ANNUAL REPORT

2013

# ANNUAL REPORT 2013 Year ended March 31, 2013



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The cover illustration is from Koguma and Mikazuki (Bear Cub and Crescent Moon), a picturebook published through the Nippon Shinyaku Children's Literary Awards contest. For more information about the contest, please refer to page 25 of this report.





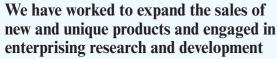


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Special Feature: Helping with recovery from alcohol dependence This long-awaited drug launched

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# Helping people lead healthier, happier lives

Nippon Shinyaku has provided products that help people lead healthier and happier lives through our pharmaceuticals business—part of our company since day one-and our functional food business, which operates under the belief that food is a form of medicine. In the pharmaceuticals segment, we believe that our mission is to continually develop novel and unique medicines that benefit patients. In the functional food segment, we leverage our expertise in pharmaceuticals to deliver proprietary functional food ingredients that are beneficial to society and that help people live healthier lives.

## **Pharmaceuticals**

Drugs for pain, inflammation, and allergies Drugs for urological malignancies diseases



Eviprostat

Bladderon

Estracyt<sup>e</sup>

Cialis<sup>®</sup>

19-90 • Vidaza®

Tramal Erizas<sup>®</sup> Baynas Azunol<sup>®</sup> Garale Liquid Livostin<sup>®</sup> Hypen<sup>6</sup>

In June 2013 the new indication of chronic pair was added to Tramal® sold in over 100 countries worldwide and recommended in various guidelines, and this is expected to be welcome news for more than 20 million patients in Japan.

Eviprostat<sup>®</sup>, a treatment for benign prostatic hypertrophy, has been prescribed for many years, primarily by urologists. We began selling erectile dysfunction (ED) treatment Cialis® in July 2009, and sales have been growing ever since.

 Cylocide<sup>®</sup> Trisenox® Amnolake®

Vidaza<sup>®</sup>, the treatment for myelodysplastic syndrome (MDS) that we launched in March 2011, is the only medicine in the world that has been shown to prolong survival in MDS patients. This has helped it penetrate the market quite quickly.

Protein preparations and

nutritional ingredients

## **Functional Food**

Health food ingredients



Mikaku Fine Z

Mikaku Fine BK

Neto Killer A40

Glycine GX-2

Cheflead V

KC-20



Hyaluronic acid 3000 NSCP aqua Garcinia Powder J Mangosteen aqua NS Amla extract powder Morus leaves extract

We leverage expertise in We supply preservatives of safety and quality control consistent quality that both practices developed in our extend the shelf life of various foods and minimize pharmaceuticals business to provide health food the impact on flavor by using ingredients beneficial to proprietary formulation maintaining and improving techniques. Our extensive human health based on lineup can be used for just assured quality and about any application in the evidence of efficacy. food industry



Dried Egg White H Sodium Caseinate CW Enlacto HG Fitness S Lactocrystal PRODIET85B

> We provide dried egg whites, sodium caseinate and sov protein for use in general foods such as processed meats and fish pastes, and milk protein and peptides for hospital-use nutritional foods



Fiscal 2012 (April 1, 2012–March 31,

2013). Some sections of the report also discuss initiatives since April

**Editorial Policy** 

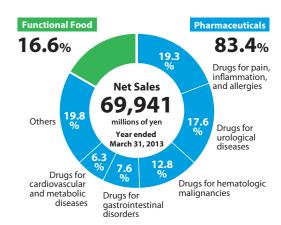
Period Covered

2013

Nippon Shinyaku's Financial Report for the vear ended March 31, 2013. As figures have been rounded, totals may not exactly equa the sum of their composite statistic

#### 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.



#### Drugs for hematologic Drugs for gastrointestinal Drugs for cardiovascular disorders



Although the market for protective factor potentiators has contracted slightly, we are seeing further growth in market share of our mucosal protective Gaslon N®, a remedy for gastric ulcers and gastritis, thanks to new evidence of its efficacy.

## and metabolic diseases



Selectol®

Launched in December 2009, Adcirca® is a remedy for pulmonary arterial hypertension, which is considered to be an intractable disease. Taken orally once a day, it works by inhibiting phosphodiesterase-5

#### Others



Regtect® for supporting maintenance of abstinence in patients with alcohol dependence launched in May 2013 is the only pharmaceutical in Japar that works on the central nervous system to reduce the urge to drink alcohol.

