaceutical Holdings Ltd.					
NS-065/ NCNP-01	PΙΙ	Intractable disease-orphan disease	Duchenne muscular dystrophy	Co-development: NCNP	Nippon Shinyaku					
NS-018	PI/II	Hematologic malignancies	Myelofibrosis	Nippon Shinyaku	Nippon Shinyaku					



Pharmaceuticals Sales

Becoming a trusted partner in medical treatment by providing timely, accurate information

Situation in FY2017

New product lines in our main fields of focus are all doing well

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

Zalutia, a PDE5 inhibitor, offers a novel mechanism of action. In April 2017, The Japanese Urological Association issued a new clinical guideline for male lower urinary tract symptoms and benign prostatic hypertrophy. Since its positioning as a first-line therapy, Zalutia has permeated the benign prostatic hypertrophy market and sales of Zalutia have risen to over 10 billion yen.

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 exceeding initial estimates.

In the PAH field, Nippon Shinyaku is the only company in the world to offer oral preparations with three different action mechanisms—Adcirca, Opsumit, and Uptravi. By providing accurate information on these three agents to medical specialists, we propose optimal solutions to medical professionals, making an important contribution to PAH treatment.

Our Future Growth Strategy

Improving the quality of MR activities and focusing on local area marketing

Our Sales and Marketing Division has created an internal culture that emphasizes ongoing learning, raising academic levels within the division. We have also established a Marketing & Development Department for each of our three main fields of focus to more systematically provide high-quality information to medical professionals. Starting in fiscal 2018, in order to improve the quality of each and every meeting between medical professionals and medical representatives (MRs), all MRs are being encouraged to ascertain the true needs of medical personnel and to acquire the skills to satisfy those needs, which involves thinking for themselves and working to improve their academic knowledge.

Meanwhile, the government has put in place a system that encourages collaboration in healthcare between companies and medical providers in local communities, which increases the importance of local area marketing. We thus restructured our sales organization, subdividing it into 43 business branches and 115 sales teams across the country. Based on a top-down strategy from head office, we set up a system that will allow us to formulate and execute strategy in a way that matches needs in each locality. In addition, to build strong teams and strengthen communication within them, we began using the LINE WORKS application, a communications tool through which we are working to share information promptly.



Activity Highlights

Supplying Information to Medical Practitioners and Patients

System for Supplying Information to Medical Practitioners

Nippon Shinyaku introduced an in-house qualification system in fiscal 2013 to improve the quality of information provision. All personnel in the Sales and Marketing Division took the test and became qualified according to their level of knowledge—Basic, Advanced, and Specialist. By encouraging each MR to acquire a higher level of expertise, the qualification system helps to produce qualified MRs worthy of partnering with medical practitioners.

In addition, to carry out information-supplying activities that match community needs, we established a Key Account Management Department in fiscal 2017 to build a foundation for local area marketing, and will continue working to provide information that meets the particular needs of each community.

Providing Product Information

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

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

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

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

Educating Patients through Websites and Smartphone Applications

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

On our "Pulmonary Hypertension Treatment Support" website (Japanese only; http://pah-support.jp/), we provide information to deepen understanding of the rare PAH disease and how it is treated, along with explanations of medical expenses and systems.

Our Japanese-language website for men concerned about urinary problems (https://otoko-jishin.com/) explains the causes of urinary trouble and provides a simple check sheet that can be used for actual hospital visits. These sites can be accessed by computer, smartphone, or tablet computer.

Examples of Websites Used to Educate Patients

"Talking about Menstrual Cramps

(Japanese only; http://seiritsu.jp/)

We provide information to patients concerned about menstrual cramps.

"Support Site for Alcohol Dependence"

(Japanese only; http://alcoholic-navi.jp/)
We provide information on alcohol dependence and abstinence success stories.

"FD Care Support"

(Japanese only; http://www.ed-care-support.jp/)

A website which introduces medical institutions where individuals can receive consultation on erectile dysfunction and dispel misunderstandings about the condition to relieve any psychological resistance to seeking out help.

We also offer smartphone apps—"Lunabell Diary" and "PAH Care Notebook"—that patients can use to track their medication, record symptoms, and communicate with medical professionals. We want people to use these apps to facilitate their communication with medical professionals.





"Zalutia Product Information" website

"PAH Care Notebook' smartphone application

Measures Against Counterfeit Drugs

Nippon Shinyaku recognizes that raising awareness of counterfeit medications is one important way to ensure patient safety. To combat the counterfeiting of ED medicines, we are partnering with three companies involved in the manufacture and distribution of ED treatments to jointly hold press seminars for media-related parties, and are working to raise awareness of the issue through exhibits about counterfeit drugs at academic society meetings.

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

Pharmaceuticals Production

Steadily supplying high-quality pharmaceuticals that people need

Situation in FY2017

Reducing manufacturing costs and raising productivity

As a result of the Japanese government putting in place a policy to promote generic medicines, the production volume of long-listed products has been declining at the Odawara Central Factory. Although the overall decline in production has led to rising manufacturing costs, the introduction of a qualification certification system at the factory is helping to cross-train workers, and we are able to carry out manufacturing with fewer capable workers. This, combined with production streamlining and 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 all employees working in the Resource Procurement, Production & Assurance Division. To lower distribution costs, we reviewed supply methods from subcontractors to our Logistic Centers, which has brought cost reductions in warehousing and shipping between eastern and western Japan.

Utilizing our technical capabilities as a manufacturer of new drugs to expand contract production

At the Odawara Central Factory, making use of a dormant injection packaging line and taking advantage

of our developmental capabilities in the formulation of new drugs, in fiscal 2017 we took on contracts to manufacture thirteen products for seven companies. All of the contracting companies gave Nippon Shinyaku high ratings for both technological capabilities and product quality. We are thus able to utilize specialized facilities and a developmental capability that other contract manufacturers do not possess. We also plan to further expand these efforts with the cooperation of departments outside of Resource Procurement, Production & Assurance Division.

Our Future Growth Strategy

Increasing production capacity to meet anticipated growth in demand

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.



Activity Highlights

Quality Assurance and Supply Stability

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

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

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

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

Pharmaceutical Products Reliability Assurance

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

Post-manufacture and marketing							
		Maintenance and management of approval and authorization					
Post-manufacture, post-marketing quality assurance based on GMP and GQP	Post-manufacture and marketing safety management based on GVP	Maintenance and management of manufacture and marketing approval and marketing authorization, etc.					

Pharmaceutical Risk Management

We carry out risk management in accordance with a pharmaceutical risk management plan (RMP)*1. The RMP is created with the purpose of maintaining the safety of post-market drugs by evaluating the benefits and risks through all periods from the development phase to post-marketing; we carry out necessary safety measures based on the results. The RMP is open to the public, and information is shared with medical practitioners and patients to implement improved post-market safety measures. At present, Nippon Shinyaku has created RMPs for the tramadol formulations Tramal OD and Onetram, as well as Uptravi. This information is made public on the websites of both the Pharmaceuticals and Medical Devices Agency (PMDA) and Nippon Shinyaku.

*1 Risk Management Plan: A document that defines critical risks with post-marketed pharmaceuticals and outlines the efforts made by the company to reduce those risks

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*2) management method and are establishing strategy from a many-sided perspective that incorporates financials, customers, business processes, human resources, innovation, and more. We set KPls*3 to manage our progress toward achievement of this strategy and vision. Our distribution framework is configured not only to help maintain quality, for instance through temperature control during transit and storage, but also incorporates ideas such as use of multiple storage sites to minimize loss risks in contingencies such as disasters.

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

Framework for Supplying Products

We implement a framework to secure the rapid and stable supply of high-quality pharmaceuticals through the use of sophisticated supply chain management (SCM), covering production and quality control through to logistics management.

Our diverse initiatives in this area include efforts to reduce lead times by enhancing the efficiency of our overall production process including quality control processes, and regularly evaluating our suppliers to encourage improvement.

Framework for Supplying Products

SCM Supply Chain Management

Sourcing and
Purchasing Departmen
Manufacturing
Planning Department
Odawara Central Factor
Logistic Control
Department

Regulatory Affairs Supervision and Assurance Division



Functional Food

Developing and supplying original, high-added-value ingredients to support a healthy, varied food life

Situation in FY2017

Selecting and focusing on high-added-value product lines

With the aging of society and recent health-conscious trends, people are becoming more interested in health and there is strong demand in the health food market. In 2017 the Japanese government revised its labeling system for foods with function claims, driving a steady increase in new products and the expansion of the health food market. In this climate we are concentrating on sales of high-value products in the fields of health food ingredients, preservatives, protein preparations, and end product business that directly delivers value to consumers.

In the end product business that we began in 2016, we have steadily expanded our lineup, including the WINZONE ENERGY × ENERGY supplement, and are establishing a new presence in the mail-order market. Looking ahead, we intend to expand our marketing activities and give our brands greater exposure in the

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

In the field of preservatives, we are strengthening our

efforts for ready-made meals sold at convenience stores and supermarkets (bento box lunches and prepared foods, and processed foods for commercial use) with a focus on our Mikaku Fine series, which extends shelf life with minimal impact on flavor.

In the field of protein preparations, we aim to become the most important protein product manufacturer for the processed food and nutrition markets, utilizing our strength in research to supply a wide range of items and develop unique, high-added-value products.

Our Future Growth Strategy

Positioning end products as a driver of growth and raising profitability

Our mission is to contribute to people's healthy longevity and active living through food. We plan to build on a solid foundation established over many years by positioning end products developed for direct sales to consumers as a growth driver. This will transform our functional food business into a more highly profitable business.

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.



Nippon Shinyaku and **ESG** Initiatives

While Nippon Shinyaku, through its business activities, provides customers with high-quality pharmaceuticals, it also considers itself a member of society and the regions in which it operates, and is aware of its responsibilities to contribute to their development. By promoting initiatives for ESG (Environment, Society and Governance) issues, we contribute to the achievement of SDGs (Sustainable Development Goals) and aim to make a broader contribution to society.



Our Basic CSR Policies can be found on our website, at: http://www.nippon-shinyaku.co.jp/english/csr/

Business Activities

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





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 global environment. Based on the Nippon Shinyaku Basic Environmental Policy, we are working to further reduce our impact on the environment

Related SDGs







As a corporate citizen, we are working to contribute to the development of society and communities. We believe that through the growth of an individual, the company as a whole also grows, which is why we endeavor to provide a business environment where everyone can feel comfortable and where every single employee has the opportunity to grow and develop.









Jovernance

At Nippon Shinvaku we recognize that it is a critical management priority to be transparent and accountable to all stakeholders. 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.

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Governance

Governance

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 operates with a Board of Auditors, comprised of 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

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. Under the Corporate Governance Report released in November 2017, we carry out "Disclosure Based on the Principles of the Corporate Governance Code" and currently disclose "Reasons for Non-compliance with the Principles of the Corporate Governance Code".

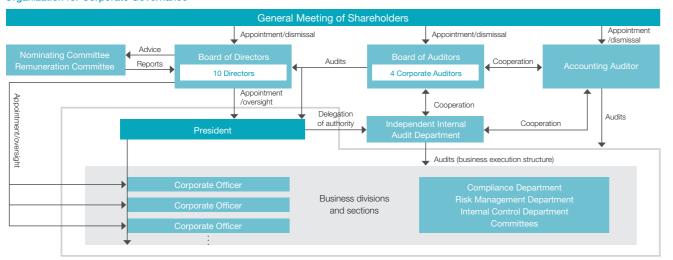
Internal Control System

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

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

The Internal Audit Department examines the processes behind risk management, control and governance of the entire group and assesses their effectiveness. Information about their results is then shared with the Board of Auditors and the accounting auditor.

Organization for Corporate Governance



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

Message from External Directors

Develop Innovative Pharmaceuticals, Strengthen Management, and Improve Profitability

Fundamental reforms the Japanese government has made to the NHI drug price system and its push for the use of generic drugs in recent years have created tough conditions for new drug manufacturers. Efforts to achieve sustainable universal health coverage while promoting innovation are important, but concerns over the hollowing out of the pharmaceutical industry in Japan are being raised due to the deceleration of growth in long-listed products and acceleration of overseas expansion. In such circumstances, it becomes ever more important to sustainably discover and develop products in-house and set up a new generation of product pipelines. I plan to use my specialized knowledge and expertise as a pharmacologist to help develop innovative pharmaceuticals and strengthen management associated with those efforts. I also aim to concentrate on improving profitability. Other areas I plan to focus on include enhancing corporate governance and cultivating human resources for managing drug discovery and individuals with an open mind needed to lead the organization into the future.



Yukio Sugiura

Directors Should Take a More Broad-Minded Approach to Important Issues



Hitoshi Sakata

Nippon Shinyaku will celebrate its 100th anniversary in 2019. Everyone in the company needs to be working together toward the goals of developing new drugs and transforming ourselves into a global company, both of which will be vital to sustaining growth in the future. The role of the outside director is to focus on improving corporate governance so that these efforts can have the maximum effect. We must help create an environment that enables executives to make decisions in a rational and transparent way.

In fiscal 2017, individual directors initiated topics that led to vibrant discussions and better evaluations by the Board of Directors. This fiscal year, building upon this open atmosphere, I feel that the directors must take a more broad-minded approach to important issues. This will surely lead to improved corporate value for Nippon Shinyaku.

Active Discussions by Board of Directors Open to Varied Questions and Opinions

In recent years, significant changes have been taking place in the business environment for pharmaceutical companies, such as fundamental reform to NHI drug price revisions. Nippon Shinyaku has been responding by developing new drugs, expanding globally, and implementing innovative workplace reforms. To help further this development, as an outside director I aim to provide multilateral, diverse views, thereby helping to stimulate and calibrate corporate activities.

The Board of Directors has been open to questions and opinions coming from a variety of perspectives, and has actively engaged in discussions, so it has deemed to have performed its role effectively. In the past year, I personally joined preliminary briefings of the Board of Directors, as well as training seminars held on suitable current topics and other meetings, through which I gained a deeper understanding of the business. So, this year I will continue to study more and will work hard to help Nippon Shinyaku achieve further progress.



Governance

Board of Directors. Corporate Officers and Corporate Auditors



Shigenobu Maekawa

President

- 1976 Joined Nippon Shinyaku Co., Ltd.
- 1992 Temporarily transferred to Japan Federation of Employers' Associations
- 2002 Department Manager, Corporate Planning Dept., Corporate Strategy Office
- 2004 Corporate Officer
- 2005 Director
- 2005 General Manager, Corporate Planning, Finance & Accounting, and Information System; Department Manager, Corporate Planning Dept.
- 2006 Managing Director
- 2007 General Manager, Corporate Planning, Finance & Accounting, and Information Syste
- 2007 President (current position)

Attendance at board meetings (FY2017): 13/13



Takashi Takaya

Director General Manager, Administration

- 1984 Joined Nippon Shinyaku Co., Ltd.
- 2005 Department Manager, Marketing Dept., Sales and Marketing
- 2009 Department Manager, Marketing Dept., Sales and Marketing Planning Div., Sales and Marketing 2010 Department Manager, Marketing and Planning
- Dept., Sales and Marketing Planning Div., Sales and Marketing
- 2011 Head of Sales and Marketing Planning Div., Sales and Marketing
 2012 Corporate Officer; Head of Sales and Marketing
- Planning Div., Sales and Marketing
- 2018 Director (current position)
- 2018 General Manager, Administration (current position)



Tomoyuki Oota

Standing Corporate Auditor

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

Attendance at board meetings (FY2017): 13/13



Akira Matsuura

Managing Director

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

Attendance at board meetings (FY2017): 13/13



Takanori Edamitsu

General Manager, Business Management

- 1989 Joined Nippon Shinyaku Co., Ltd.
- 2011 Department Manager, Corporate Planning Dept.
- 2013 Corporate Officer; Department Manager, Corporate Planning Dept.
- 2018 Director (current position)
- 2018 General Manager, Business Management (current



Hideya Mukai

Standing Corporate Auditor

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

Attendance at board meetings (FY2017): 13/13



Hitoshi Saito

Director

General Manager, Resource Procurement, Production & Assurance

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

Attendance at board meetings (FY2017): 13/13



Yukio Sugiura

External Director

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

Attendance at board meetings (FY2017): 13/13



Kazuhiro Imai

Outside Auditor

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

Attendance at board meetings (FY2017): 12/13

Osaka Regional Taxation Bureau



Kenro Kobayashi

Director General Manager, Functional Food

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

Attendance at board meetings (FY2017): 13/13



Hitoshi Sakata

External Director

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

Attendance at board meetings (FY2017): 13/13



Tsuyoshi Kondo

Outside Auditor

- 1993 Completed legal training at The Legal Training and
- Research Institute of Japan 1993 Qualified as a lawyer
- 1993 Worked for Kondo Chiaki & Tsuyoshi Law Office
- 2001 President of Kondo Law Office (current position) 2003 Registered as a patent attorney
- 2010 Specially appointed professor, Graduate School of
- Law. Kansai University (current position)
- 2016 Company Auditor (current position) 2018 Outside Director, Senshu Electric Co., Ltd. (current
- Attendance at board meetings (FY2017): 13/13



Shouzou Sano

Director

General Manager, Sales and Marketing

- 1984 Joined Nippon Shinyaku Co., Ltd.
- 2008 Department Manager, Saitama Business Office. Sales and Marketing
- 2010 Corporate Officer: Department Manager, Osaka Business Office, Sales Promotion Div., Sales and Marketing
- 2013 Corporate Officer; Head of Tokyo Area Div., Sales
- and Marketing

 2015 Corporate Officer; Head of Sales and Marketing
- 2015 Director (current position)
- 2015 General Manager, Sales and Marketing; Head of Sales and Marketing (current position)

Attendance at board meetings (FY2017): 13/13



Miyuki Sakurai

External Director

- 1992 Completed legal training at The Legal Training and
- Research Institute of Japan

 1992 Registered with Osaka Bar Association

2017 Director (current position)

- 1992 Joined Nishimura Law and Accounting Office 2003 Joint Owner, Hanamizuki Law Office (current
- position) 2015 Auditor, Nippon Life Inst. Foundation (current
- position)
 2016 Auditor, Osaka University (current position)

Attendance at board meetings (FY2017): 10/11

Corporate Officers Taro Sakurai Department Manager, Finance & Accounting Dep

Hiromu Nakajima Chief Medical Officer

Head of Medical Supervisory Div. Yuji Kamiyoshi

Department Manager, Discovery Research Labs., R&D Department Manager, Nagoya Business Office, Sales and Marketing

Hisashi Suehara Hitoshi Ishizawa

Supervision and Assurance Div. Koji Honma Hayato Wada

Hideki Sasaki Department Manager, Odawara Central Factory

Current as of June 29, 2018

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Hirokata Harada Kazuya Mori

Head of R&D Administration Div., R&D Kazuchika Takagaki

Department Manager, Osaka Business Office, Sales and Marketing Head of Regulatory Affairs

Department Manager, Tokyo Business Office, Sales and Marketing Department Manager Personnel Dept.

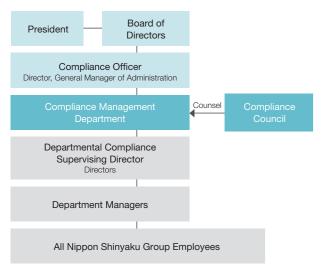
The Basis of Value Creation Governance

Compliance

Framework for Compliance

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

Compliance Framework Chart



Compliance Initiatives

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

In April and October of 2017, the President and the compliance

officer announced an appeal for the strengthening of compliance implementation and the establishment of a corporate culture where no compliance breach would be ignored or condoned. Alongside this announcement we implemented the training and education activities outlined below throughout the year.

Compliance Training in Fiscal 2017

Type of Training	Description
Departmental compliance training (monthly)	Departmental training incorporating company-wide content and department-specific content.
Training for new employees (April)	Training that focuses on teaching new employees about compliance concepts and approaches, and stressing the importance of compliance.
Training for newly promoted managers (March, October)	Training that focuses on teaching compliance to newly promoted managers.
Enhanced Training (October–November)	Departmental compliance training in October followed-up by supplemental training through e-learning in November; the theme for fiscal 2017 was "Harassment Prevention: Power Harassment."
Training on the Charter of Business Conduct for new employees (as and when required)	Enhancing understanding of and compliance with the Charter of Business Conduct.

Education Initiatives

- Conducted e-learning education for compliance for employees in their second year of employment.
- Prepared compliance education posters with slogans that were selected as winners in an internal competition, and put up posters in each department.
- Created compliance cards combined with safety contact cards and distributed these to new employees among others.

Employee Hotline for Compliance Reporting

We operate an employee hotline for compliance reporting, so that any employee of Nippon Shinyaku or group companies can report on or discuss regulatory violations or other compliance issues, as a means of self-policing. We have set up hotline call centers both within and outside the company and these can be reached through a dedicated phone number or e-mail address, with guidelines in place to protect the privacy of reporting employees and to secure confidentiality.

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

Furthermore, with regard to "Compliance Reporting System" we communicate information on a regular basis in order to further spread awareness throughout our group companies.

Responsible Procurement

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

At Nippon Shinyaku, our policies, including our desire to earn the trust of society at large, are promoted by, and enshrined in, our Responsible Procurement Guidelines.

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.

Web

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

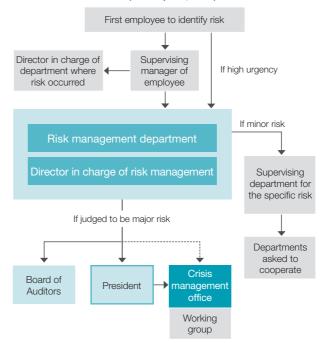
Risk Management

Framework for Risk Management

Nippon Shinyaku Group investigates various risks and departments managing risks formulate preventive policies and methods for responding to them. This is done based on the Basic Risk Management Rules. Additionally, each year we identify highly critical risks. In fiscal 2017, these were "cyber-attacks," "information leakage," "disasters," "harassment," and "breaches of labor laws", 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 an incident does occur, the director in charge of risk management receives a report from the risk management department, and then determines the effect the incident will exert on business operations. If the effect is considered minor, the department assigned to handle such an incident will be directed to respond. If, on the other hand, it is deemed that the incident will have a serious effect on business operations, the President will be immediately notified, while a temporary crisis management office will be established to respond to the incident in a timely manner.

Path of Risk Notification (as of April 1, 2018)



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 2017 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 the disclosure of information as well as taking out cyber-insurance for all group companies. Furthermore, to counter the troubling recent development of targeted email attacks (ransomware, etc.), we are improving our internal measures through the strengthening of our system, and thorough education and training for all employees. In the future we will continue to strengthen our information security.

Anti-Harassment Action

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

Disaster Countermeasures (Formulating the BCP)

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

Respect for and Protection of Intellectual Property Rights

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

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

Society

Society

Human Resources/Organization

Promoting Work-Life Balance

Our Basic Approach to Work-Life Balance

As part of work-life balance promotion efforts, 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

As a first step in improving the work environment for employees, following our business philosophy of "helping people lead healthier, happier lives," we introduced a flextime system for MR positions in January 2018. Without changing their fixed monthly working hours, we eliminated fixed break times and fixed starting and ending times to the work day. By thus enabling flexible working hours, we aim to increase work productivity and enable working styles that can be adapted to individual lifestyles.

Challenge 100 to Improve Productivity

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

Promoting Diversity

Promoting Women in the Workplace

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

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

In fiscal 2017, we held "Happy Career Seminars" for women who work as production engineers and who aim to be future leaders. With a "hints to make working fun" theme, seminar participants studied work-life balances and how to pursue career development. Female management candidates participated in a seminar sponsored by the Japan Institute for Women's Empowerment & Diversity Management-A 21st-Century Women's Empowerment Tutorial—and were given an opportunity to build an external network as well as personal skills.





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 2017, we held a training course for "work supporters" at the head office to encourage understanding of people with disabilities at departments taking in new workers, and also held workplace tours for people with disabilities. The activities were designed to help create a more open workplace. *A training system that combines corporate internship with education at a special-needs support school





Employees at work

Personnel Training

Basic Approach to 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.

Cultivating Global Talent

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

staff in fiscal 2015 and, from fiscal 2016, held two kinds of English training courses, one for elite employees and one for those who attended of their own accord.



Elite employees undergoing English training

Career Support System: "Developing Each Employee"

Nippon Shinyaku has established a Career Support Academy (CASA) to supply employees with opportunities for development. This system is structured on the twin aspects of level-based education and training, and elite education and training. We revamped our level-based education and training in fiscal 2016 to enable participants to select their own subjects. By making it elective, we sought to align training more closely with each individual's efforts to improve their skills because we believe that encouraging employees to think about their own growth will lead them to consider their career trajectory as a whole. Elite education and training targeting core personnel includes the six-month Next-Generation Leader Development Program. Support is also available for employees seeking to attain higher level degrees such as a doctorate or MBA. Our intention is to upgrade the skills of our employees, as well as to create a challenging and active organizational environment.

Shaping the Work Environment

Occupational Health and Safety

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

We conduct risk assessment and risk prediction activities, and we are practicing the "5S activities" 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. We also consider maintaining employee health by working with the health insurance association to promote activities based on health management.



Mental Healthcare

Nippon Shinyaku introduced an externally developed Employee Assistance Program (EAP) in March 2003, and has been carrying out stress checks once a year for prevention, early detection, and early response to mental illness. With stress checks legally stipulated since December 2015, the EAP is being further utilized to improve the workplace environment.

VOICE

Flextime system enables a good balance between work and child-raising

In October 2017, I returned to work from childcare leave and took on MR duties on shorter work hours. A flextime system was adopted for MR positions in January 2018 so that I could schedule my work around nursery school pickup times, or the physical condition of my child. The new system also made it possible to go home during breaks and take care of household chores, and in other ways use time more effectively than before. Immediately upon my return from childcare leave I felt anxious and wondered whether I could work as I had before, but thanks to this flextime system I was able to adjust the cycles of my workday, and soon the anxiety went away. Sometimes unplanned things happen, like my child suddenly getting sick, but with support from the others on my team, I am able to work and have an enjoyable time doing so.



Ayako Tameike No. 1 GP Team, No. 2 Marketing Office, Osaka Business Office

The Basis of Value Creation Society

Social Contributions

Activities that Benefit Society

Nippon Shinyaku Children's Literary Awards

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

Local children were invited to the awards ceremony held in October 2017, where the picture book *Kotoba Nimpo Onomatope* ("Kotoha the Onomatopoeia Ninja"), the winner of the 9th award, was presented. The Japanese pronunciation comes from the French word for onomatopoeia, "onomatopée," and since many Japanese words that express sounds and actions appear in the book, we conducted a program for children to experience the wonders of sounds in a science show.

Also, upon the recommendation of Kyoto City, which sponsors the Nippon Shinyaku Children's Literary Awards, it was presented with the Minister of State

for Special Missions' Award in the Development and Support for Children and Young People category of the Cabinet Office's Awards for Supporters of Children/Family and Youth.



Previously produced picture bool



The Awards for Supporters of Children/Family and Youth ceremony

Nippon Shinyaku & Seitaro Kuroda Smiles Art Project

We have visited a number of locations throughout Japan for the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project. Led by illustrator Seitaro Kuroda, this project centered on locals banding together to create wall art. We launched the initiative at the Public Ono Town General Hospital in Fukushima Prefecture in March 2013. Since then hospitals and other medical facilities across the

country, like Nagano Children's Hospital or Saitama Children's Medical Center, have had their walls painted.

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



Activity at the Saitama Children's Medical Cente

The Yamashina Botanical Research Institute

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

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

In fiscal 2017, the institute received the Aboc-Culta Award from

the Japan Association of Botanical Gardens for the achievement of popularizing the scientific names of plants. The institute also held four tours in spring and autumn on national holidays, tours for the general public, tours for local elementary school students, summer vacation indigo dyeing workshops, and other events. Last year there were more than 1,700 visitors.



apan Association of Botanical Gardens Tsukasa Iwashina, President (right)

Activities to Preserve and Maintain the Culture of Kyoto

For more than half a century Nippon Shinyaku has annually produced washcloths and calendars with pictures made using *Kataezome*, a traditional stencil dyeing technique unique to Kyoto. These works feature Kyoto's seasonal scenery, customs, and

historical events. Also, four times a year, we publish an independent quarterly magazine called *Kyo*. This publication showcases the profound appeal of Kyoto from a number of perspectives—it carries in-depth articles introducing the wonders of Kyoto, from proud cultural assets like its shrines and temples, to its cuisine and famous local products.





Calendar and the quarterly magazine Kyo

A washcloth featuring a motif of pictures made using Kataezome

Supporting Education through Sports

The Nippon Shinyaku amateur baseball team provides practical coaching guidance to elementary, junior and senior high school students to promote sports in the local community. In November 2017, the Kyoto High School Baseball Federation winter training was held at Wakasa Stadium Kyoto. There we provided coaching for about 300 team members from 73 high school teams in Kyoto Prefecture. In addition, we also held several baseball workshops for elementary and junior high school students to work on their baseball skills.

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



Teaching high school students

Contributing to the Field of Medicine

Educating People About Illnesses

We have hosted public lectures by doctors since 1998. In February 2018, we held a medical symposium on "Urinary Disorders and Lifestyle Diseases" attended by 262 people. The venue was filled and the symposium was a great success. We have been distributing the content of the symposium as

newspaper articles and to medical institutions as materials for patients in the effort to disseminate correct, up-to-date information on such disorders and medicine for treatment.



Public lecti

Promoting Understanding of Rare and Intractable Diseases

To coincide with Rare Disease Day—the last day of February—we held an informal meeting with specialists and university students aiming to become doctors and pharmacists on the

theme of "support for patients with intractable diseases." We are publishing the content as newspaper articles to promote better understanding of intractable diseases.



Informal meeting on support for patients with intractable diseases

VOICE

Wonderful picture books that touch children's hearts

The Nippon Shinyaku Children's Literature Award was established in 2009. Since that time, Nippon Shinyaku Co., Ltd. has sent picture books annually to kindergartens and elementary schools in the city of Kyoto, where the company was founded.

Every time I see an award-winning work, I feel that it has been chosen to stimulate the imagination and rich sensitivity of children from the unique perspective of a company that has a long history of building the future through new medicine. The works also touch the hearts of adults and I look forward to seeing a new picture book every year.

I wish to see children grow up with a kind heart, robust mind, and strong will to fulfill their dreams. I also wish to express my heartfelt gratitude to Nippon Shinyaku for promoting these efforts to support children's healthy development.



Masahide Arita
Superintendent of Education,
Kyoto City Board of Education

The Basis of Value Creation Environment

Environment

Environmental Management

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.

- We will effectively operate an internal organization responsible for environmental issues and establish clear targets for our collective pursuit of environmental conservation initiatives.
- 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.
- 4. We will train and educate all employees to recognize the importance of environmental conservation and act in a responsible manner.
- We will be considerate of biodiversity when pursuing our business activities, and encourage the sustainable development of our society.
- We will proactively publish information about our environmental preservation activities, and communicate with our local communities and other stakeholders.

Environmental Management System

Nippon Shinyaku formulated the Nippon Shinyaku Basic Environmental Policy as the guideline for our environmental conservation activities. The Environment Committee, chaired by Director, General Manager of Administration, was established to put this policy into practice and determines the direction and targets of our environmental preservation activities.

Environmental Management Structure



Putting Environmental Management System Certification into Action

At our Odawara Central Factory production site, Nippon Shinyaku acquired ISO 14001 for international environmental management in August 2004 as a mechanism for promoting continuous environmental improvements, and is engaged in ongoing environmental management activities. At the head office, our site for research and development, we acquired KES Environmental Management System Standard Step 2 (hereinafter KES Step 2) certification in June 2012 and are engaged in environmental management activities.

In fiscal 2017, periodic audits were conducted at the Odawara Central Factory and renewal audits were carried out at

the head office. No serious problems that would lead to environmental pollution were found, and the certification was continued.

Environmental Accounting

The following is an accounting of the environmental costs and benefits in fiscal 2017.

Environmental conservation costs

(thousands of yen

Environmental concervation coole		(thousands of yen)
Costs	Investments	Expenses
Costs within our business areas	92,492	268,945
Pollution prevention costs	27,015	60,773
Global environmental conservation costs	65,477	116,348
Resource recycling costs	0	91,824
Upstream & downstream costs	0	7,394
Management activity costs	18,125	84,452
R&D costs	0	78
Social activity costs	0	3,674
Environmental remediation costs	0	0
Total	110,617	364,542

(excluding our sales offices)

Environmental conservation benefits

Benefit verification	Units	FY2017 results	Year-on-year change
CO ₂ emissions	Tons	13,314	377
Electricity usage	1,000 kWh	14,949	936
Heavy oil & kerosene usage	kl	3	0
City gas & LPG usage	1,000 m ³	1,622	33
Gasoline & diesel usage	kl	949	-22
Water consumption (main business locations)	1,000 m ³	275	9
Waste substances generated (main business locations)	Tons	508	84
Final amount of landfilled waste (main business locations)	Tons	2.0	-0.7

● The 5th Nippon Shinyaku Environmental Targets Plan (FY2017–2019)

The Nippon Shinyaku Environmental Targets Plan sets specific voluntary targets for the company to carry out its Basic Environmental Policy. The 5th Nippon Shinyaku Environmental Targets Plan, a three-year plan that began in April 2017, adds to

previous targets a new set of numerical targets—basic units for CO₂ emissions and volume of waste generated, and for the waste recycling rate.

The 5th Nippon Sh	ninyaku Environmental Targets Plan*1	Numerical Targets	Results in FY2017	Progress Toward Numerical Targets
Promotion of Energy Conservation	Reduce total energy consumption (GJ) in FY2019 to below FY1990 levels.	230,432 GJ or less	Total energy consumption: 209,480 GJ → 9% reduction from FY1990 level	Reached
and Global Warming Countermeasures	Reduce the CO ₂ emissions*2 basic unit*3 by about 40% from the FY1990 level by FY2019.	0.13 or less	Basic unit of CO₂ emissions: 0.10 → 53% improvement from FY1990 level	Reached
	Reduce the final amount of landfilled waste by about 70% from the FY2005 level by FY2019.	4.38 tons or less	Final amount of landfilled waste: 2.0 tons → 86% reduction from FY2005 level	Reached
Saving Resources,	Reduce the basic unit of waste generated*4 by about 50% from the FY2005 level by FY2019.	0.53 or less	Basic unit of waste generated: 0.50 → 52% reduction from FY2005 level	Reached
Reducing Waste and Promoting the 3Rs	Keep the waste recycling rate at 55% or more by FY2019.	55% or more	Waste recycling rate: 55%	Reached
	Promote green purchasing and procurement practices.	_	We added a function to the in-house purchasing system that allows us to look up whether or not products are labelled "Green Products" when placing orders, making it easier to implement green purchasing.	_
Promote Proper Management of Chemical Substances	Promote the proper management of chemical substances, including those stipulated under the Pollutant Release and Transfer Register (PRTR) system, and continuously reduce their emission into the natural environment.	_	The amounts of acetonitrile and n-hexane used decreased by 3.5% and 2.3%, respectively, compared with FY2016. Dichloromethane use increased by about 40%.	_
Promote an Environmental Management System (EMS)	Effectively improve the results of our environmental performance by maintaining certifications for environmental management systems (ISO 14001 and KES*5).	_	Environmental management system certification was carried forward. • Odawara Central Factory: ISO 14001 • Head Office: KES Step 2	_
	Appropriately disclose information to society and to the local areas of our business offices.	_	Information is disclosed on the Nippon Shinyaku website and in Nippon Shinyaku reports.	_
Communication with Society and Local Neighbors	Actively participate in activities to give back to the areas where we do business.	_	Cleanup activities, school workshops, research laboratory tours, charitable donations, etc.	_
	Promote activities related to biodiversity that benefit society.	_	Ongoing cultivation of endangered plants	_

^{*1} Progress toward numerical targets is evaluated on the basis of the sum total from the head office, Odawara Central Factory and Discovery Research Laboratories in Tsukuba

^{*2} Calculated using the actual CO₂ emission factor from the Ministry of Economy, Trade and Industry

^{*3} Value of CO₂ emissions (tons) divided by unit sales (100 million yen)
*4 Value of waste generated (tons) divided by unit sales (100 million yen)

^{*5} Abbreviation for Kyoto Environmental management system Standard, originating in Kyoto

The Basis of Value Creation Environment

Details on environmental data are on our website (Japanese only). ▶ http://www.nippon-shinyaku.co.jp/csr/environment_manage.html

Environmental Performance

Promotion of Energy Conservation and Global Warming Countermeasures

Nippon Shinyaku has established guidelines for saving electricity and energy to promote power savings among all employees. The guidelines cover, for example, appropriate indoor temperature settings, turning off unnecessary lighting, and recommending the use of stairs. Starting in April 2018, a "year-round no-necktie" policy*1 is being implemented to further promote energy conservation.

On the facility side, a plan to promote more efficient use of electricity is being implemented through the systematic upgrading of and cleaning of large-scale air conditioning equipment by professional contractors. In lighting equipment, we have been sequentially replacing existing light bulbs with LEDs at major offices since fiscal 2016. In the head office area, we were able to reduce power consumption in lighting by about 4%.

As a result of these efforts, we achieved our targets for total energy consumption and CO_2 emissions basic unit in fiscal 2017. In comparison to fiscal 2016, energy usage increased by 5.4% and CO_2 emissions increased by 4.4% at major offices, but this was due to a study being conducted to prepare for

industrialization in the new building at the Odawara Central Factory, completed in July 2017, which was factored into planned business activities.

*1 We do not set seasonal dress codes such as Cool Biz or Warm Biz, but allow employees to wear a jacket as practical, or a necktie or other wear as desired, to promote a flexible business style throughout the year.

Reducing Volume of Waste

We achieved all three targets in fiscal 2017—final amount of landfilled waste, basic unit of waste generated, and waste recycling rate. Waste generation increased about 20% over fiscal 2016, but this was due to wastewater generated in the planned industrialization study (mentioned above) conducted at the Odawara Central Factory's new building. After full detoxification, the water met environmental standards and was released into the surrounding environment.

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

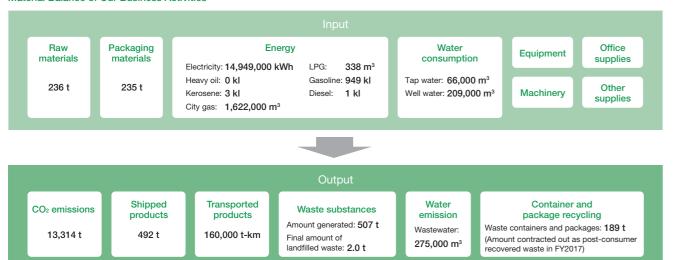
Awarded for Environmental Excellence Based on Kyoto City Global Warming Countermeasure Ordinances

Businesses in the city of Kyoto are obligated by ordinance to formulate a three-year plan with regard to CO_2 emissions control and to report on the status of implementation, the results of which are made public. Nippon Shinyaku's plan, completed in March 2017, received the highest S-class designation (excellent business operator), for which we received an award from the mayor of Kyoto.



Environmental excellence award ceremony

Material Balance of Our Business Activities



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. This applies to acetonitrile and n-hexane for the head office, and dichloromethane for Discovery Research Laboratories in Tsukuba; both were reported appropriately.

The amounts of acetonitrile and n-hexane used decreased by 3.5% and 2.3%, respectively, compared to fiscal 2016, but dichloromethane increased about 40%.

The Odawara Central Factory's new building was completed in July 2017. It has numerous advanced features to ensure maximum safety, quality and environmental protections. These include the prevention of external leakage of highly active substances using containment equipment (primary), containment by airflow and chamber pressure (secondary), and containment by the building (tertiary).

Communication on the Environment

We participate in or cooperate with many types of community environmental activities, and also give environment-related donations and offer school workshops.



School kids enjoy Nippon Shinyaku workshop

Helping Local Clean-up Initiatives

- Head Office: Nishioji Station vicinity clean-up groups
- Odawara Central Factory: "Clean Sakawa" and factory vicinity clean-up activities
- Discovery Research Laboratories in Tsukuba: Clean-up activities run by Tsukuba City

Environment-related Donations

- Proceeds from the sale of metal scraps and recyclable paper are donated to the Nippon Shinyaku Kira-Kira Mirai Kodomo Bokin children's fund
- Recyclable waste with resale value provided to designated consultation support office for disabled children
- Books and DVDs collected for Kanagawa Kintaro Book Donation program
- Plastic bottle caps supplied for vaccine exchange program
- Funds collected using drink vending machines for the Red Feather Fund and Green Fund

School Workshops

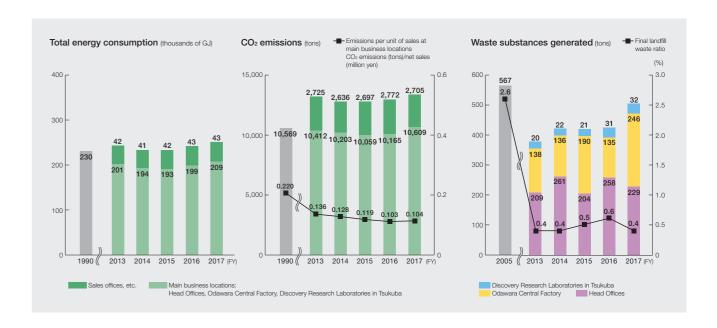
 3 workshops on the Environment and Medicine: Connected by Plants lecture for 4th and 5th graders at Syoho Elementary and other schools

Research Laboratory Tours

 9 lab tours for Ritsumeikan High School, junior high to college students, adults

Contributions to Biodiversity

- Raising Japanese wild ginger (Asarum caulescens) for the Aoi Festival (Kamigamo Shrine)
- Raising Chrysanthemum seticuspe for the Green Water Corridor (Kyoto Station) and Kikutani Forest of Flowering Chrysanthemums (Kyoto City)
- Participation in Rice Paddy Appreciation Association and Sakawa River System Medaka Supporters Association (Odawara City) activities, lending of parking lot



Summaries and Highlights

Summary of Consolidated Financial Indicators

	2013	2014	2015	2016	2017	2017
or the year					Millions of Yen	Thousands of U.S. Dollars
Net sales	76,517	79,991	84,209	98,781	101,448	957,05
Pharmaceuticals	63,345	66,340	70,489	85,315	87,416	824,67
Functional food	13,172	13,651	13,720	13,466	14,031	132,36
Operating income	8,038	8,562	8,549	15,280	17,079	161,12
Net income attributable to owners of the parent	5,750	5,882	6,340	11,749	12,953	122,19
Depreciation and amortization	2,704	2,665	2,452	2,648	2,773	26,16
Capital investment	1,072	1,239	3,554	3,949	2,811	26,51
R&D expenses	9,530	8,968	9,739	14,903	13,221	124,73
ind of the year					Millions of Yen	Thousands U.S. Dollar
Total assets	118,188	129,757	135,370	150,905	158,192	1,492,37
Net assets	93,186	101,207	102,762	114,316	125,689	1,185,74
Financial information per share					Yen	U.S. Dollar
Earnings per share	85.25	87.26	94.10	174.42	192.31	1.8
			28	48	52	0.4

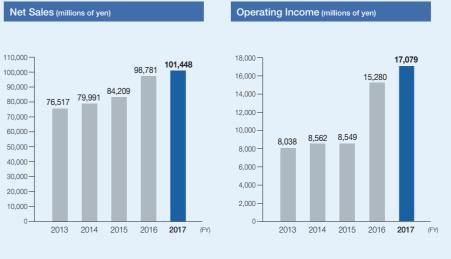
<u></u>					
Ratio of net worth	78.7	77.8	75.8	75.6	

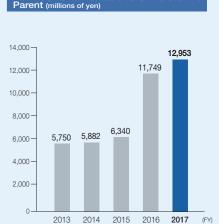
Ratio of net worth	78.7	77.8	75.8	75.6	79.3	-
Return on equity	6.3	6.1	6.2	10.8	10.8	-
Pay-out ratio	27.0	28.7	29.8	27.5	27.0	-

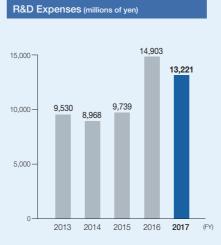
Summary of ESG Indices

·						
Total energy consumption (thousands of GJ)	201	194	193	199	209	-
CO ₂ emissions (t)	10,412	10,203	10,059	10,165	10,609	-
CO ₂ per unit of revenue (t/million yen)	0.136	0.128	0.119	0.103	0.104	-
Number of employees (people)	1,899	1,939	1,950	2,011	2,055	-

Financial Highlights



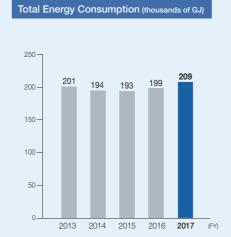


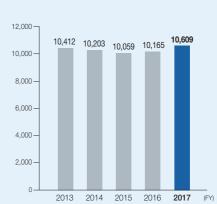




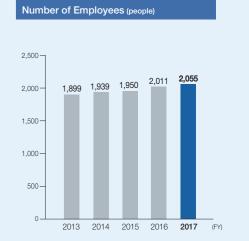


Non-Financial Highlights





CO₂ Emissions (t)



Financial Section

Operating Results

1. Fundamental Policy Regarding Profit Sharing

Under our strategy to maximize corporate value, we strive to bolster R&D to expand our product development pipeline. We also have to consider the balance between investment, in equipment or facilities to allow us to maintain a corporate position that can withstand increasingly competitive conditions, and returns of profit, in order to strengthen our business foundations.

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, 2018 (fiscal 2017), we issued an annual cash dividend of ¥52 per share, comprising an interim dividend of ¥26 per share and year-end dividend of ¥26 per share

For the year ending March 31, 2019, we are projecting an annual dividend of ¥58 per share, comprising an interim dividend of ¥29 per share and year-end dividend of ¥29 per share.

2. Financial Condition

Increases in marketable securities, notes receivable, accounts receivables, inventory assets and others, and a decrease in cash and deposits compared to the previous fiscal year end caused current assets to total ¥97,953 million.

Fixed assets totaled ¥60,238 million due to increases in investment securities, long-term prepaid expenses and tangible fixed assets compared to the previous fiscal year end.

As a result, total assets increased by ¥7,286 million compared to the previous fiscal year end, to ¥158,192 million.

Current liabilities totaled ¥22,454 million due to an increase in notes and accounts payable-trade, and decreases in accrued liabilities and income taxes payable etc. compared to the previous fiscal year end.

Fixed liabilities totaled ¥10,048 million, due to increases in deferred tax liabilities compared to the previous fiscal year end.

As a result, total liabilities decreased by ¥4,085 million compared to the previous fiscal year end, to ¥32,503 million.

Equity increased by ¥9,167 million compared to the previous fiscal year end, to ¥116,234 million. Accumulated other comprehensive income increased by ¥2,194 million to ¥9,216 million

As a result, net assets increased by ¥11,372 million to ¥125,689 million. The equity ratio was 79.3%.

Net cash provided by operating activities amounted to $\pm 6,719$ million. The main cash inflows were income before income taxes of $\pm 17,451$ million, depreciation costs of $\pm 2,773$ million, and an increase in trade notes and trade accounts payable of $\pm 2,407$ million, while the main outflows were income tax, etc. paid of $\pm 6,220$ million and an increase in accounts receivable of $\pm 3,286$ million.

Net cash used in investing activities amounted to ¥11,342 million. The main cash outflows were expenditures for the acquisition of marketable securities of ¥4,420 million, and the acquisition of long-term prepaid expenses of ¥4,004 million.

Net cash used in financing activities amounted to ¥3,787 million, primarily comprising cash payment of dividends and other factors

As a result, cash and cash equivalents as of March 31, 2018 decreased by ¥8,404 million compared to the previous fiscal year end, to ¥27,510 million.

3. Summary of Consolidated Business Results

(1) Pharmaceuticals

In the Pharmaceuticals segment, although no revenue was

recorded for the active pharmaceutical ingredient of Uptravi (a treatment for pulmonary arterial hypertension that was released in Japan in November 2016), payments for which were calculated in the previous fiscal year, there has been growth in our new product suites—such as Zalutia, a drug for urinary disorders caused by benign prostatic hypertrophy, Vidaza, a myelodysplastic syndrome treatment, Tramal and Onetram for cancer pain and chronic pain, and Adcirca for pulmonary arterial hypertension. There has been a rise in income from co-promotion, and growth in domestic sales of Uptravi along with rising royalty income from its overseas sales. These developments led to net sales of ¥87,416 million (a year-on-year increase of 2.5%). Uptravi is also sold overseas by Actelion Pharmaceuticals under the trade name UPTRAVI.

(2) Functional Food

In the Functional Food segment, sales increased in protein preparations, preservatives and health food ingredients. As a result, net sales increased by 4.2% year-on-year to ¥14,031 million.

Business Risks

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

Regulatory Control Risks

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

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

2. R&D Risks

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

3. Side Effect Risks

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

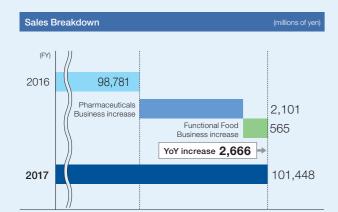
4. Drug Price Revision Risks

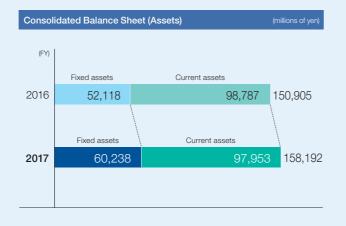
Selling prices of drugs used for medical care are set based on drug price standards under the national health insurance system. Drug price standards are generally revised downward every two years. Depending on extent of the price decrease, it could impact the business results of the Nippon Shinyaku Group.

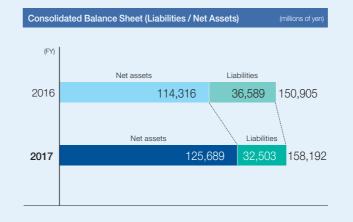
5. Manufacturing and Procurement Risks

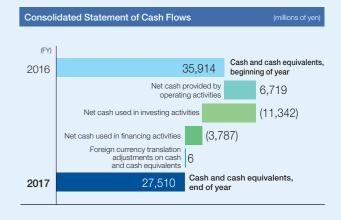
The Nippon Shinyaku Group is improving its production efficiency by concentrating its manufacturing facilities. At the same time, if operations at manufacturing facilities cease due to natural disasters or other circumstances, they could interrupt the supply of products and impact our business results.

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









Consolidated Financial Statements

Consolidated Balance Sheet				
lippon Shinyaku Co., Ltd. and Consolidated Subsidiaries larch 31, 2018	Millions	s of Yen	Thousands of U.S. Dollar (Note 1)	
SSETS	2018	2017	2018	
CURRENT ASSETS:				
Cash and cash equivalents (Note 11)	¥ 27,510	¥ 35,914	\$ 259,528	
Time deposits (Note 11)	957	867	9,028	
Marketable securities (Notes 3 and 11)	4,420	2,657	41,698	
Notes and accounts receivables (Note 11):				
Trade notes	702	556	6,222	
Trade accounts	39,462	36,322	372,283	
Other	225	347	2,122	
Total notes and accounts receivables	40,390	37,226	381,037	
Inventories (Note 4)	20,345	18,577	191,933	
Deferred tax assets (Note 10)	2,777	2,408	26,198	
Other current assets	1,551	1,135	14,632	
Total current assets	97,953	98,787	924,084	
PROPERTY, PLANT AND EQUIPMENT:				
Land	7,463	7,463	70,405	
Buildings and structures	27,178	25,187	256,396	
Machinery, equipment, and vehicles	12,330	10,834	116,320	
Tools, furniture, and fixtures	8,679	8,577	81,877	
Construction in progress	67	2,153	632	
Total	55,718	54,216	525,641	
Accumulated depreciation	(34,616)	(34,173)	(326,566)	
Net property, plant and equipment	21,102	20,043	199,075	
		.,		
INVESTMENTS AND OTHER ASSETS:				
Investment securities (Notes 3 and 11)	26,309	21,681	248,198	
Long-term prepaid expenses	9,621	7,085	90,764	
Deferred tax assets (Note 10)	45	55	424	
Other assets	3,161	3,252	29,820	
Total investments and other assets	39,136	32,074	369,207	
TOTAL	¥ 158,192	¥ 150,905	\$ 1,492,377	
See notes to consolidated financial statements	,		+ -,,	

See notes to consolidated financial statements.

		Million	ns of Yen		T TOGGG	ds of U.S (Note 1)
ABILITIES AND EQUITY	20	18		2017		2018
CURRENT LIABILITIES:						
Notes and accounts payables (Note 11):						
Trade notes	¥	2,016	¥	1,966	\$	19,01
Trade accounts		6,622		4,265		62,47
Other		5,727		9,285		54,028
Total notes and accounts payables	1-	4,367		15,517		135,537
Income taxes payable (Note 11)		2,115		3,892		19,95
Accrued expenses		4,228		3,942		39,880
Deposits from customers		255		263		2,40
Other current liabilities		1,488		3,384		14,03
Total current liabilities	2	2,454		27,001		211,830
LONG-TERM LIABILITIES:						
Liability for retirement benefits (Note 5)		7,422		8,064		70,018
Deferred tax liabilities (Note 10)		2,305		1,121		21,74
Other long-term liabilities		321		401		3,028
Total long-term liabilities	1	0,048		9,587		94,792
EQUITY (Notes 6 and 14):						
Common stock, authorized, 200,000,000 shares;						
issued 70,251,484 shares		5,174		5,174		48,81
Capital surplus		4,445		4,445		41,93
Retained earnings	10	9,078		99,897	1	,029,03
Treasury stock - at cost, 2,896,632 shares in 2018 and						
2,894,408 shares in 2017	(2	2,464)		(2,450)		(23,245
Accumulated other comprehensive income (loss):						
Unrealized gain on available-for-sale securities	1	1,469		9,235		108,19
Deferred loss on derivatives under hedge accounting		(5)		(5)		(47
Foreign currency translation adjustments		4		11		3
Defined retirement benefit plans	(2	2,252)		(2,217)		(21,245
Total	12	5,451		114,089	1	,183,500
Noncontrolling interests		237		226		2,23
Total equity	12	5,689		114,316	1	,185,74

Consolidated Financial Statements

Consolidated Statement of Income					
Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Year Ended March 31, 2018			Thousands of U.S. Dollars		
<u> </u>		s of Yen	(Note 1)		
NET CALED (ALL LAC)	2018	2017	2018		
NET SALES (Note 15)	¥ 101,448	¥ 98,781	\$ 957,056		
COST AND EXPENSES:					
Cost of sales	46,929	44,835	442,726		
Selling, general, and administrative expenses (Notes 7 and 8)	37,439	38,666	353,198		
Total	84,368	83,501	795,924		
Operating income (Note 15)	17,079	15,280	161,122		
OTHER INCOME (EXPENSES):					
Interest and dividend income	486	434	4,584		
Interest expense	(3)	(3)	(28)		
Impairment loss (Note 9)		(766)			
Other – net	(111)	(533)	(1,047)		
Other income – net	371	197	3,500		
INCOME BEFORE INCOME TAXES	17,451	15,477	164,632		
INCOME TAXES (Note 10):					
Current	4,622	4,864	43,603		
Deferred	(140)	(1,152)	(1,320)		
Total income taxes	4,482	3,712	42,283		
NET INCOME	12,969	11,765	122,349		
NET INCOME ATTRIBUTABLE TO NONCONTROLLING INTERESTS	15	15	141		
	V 40.050	V 44 740	A 100 105		
NET INCOME ATTRIBUTABLE TO OWNERS OF THE PARENT	¥ 12,953	¥ 11,749	\$ 122,198		

	Ye	n	U.S. Dollars
PER SHARE OF COMMON STOCK (Notes 2 and 13):			
Basic net income	¥ 192.31	¥ 174.42	\$ 1.81
Cash dividends applicable to the year	52.00	48.00	0.49

See notes to consolidated financial statements.

Consolidated Statement of Comprehensive Income			
Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Year Ended March 31, 2018	Millions	Thousands of U.S. Dollars (Note 1)	
	2018	2017	2018
NET INCOME	¥ 12,969	¥ 11,765	\$122,349
OTHER COMPREHENSIVE INCOME (LOSS) (Note 12):			
Unrealized gain on available-for-sale securities	2,234	143	21,075
Deferred (loss) gain on derivatives under hedge accounting		(3)	
Foreign currency translation adjustments	(6)	(6)	(56)
Defined retirement benefit plans	(34)	1,203	(320)
Total other comprehensive income	2,194	1,337	20,698
COMPREHENSIVE INCOME	¥ 15,163	¥ 13,102	\$143,047
TOTAL COMPREHENSIVE INCOME ATTRIBUTABLE TO:			
Owners of the parent	¥15,147	¥13.087	\$142,896
Noncontrolling interests	¥15,147 15	¥13,067	\$142,090 141
Noncontrolling interests	15	15	141

See notes to consolidated financial statements.

Consolidated Statement of Changes in Equity	
Ninnon Shinyaku Co. Ltd. and Consolidated Subsidiaries	

Nippon Shinyaku Co., Ltd. and Cons Year Ended March 31, 2018

Ye	ar E	nde	ed N	/larc	h 31	, 2	018	d

Year Ended March 31, 2018												
	Thousands						Millions of Yer	1				
						Accum	ulated Other C	omprehensive	Income			
	Outstanding Number of Shares of Common Stock	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available -for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting		Defined Retirement Benefit Plans	Total	Noncontrolling Interests	Total Equity
BALANCE, APRIL 1, 2016	67,363	¥ 5,174	¥ 4,445	¥ 89,658	¥ (2,413)	¥ 9,091	¥ (2)	¥ 17	¥ (3,421)	¥ 102,549	¥ 213	¥ 102,762
Net income attributable to												
owners of the parent				11,749						11,749		11,749
Cash dividends, ¥32.00 per share				(2,155)						(2,155)		(2,155)
Purchase of treasury stock	(6)				(36)					(36)		(36)
Change of scope of consolidation	1			645						645		645
Net change during the year						143	(3)	(6)	1,203	1,337	13	1,351
BALANCE, MARCH 31, 2017	67,357	5,174	4,445	99,897	(2,450)	9,235	(5)	11	(2,217)	114,089	226	114,316
Net income attributable to												
owners of the parent				12,953						12,953		12,953
Cash dividends, ¥56.00 per share				(3,771)						(3,771)		(3,771)
Purchase of treasury stock	(2)				(14)					(14)		(14)
Net change during the year						2,234		(6)	(34)	2,194	11	2,205
BALANCE, MARCH 31, 2018	67,354	¥ 5,174	¥ 4,445	¥ 109,078	¥ (2,464)	¥ 11,469	¥ (5)	¥ 4	¥ (2,252)	¥ 125,451	¥ 237	¥ 125,689

					Thousand	ls of U.S. I	Dollars (Note	1)				
					Accum	ulated Oth	ner Compreh	ensive	Income			
	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available -for-sale Securities	Deferre Loss on Deriva under He Account	Fore tives Curre	ency ation	Defined Retirement Benefit Plans	Total	Noncontroll Interests	
BALANCE, MARCH 31, 2017	\$ 48,811	\$ 41,933	\$ 942,424	\$ (23,113)	\$ 87,122	\$	(47) \$	103	\$ (20,915)\$	1,076,311	\$ 2,13	2 \$1,078,452
Net income attributable to owners												
of the parent			122,198							122,198		122,198
Cash dividends, \$0.52 per share			(35,575)							(35,575)		(35,575)
Purchase of treasury stock				(132)						(132)		(132)
Net change during the year					21,075			(56)	(320)	20,698	10	3 20,801
BALANCE, MARCH 31, 2018	\$ 48,811	\$ 41,933	\$1,029,037	\$ (23,245)	\$ 108,198	\$	(47) \$	37	\$ (21,245)\$	1,183,500	\$ 2,23	5 \$1,185,745

See notes to consolidated financial statements.

Consolidated Financial Statements

oon Shinyaku Co., Ltd. and Consolidated Subsidiaries			
Ended March 31, 2018	Milli	Thousands of U.S. Do (Note 1)	
	2018	2017	2018
OPERATING ACTIVITIES:			
Income before income taxes	¥ 17,451	¥ 15,477	\$ 164,632
Adjustments for:			
Income taxes – paid	(6,220)	(3,084)	(58,679)
Depreciation and amortization	2,773	2,648	26,160
Impairment loss		766	
Changes in assets and liabilities:			
Increase in trade notes and trade accounts receivables	(3,286)	(1,742)	(31,000)
Decrease (increase) in inventories	(1,768)	352	(16,679)
Decrease (increase) in other current assets	(416)	32	(3,925)
(Decrease) increase in trade notes and trade accounts payables	2,407	(533)	22,708
Decrease in other current liabilities	(189)	(311)	(1,783)
Decrease in liability for retirement benefits	(692)	(589)	(6,528)
Other – net	(3,339)	5,901	(31,500)
Total adjustments	(10,732)	3,439	(101,245)
Net cash provided by operating activities	6,719	18,916	63,387
INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(4,017)	(4,131)	(37,896)
Purchases of investment securities	(1,431)	(1)	(13,500)
Purchases of software	(160)	(221)	(1,509)
Acquisition of long-term prepaid expenses	(4,004)	(864)	(37,774)
Other – net	(1,728)	(532)	(16,302)
Net cash used in investing activities	(11,342)	(5,750)	(107,000)
FINANCING ACTIVITIES:	(0.700)	(0.454)	(05.547)
Cash dividends paid	(3,768)	(2,154)	(35,547)
Repurchase of treasury stock	(14)	(36)	(132)
Other – net	(4)	(1)	(38)
Net cash used in financing activities	(3,787)	(2,193)	(35,726)
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON			
CASH AND CASH EQUIVALENTS	6	125	57
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(8,404)	11,098	(79,283)
CASH AND CASH EQUIVALENTS OF NEWLY-	(0,101)	11,000	(10,200)
CONSOLIDATED SUBSIDIARIES, BEGINNING OF YEAR		67	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	35,914	24,748	338,811
ONOTIFIED ONOTI EQUITALENTO, DEGINATING OF TEAM	00,017	27,170	000,011

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements

1. BASIS OF PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations and in accordance with accounting principles generally accepted in Japan, which are different in certain respects as to the 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 2017 consolidated financial statements to conform to the classifications used in 2018.

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. 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 ¥106 to \$1, the approximate rate of exchange at March 31, 2018. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

- a. Consolidation The consolidated financial statements as of March 31, 2018 and 2017, include the accounts of the Company and its three domestic subsidiaries and one overseas subsidiary (collectively, the "Companies").
 - Under the control and influence concepts, those companies in which the Company, directly or indirectly, is able to exercise control over operations are fully consolidated, and those companies over which the Companies have the ability to exercise significant influence are accounted for by the equity method.
- All significant intercompany balances and transactions have been eliminated in consolidation. All material unrealized profit included in assets resulting from transactions within the Companies is eliminated.
- b. Cash Equivalents Cash equivalents are short-term investments that are readily convertible into cash and that are exposed to insignificant risk of changes in value. Cash equivalents include time deposits, certificates of deposit, and commercial paper, all of which mature or become due within three months of the date of acquisition.
- c. Marketable and Investment Securities Marketable and investment securities are classified and accounted for, depending on management's intent, as follows: i) held-to-maturity debt securities, which management has the positive intent and ability to hold to maturity, are reported at amortized cost; and ii) available-for-sale securities that are not classified as held-to-maturity

- securities and are reported, except for nonmarketable available-for-sale securities, at fair value, with unrealized gains and losses, net of applicable taxes, are reported as a separate component of equity. Realized gains and losses on available-for-sale securities are included in earnings and are calculated by using the moving-average method to determine the cost of securities sold. Nonmarketable available-for-sale securities are stated at cost, cost being determined principally by the moving-average method. Write-downs are recorded in earnings for securities with a significant decline in value that is considered to be other than temporary.
- d. Inventories Inventories held for sale in the ordinary course of business are measured at the lower of cost, determined mainly by the average cost method, or net selling value, which is defined as the selling price, less additional estimated manufacturing costs and estimated direct selling expenses. The replacement cost may be used in place of the net selling value, if appropriate.
- e. Property, Plant and Equipment Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment of the Companies is computed by the straight-line method based on the estimated useful lives of the assets. The range of useful lives is principally from 10 to 50 years for buildings and structures, from 8 to 10 years for machinery, equipment, and vehicles, and from 4 to 6 years for tools, furniture, and fixtures.
- f. Long-Lived Assets The Companies review their long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss would be measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from the continued use and eventual disposition of the asset or the net selling price at disposition.
- g. Retirement and Pension Plans The Company has contributory funded defined benefit pension plans, unfunded retirement benefit plans and a defined contribution pension plan for employees. Certain subsidiaries use a simplified method of calculated pension liabilities.

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

- h. Allowance for Doubtful Accounts The allowance for doubtful accounts is stated at an amount considered to be appropriate based on the Companies' past credit loss experience and an evaluation of potential losses in receivables outstanding.
- Leases Finance lease transactions are capitalized by recognizing lease assets and lease obligations in the consolidated balance sheet. All other leases are accounted for as operating leases.
- j. Allowance for Bonuses To prepare for the payment of employee bonuses, an amount corresponding to the current portion of estimated bonus payments to employees is recorded.
- k. Income Taxes The provision for income taxes is computed based on the pretax income included in the consolidated statement of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted income tax rates to the temporary differences.
- I. Foreign Currency Transactions All short- and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statement of income to the extent that they are not hedged by forward exchange contracts.
- m. Foreign Currency Financial Statements The 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. The foreign currency forward contracts are utilized to hedge foreign currency exposures in procurement of raw materials from overseas suppliers. Trade payables denominated in foreign currencies are

- translated at the contracted rates if the forward contracts qualify for hedge accounting.
- 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 Accounting Standards Board of Japan (ASBJ) Statement No. 24, "Accounting Standard for Accounting Changes and Error Corrections," and ASBJ Guidance No. 24, "Guidance on Accounting Standard for Accounting Changes and Error Corrections," accounting treatments are required as follows: (1) Changes in Accounting Policies—When a new accounting policy is applied following revision of an accounting standard, the new policy is applied retrospectively unless the revised accounting standard includes specific transitional provisions, in which case the entity shall comply with the specific transitional provisions. (2) Changes in Presentation—When the presentation of financial statements is changed, prior-period financial statements are reclassified in accordance with the new presentation. (3) Changes in Accounting Estimates—A change in an accounting estimate is accounted for in the period of the change if the change affects that period only, and is accounted for prospectively if the change affects both the period of the change and future periods. (4) Corrections of Prior-Period Errors—When an error in prior-period financial statements is discovered, those statements are restated.
- q. New Accounting Pronouncements On March 30, 2018, the ASBJ issued ASBJ Statement No. 29, "Accounting Standard for Revenue Recognition," and ASBJ Guidance No. 30, "Implementation Guidance on Accounting Standard for Revenue Recognition." The core principle of the standard and guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity should recognize revenue in accordance with that core principle by applying the following steps: Step 1: Identify the performance obligations in the
 - Step 2: Identify the performance obligations in the contract
 - Step 3: Determine the transaction price
 - Step 4: Allocate the transaction price to the performance obligations in the contract
 - Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

The accounting standard and guidance are effective for annual periods beginning on or after April 1, 2021. Earlier application is permitted for annual periods beginning on or after April 1, 2018.

The Company expects to apply the accounting standard and guidance for annual periods beginning on or after April 1, 2021, and is in the process of measuring the effects of applying the accounting standard and guidance in future applicable periods.

3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2018 and 2017, consisted of the following:

		Millio	ns of	Yen	Thousands of U.S. Dollars
	Ī	2018		2017	2018
Current:					
Government and corporate					
bonds	¥	4,020	¥	2,657	\$ 37,924
Other		400			3,773
Total	¥	4,420	¥	2,657	\$ 41,698
Noncurrent:					
Equity securities	¥	25,828	¥	21,611	\$ 243,661
Government and corporate					
bonds		451		70	4,524
Other		29			283
Total	¥	26,309	¥	21,681	\$ 248,198

The costs and aggregate fair values of marketable and investment securities at March 31, 2018 and 2017 were as follows:

			Millions	of Yen	1	
			Unrealized	Unre	alized	
March 31, 2018		Cost	Gains	Los	sses	Fair Value
Securities classified as:						
Available-for-sale:						
Equity securities	¥	9,636	¥ 16,191			¥ 25,499
Other		400				400
Held-to-maturity		4,500		¥	5	4,495
			Millions	of Yen	ı	
			Unrealized		alized	
March 31, 2017		Cost	Gains	Los	sses	Fair Value
Securities classified as:						
Available-for-sale:						
Equity securities	¥	8,306	¥ 12,967			¥ 21,282
Held-to-maturity		2,728		¥	6	2,721
			Thousands of	of U.S. [Dollars	
			Unrealized		alized	
March 31, 2018		Cost	Gains	Los	sses	Fair Value
Securities classified as:						
Available-for-sale:						
Equity securities	\$	90,910	\$152,750			\$243,661
Other		3,773				3,773
Held-to-maturity		42.461		\$	55	42,405

4. INVENTORIES

Inventories at March 31, 2018 and 2017, consisted of the following:

		Millio	Thousands of U.S. Dollars	
		2018	2017	2018
Finished products and				
merchandise	¥	14,337	¥ 12,291	\$ 135,254
Work in process		1,671	2,155	15,764
Raw materials and supplies		4,337	4,129	40,915
Total	¥	20,345	¥ 18,577	\$ 191,933

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, 2018 and 2017 were as follows:

Millions of Yen Thousands of U.S. Dollars 2018 2017 2018 Balance at beginning of year Current service cost Interest cost Interest cost Actuarial (gains) losses Actuarial (gains) losses Benefits paid ¥ 28,662 ¥ 30,019 \$270,396 1,081 1,090 10,198 193 2,226 Actuarial (gains) losses 422 (1,090) 3,981 Benefits paid (1,381) (1,551) (13,028) Balance at end of year ¥ 29,020 ¥ 28,662 \$273,773						
Balance at beginning of year ¥ 28,662 ¥ 30,019 \$270,396 Current service cost 1,081 1,090 10,198 Interest cost 236 193 2,226 Actuarial (gains) losses 422 (1,090) 3,981 Benefits paid (1,381) (1,551) (13,028)			Millions of Yen			
Current service cost 1,081 1,090 10,198 Interest cost 236 193 2,226 Actuarial (gains) losses 422 (1,090) 3,981 Benefits paid (1,381) (1,551) (13,028)			2018		2017	2018
Interest cost 236 193 2,226 Actuarial (gains) losses 422 (1,090) 3,981 Benefits paid (1,381) (1,551) (13,028)	Balance at beginning of year	¥	28,662	¥	30,019	\$270,396
Actuarial (gains) losses 422 (1,090) 3,981 Benefits paid (1,381) (1,551) (13,028)	Current service cost		1,081		1,090	10,198
Benefits paid (1,381) (1,551) (13,028)	Interest cost		236		193	2,226
	Actuarial (gains) losses		422		(1,090)	3,981
Balance at end of year ¥ 29,020 ¥ 28,662 \$273,773	Benefits paid		(1,381)		(1,551)	(13,028)
	Balance at end of year	¥	29,020	¥	28,662	\$273,773

(2) The changes in plan assets for the years ended March 31, 2018 and 2017 were as follows:

	Million	Thousands of U.S. Dollars	
	2018	2017	2018
Balance at beginning of year ¥	20,597	¥ 19,609	\$194,311
Expected return on plan assets	823	781	7,764
Actuarial losses	(152)	(84)	(1,433)
Contributions from the employer	1,666	1,825	15,716
Benefits paid	(1,337)	(1,456)	(12,613)
Others		(78)	
Balance at end of year ¥	21,597	¥ 20,597	\$203,745

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

		Millio	ns of	Yen		ousands of .S. Dollars
		2018		2017		2018
Funded defined benefit						
obligation	¥	26,415	¥	26,123	\$ 2	249,198
Plan assets		(21,597)		(20,597)	(2	203,745)
		4,818		5,525		45,452
Unfunded defined						
benefit obligation		2,604		2,538		24,566
Net liability arising from defined						
benefit obligation	¥	7,422	¥	8,064	\$	70,018
	Millions of Yen		Yen		ousands of .S. Dollars	
		2018		2017		2018
Liability for retirement benefits	¥	7,422	¥	8,064	\$	70,018
Net liability arising from						
defined benefit obligation	¥	7,422	¥	8,064	\$	70,018

(4) The components of net periodic benefit costs for the years ended March 31, 2018 and 2017 were as follows:

	Millio	ns of	Yen	ousands of .S. Dollars
	2018		2017	2018
Service cost ¥	1,081	¥	1,090	\$ 10,198
Interest cost	236		193	2,226
Expected return on plan assets	(823)		(781)	(7,764)
Amortization of prior service cost	479		716	4,518
Recognized actuarial losses	45		45	424
Others	6		30	56
Net periodic benefit costs ¥	1,024	¥	1,294	\$ 9,660

(5) Amounts recognized in other comprehensive income (before income tax effect) in respect of defined retirement benefit plans for the years ended March 31, 2018 and 2017 were as follows:

		Millions of Yen 2018 2017			Thousands of U.S. Dollars		
					2018		
Prior service cost	¥	(45)	¥	(45)	\$	(424)	
Actuarial losses (gains)		94		(1,722)		886	
Total	¥	49	¥	(1,768)	\$	462	

(6) Amounts recognized in accumulated other comprehensive income (before income tax effect) in respect of defined retirement benefit plans as of March 31, 2018 and 2017 were as follows:

	Millions of Yen			Thousands of U.S. Dollars		
	2018	2018 2017			2018	
Unrecognized prior service cost ¥	20	¥	65	\$	188	
Unrecognized actuarial losses	3,220		3,125		30,377	
Total ¥	3,241	¥	3,191	\$	30,575	

(7) Plan assets

a. Components of plan assets
 Plan assets as of March 31, 2018 and 2017
 consisted of the following:

	2018	2017	
Domestic bonds	17.2%	18.3%	
Domestic stocks	15.8	16.1	
Foreign bonds	12.4	12.7	
Foreign stocks	10.2	11.1	
General accounts	31.5	29.1	
Alternative	9.3	9.5	
Others	3.6	3.2	
Total	100.0%	100.0%	

 Method of determining the expected rate of return on plan assets

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

(8) Assumptions used for the years ended March 31, 2018 and 2017 are set forth as follows:

	2018	2017	
Discount rate	0.1 - 0.8%	0.1 - 0.9%	
Expected rate of return on			
plan assets	4.0%	4.0%	

2. Defined Contribution Pension Plan
Premiums for defined contribution pension plan were
¥73 million (\$688 thousand) and ¥66 million for the years
ended March 31, 2018 and 2017, respectively.

6. EQUITY

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

(a) Dividends

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

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

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

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

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

(c) Treasury stock and treasury stock acquisition rights

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

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

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

7. RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥13,221 million (\$124,732 thousand) and ¥14,903 million for the years ended March 31, 2018 and 2017, respectively.

8. LEASES

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

Total rental expenses for the years ended March 31, 2018 and 2017, were ¥1,311 million (\$12,368 thousand) and ¥1,266 million, respectively.

Future minimum payments under noncancelable operating leases are as follows:

		Operating Leases					
		2018					
	Million	is of Yen		sands of Dollars			
Due within one year	¥	11	\$	110			
Due after one year		42		396			
Total	¥	53	\$	500			

9. LONG-LIVED ASSETS

The Companies reviewed their long-lived assets for impairment as of March 31, 2017. As a result, the Companies recognized an impairment loss of ¥766 million 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. No impairment loss was recognized in 2018.

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 30.5% and 31.0% for the years ended March 31, 2018 and 2017, respectively.

The tax effects of significant temporary differences and tax loss carryforwards which resulted in deferred tax assets and liabilities at March 31, 2018 and 2017 are as follows:

	Millions of Yen			ousands of .S. Dollars
	2018	2017		2018
Deferred tax assets:				
Retirement benefits ¥	2,267 ¥	2,459	\$	21,386
Accrued expenses	1,087	1,088		10,254
Property, plant and equipment	31	39		292
Other	3,156	2,805		29,733
Less valuation allowance	(309)	(309)		(2,915)
Deferred tax assets	6,231	6,083		58,783
Deferred tax liabilities:				
Unrealized gain on available-				
for-sale securities	4,721	3,740		44,537
Deferred gains on sales of				
property	970	976		9,150
Other	21	23		198
Deferred tax liabilities	5,714	4,740		53,905
Net deferred tax assets ¥	517 ¥	1,342	\$	4,877

A reconciliation between the normal effective statutory tax rates and the actual effective tax rates reflected in the accompanying consolidated statement of income for the year ended March 31, 2018, with the corresponding figures for 2017, is as follows:

	2018	2017
Normal effective statutory tax rate	30.5%	31.0%
Expenses not deductible for income tax purposes	0.6	0.8
Income not taxable for income tax purposes	(0.5)	(0.5)
Tax credits for research and development costs	(6.1)	(7.6)
Inhabitant tax on per capita basis	0.4	0.4
Other – net	8.0	(0.1)
Actual effective tax rate	25.7%	24.0%

11. FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

(1) Group policy for financial instruments

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

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

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

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

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

(3) Risk management for financial instruments Credit risk management

Credit risk is the risk of economic loss arising from a counterparty's failure to repay or service debt according to the contractual terms. The Companies manage their credit risk from receivables on the basis of internal guidelines, which include monitoring payment terms and balances of major customers by the business administration and finance and accounting departments to identify the default risk of customers 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 to only

for the purpose of reducing market risks.

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

Liquidity risk management

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

(4) Fair values of financial instruments

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

(a) Fair value of financial instruments

Income taxes payable

Total

March 31, 2018		arrying mount	F	Fair Value	U	nrealized Loss
Cash and cash equivalents	¥ 2	27,510	¥	27,510		
Time deposits		957		957		
Notes and accounts receivables	, 4	40,390		40,390		
Marketable and investment						
securities	;	30,399		30,394	¥	5
Total	¥	99,258	¥	99,252	¥	5
Notes and accounts payables	¥ ·	14,367	¥	14,367		
Income taxes payable		2,115		2,115		
Total	¥ ·	16,482	¥	16,482		
			Mil	lions of Yen		
		arrying			U	nrealized
March 31, 2017	Α	mount	F	air Value		Loss
Cash and cash equivalents	¥ 3	35,914	¥	35,914		
Time deposits		867		867		
Notes and accounts receivables	3	37,226		37,226		
Marketable and investment						
securities	2	24,009		24,003	¥	6
Total	¥	98,018	¥	98,011	¥	6
Notes and accounts payables	¥ ·	15,517	¥	15,517		

	Thousands of U.S. Dollars									
	Carrying		Unr	ealized						
March 31, 2018	Amount	Fair Value	L	LOSS						
Cash and cash equivalents	\$259,532	\$259,532								
Time deposits	9,028	9,028								
Notes and accounts receivables	381,045	381,045								
Marketable and investment										
securities	286,792	286,736	\$	55						
Total	\$936,399	\$936,344	\$	55						
Notes and accounts payables	\$135,537	\$135,537								
Income taxes payable	19,952	19,952								
Total	\$155,490	\$155,490								

3,892

¥ 19,410

3,892

¥ 19,410

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

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

Marketable and investment securities

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

Notes and accounts payables and income taxes payable

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

Derivatives

Fair value information for derivatives is omitted because fair values and unrealized gains were immaterial for the years ended March 31, 2018 and 2017.

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

	Carrying Amount					
	Millions	of Yen	Thousands of U.S. Dollars			
_	2018	2017	2018			
Investments in equity instruments						
that do not have a quoted marke	et					
price in an active market	¥329	¥329	\$3,104			

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

			Millions	s of '	Yen	
			e after	Du	e after	
	Due in		Year	-	Years	D 4.
March 31, 2018	1 Year or Less		ough ⁄ears		rough Years	Due afte 10 Years
Cash and cash equivalents	¥ 27,510					
Time deposits	957					
Notes and accounts receivables	40,390					
Marketable and investment securities:						
Held-to-maturity securities	4,040	¥	160	¥	300	
Available-for-sale securities with						
contractual maturities	400					
Total	¥73,298	¥	160	¥	300	

			Millions	of Yen	
March 31, 2017	Due in 1 Year or Less	1 Y	after /ear ough ears	Due after 5 Years through 10 Years	Due after
Cash and cash equivalents	¥ 35,914				
Time deposits	867				
Notes and accounts receivables	37,226				
Marketable and investment securities:					
Government and corporate bonds	2,657	¥	70		
Total	¥ 76,666	¥	70		

		Tho	usands d	of U	.S. Dollar	3
		Dι	ue after	D	ue after	
	Due in		Year	_	Years	
	1 Year		irough		nrough	Due afte
March 31, 2018	or Less	5	Years	1	0 Years	10 Years
Cash and cash equivalents	\$259,532					
Time deposits	9,028					
Notes and accounts receivables	381,045					
Marketable and investment securities:						
Held-to-maturity securities	38,113	\$	1,518	\$	2,830	
Available-for-sale securities with						
contractual maturities	3,773					
Total	\$684,517	\$	1,518	\$	2,830	

12. OTHER COMPREHENSIVE INCOME (LOSS)

The components of other comprehensive income (loss) for the years ended March 31, 2018 and 2017 were as follows:

		Millio	ns of \	Yen		usands of 3. Dollars
		2018		2017		2018
Unrealized gain (loss) on						
available-for-sale securities:						
Gains arising during the year	¥	3,215	¥	114	\$	30,330
Amount before income						
tax effect		3,215		114		30,330
Income tax effect		(981)		28		(9,254)
Total	¥	2,234	¥	143	\$	21,075
Deferred gain (loss) on derivative	es					
under hedge accounting:						
Gains (losses) arising						
during the year	¥	1	¥	(4)	\$	9
Income tax effect				1		
Total	¥		¥	(3)	\$	
Foreign currency translation						
adjustments:						
Adjustments arising						
during the year	¥	(6)	¥	(6)	\$	(56)
Total	¥	(6)	¥	(6)	\$	(56)
Defined retirement benefit plans:						
Adjustments arising during	.,	, a	.,		_	<i></i>
the year	¥	(574)	¥	1,006	\$	(5,415)
Reclassification adjustments				704		4 0 40
to profit or loss		524		761		4,943
Amount before income tax eff	ect	(49)		1,768		(462)
Income tax effect		15		(564)		141
Total	¥	(34)	¥	1,203	\$	(320)
Total other comprehensive	v	0.404	V	1 007	¢	00.000
income (loss)	¥	2,194	¥	1,337	Þ	20,698

13. NET INCOME PER SHARE

Net EPS for the years ended March 31, 2018 and 2017 was as follows:

		Millions of Yen	Thousands of Shares		Yen	U.S. Dollars
_	Attr	et Income ibutable to wners of e Parent	Weighted- Average Shares		EP	s
For the year ended						
March 31, 2018 -						
Basic EPS						
Net income available	:					
to common						
shareholders	¥	12,953	67,355	¥	192.31	1.81
For the year ended						
March 31, 2017 -						
Basic EPS						
Net income available						
to common						
shareholders	¥	11,749	67,362	¥	174.42	

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

14. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 28, 2018, the Company's shareholders approved the following:

Payment of year-end cash dividend of ¥26 (\$0.24) per share to holders of record at March 31, 2018, for a total of ¥1,751 million (\$16,518 thousand).

15. SEGMENT INFORMATION

Under ASBJ Statement No. 17, "Accounting Standard for Segment Information Disclosures," and ASBJ Guidance No. 20, "Guidance on Accounting Standard for Segment Information Disclosures," an entity is required to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. Operating segments are components of an entity about which separate financial information is available and such information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments.

1. Description of Reportable Segments

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

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

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

3. Information about Sales, Profit, Assets, and Other Items

	Millions of Yen 2018							
		Reportable Segmen	t	_				
	Pharmaceuticals	Functional Food	Total	Reconciliations	Consolidated			
Sales:								
Sales to external customers	¥ 87,416	¥ 14,031	¥101,448		¥101,448			
Intersegment sales or transfers								
Total	¥ 87,416	¥ 14,031	¥101,448		¥101,448			
Segment profit	¥ 16,351	¥ 728	¥ 17,079		¥ 17,079			
Segment assets	88,285	10,914	99,200	¥ 58,991	158,192			
Other:								
Depreciation	2,494	240	2,734	38	2,773			
Increase in property, plant and equipment and intangible assets	2,672	138	2,810		2,811			

					Mil	lions of Yen		
						2017		
		F	Report	table Segmen				
	Pharr	maceuticals	Fund	ctional Food		Total	Reconciliations	Consolidated
Sales:								
Sales to external customers	¥	85,315	¥	13,466	¥	98,781		¥ 98,781
Intersegment sales or transfers								
Total	¥	85,315	¥	13,466	¥	98,781		¥ 98,781
Segment profit	¥	14,690	¥	589	¥	15,280		¥ 15,280
Segment assets		79,208		10,155		89,364	¥ 61,541	150,905
Other:								
Depreciation		2,370		240		2,610	38	2,648
Increase in property, plant and equipment and intangible assets		3,811		135		3,947	2	3,949
-				Thou	ısan	ds of U.S. D	ollars	
						2018		
		F	Report	table Segmen				
	Pharr	maceuticals	Fund	ctional Food		Total	Reconciliations	Consolidated
Sales:								
Sales to external customers	\$ 8	824,679	\$	132,367	\$	957,056		\$ 957,056
Intersegment sales or transfers								
Total	\$ 8	824,679	\$	132,367	\$	957,056		\$ 957,056
Segment profit	\$ 1	154,254	\$	6,867	\$	161,122		\$ 161,122
Segment assets	8	832,877		102,962		935,849	\$556,518	1,492,377
Other:								
Depreciation		23,528		2,264		25,792	358	26,160
Increase in property, plant and equipment and intangible assets		25,207		1,301		26,509		26,518

Note: Unallocated corporate assets included under "Reconciliations" for 2018 and 2017 are ¥58,991 million (\$556,518 thousand) and ¥61,541 million, respectively, and consisted primarily of funds, such as cash equivalents, investment securities, assets for administrative functions, and deferred tax as

Related Information

1. Information about products and services

			Millio	ns of Yen			
			:	2018			
	Pha	rmaceuticals	Fund	ctional Food		Total	
Sales to external customers	¥	87,416	¥	14,031	¥	101,448	
			Millio	ns of Yen			
			2	2017			
	Pha	rmaceuticals	Fund	ctional Food	Total		
Sales to external customers	¥	85,315	¥	13,466	¥	98,781	
		Thou	usands	of U.S. Dolla	ars		
			:	2018			
	Pha	rmaceuticals	Fund	ctional Food		Total	
Sales to external customers	\$	824,679	\$	132,367	\$	957,056	

2. Information about geographical areas

\$	815,619	\$	139,785	\$	1,653	\$	957,057
	Japan		Europe		Other		Total
			20	018			
			Thousands of	of U.S. Dol	lars		
¥	81,134	¥	17,393	¥	253	¥	98,781
	Japan		Europe		Other		Total
			20	017			
			Millions	s of Yen			
÷			,	•			,
¥	86,455	¥	14,817	¥	175	¥	101,448
	Japan		Europe		Other		Total
			20	018			
			Millions	s of Yen			
(1)	Sales						

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

(2) Property, plant and equipment

Information about geographical area is omitted, as property, plant and equipment located in Japan accounted for more than 90% of property, plant and equipment presented in the consolidated balance sheets as of March 31, 2018 and 2017.

3. Information about major customers

	2018				
		S	Related		
Name of Customers		Millions of Yen	Thousands of U.S. Dollars	Segment Name	
MEDICEO CORPORATION	¥	16,461	\$155,301	Pharmaceuticals	
Suzuken Co., Ltd. Alfresa Corporation		15,896	149,963	Pharmaceuticals	
		15,763	148,707	Pharmaceuticals	
Actelion Pharmaceuticals Ltd.		14,406	135,907	Pharmaceuticals	

	2017		
	Sales	Related	
	Millions	Segment	
Name of Customers	of Yen	Name	
Actelion Pharmaceuticals Ltd. 3	£ 16,768	Pharmaceuticals	
MEDICEO CORPORATION	15,934	Pharmaceuticals	
Alfresa Corporation	14,967	Pharmaceuticals	
Suzuken Co., Ltd.	13,634	Pharmaceuticals	

Deloitte.

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INDEPENDENT AUDITOR'S REPORT

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

We have audited the accompanying consolidated balance sheet of Nippon Shinyaku Co., Ltd. (the "Company") and its consolidated subsidiaries as of March 31, 2018, and the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

Management's Responsibility for the Consolidated Financial Statements

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

Auditor's Responsibility

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

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

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

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, 2018, and the consolidated results of their operations and their cash flows for the year then ended in accordance with accounting principles generally accepted in Japan.

Convenience Translation

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

Deloitte Touche Tohmatsy LLC

June 28, 2018

Deloitte Touche Tohmatsu Limited

Corporate Data / Investor Information As of March 31, 2018

Corporate Name Nippon Shinyaku Co., Ltd. Founded November 20, 1911 Date of Incorporation October 1, 1919

Head Office 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan

Phone: +81-75-321-1111 Facsimile: +81-75-321-0678

http://www.nippon-shinyaku.co.jp/english/

Paid-in Capital ¥5.2 billion (Listed in the First Section of

the Tokyo Stock Exchange)

Representative Director Shigenobu Maekawa, President

Independent and Deloitte Touche Tohmatsu Certified Public Shijokarasuma FT Square Accountants 20, Naginataboko-cho, Karasuma-higashiiru, Shijo-dori,

Shimogyo-ku, Kyoto 600-8008, Japan

Issued and Outstanding

Number of Shares 70.251.484 Number of Shareholders 4,998

Share Registrar Mitsubishi UFJ

Trust and Banking Corporation

3-6-3, Fushimi-machi, Chuo-ku, Osaka

541-8502, Japan

Major Shareholders

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

JP Morgan Chase Bank 385147 JPMC Oppenheimer JASDEC Lending Account Japan Trustee Services Bank, Ltd. (trust account 5) Tokio Marine & Nichido Fire Insurance Co., Ltd.

Network As of April 1, 2018

Main Offices

Tokyo Office

Business Offices

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

Business Branches

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

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

Domestic Subsidiaries

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

Overseas Offices and Subsidiary

NS Pharma, Inc. Beijing Representative Office London Office