#### Spices and condiments Others



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

Melon Extract

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



Suncircle H Nineace S

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

## **Consolidated Financial Highlights**

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

#### Summary of consolidated financial index

_	2013	2012	2011	2010	2009	2013
or the year			millions of yen			Thousands of U.S. Dollars
Net sales	69,941	67,304	63,525	62,932	63,072	744,059
Pharmaceuticals	58,318	55,746	52,554	52,165	50,357	620,410
Drugs for pain, inflammation, and allergies	13,499	12,760	13,766	12,866	14,237	131,220
Drugs for urological diseases	12,334	13,189	13,741	13,541	11,708	143,607
Drugs for hematologic malignancies	8,965	6,600	3,092	2,825	2,749	95,375
Drugs for gastrointestinal disorders	5,325	5,324	5,111	5,051	4,773	<b>46,92</b> 1
Drugs for cardiovascular and metabolic diseases	4,410	4,330	4,601	4,575	4,675	56,658
Functional food	11,622	11,558	10,970	10,767	12,714	123,648
Cost of sales	34,776	32,702	30,218	29,018	28,888	369,962
Gross income on sales	35,165	34,601	33,307	33,914	34,184	374,097
Selling, general and administrative expenses	28,263	28,588	28,151	27,475	26,610	300,678
Operating income	6,901	6,012	5,181	6,461	7,547	73,420
Net income	4,647	3,715	3,958	4,096	4,499	49,442
Depreciation and amortization	2,759	2,948	3,116	3,078	2,875	29,357
Capital investment	1,332	967	1,185	1,859	2,331	14,177
R&D expenses	9,049	9,414	8,967	8,440	7,853	96,271
ind of the year			millions of yen			Thousands of U.S. Dollars
Total assets	113,730	106,304	102,737	103,575	98,286	1,209,903
Net assets	89,529	84,566	81,692	80,370	76,344	952,445
inancial information per share			yen			U.S. Dollars
Book value per share	1,323.87	1,250.11	1,207.43	1,187.42	1,127.49	14.08
Earnings per share	68.87	55.04	58.62	60.63	66.56	0.73
Dividend per share	21	19	19	19	18	0.22

#### Principal financial index

						%
Ratio of net worth	78.5	79.4	79.3	77.4	77.5	_
Return on equity	5.35	4.48	4.90	5.24	5.88	_
Pay-out ratio	30.5	34.5	32.4	31.3	27.0	_

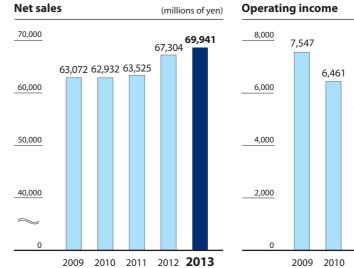
Notes: U.S. dollar amounts are converted from yen amounts at the rate of U.S.\$1 = ¥94, the approximate exchange rate on March 31, 2013.

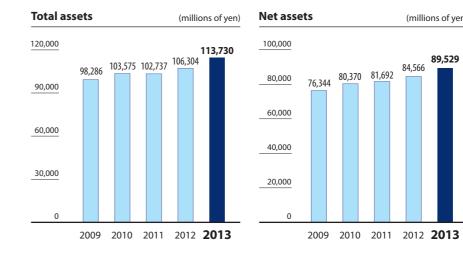
#### ESG indices<sup>®</sup> summary

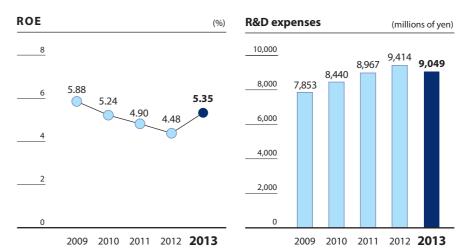
Total energy consumption (thousands of GJ)*2	231	231	245	240	247	—
CO <sub>2</sub> emissions (t) <sup>*2</sup>	11,272	9,568	10,813	10,559	10,846	—
CO <sub>2</sub> per unit of revenue (t/million yen) <sup>*2</sup>	0.162	0.143	0.171	0.168	0.173	_
Number of employees (people)	1,806	1,823	1,815	1,749	1,734	_

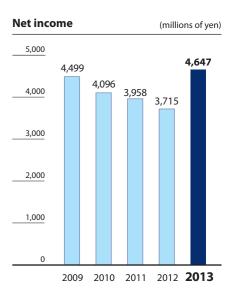
\*1 Indices related to environment, social, and corporate governance initiatives.

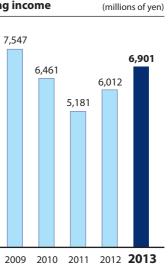
\*2 Applies to main business locations (excluding our sales offices).







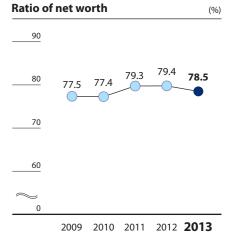


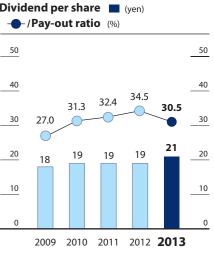


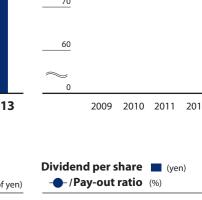
(millions of yen)

84,566

89,529







# We have worked to expand the sales of new and unique products and engaged in enterprising research and development

Difficult times continued for the year ended March 31, 2013 for the Japanese economy due to a strong yen and the financial crisis in Europe, but the change of national leadership at the end of last year has brought signs of an upturn.

The Nippon Shinyaku Group continued to face tough business conditions in the pharmaceuticals and functional food segments due to the continuing emphasis on measures to limit medical costs in the pharmaceuticals sector and the continued strong trend toward low-cost foods in the food sector alongside rising costs of imported raw materials.

Amid this environment, the Nippon Shinyaku Group has focused on expanding sales of innovative new drug products which we have continuously launched since 2008 and has conducted sales activities based on corporate strategy while establishing a larger role for these products in the market. We have also worked to improve our pipeline for research and development and have undertaken product development with an eye to steady product commercialization.

President Shigenobu Maekawa

## **Business Results for the Year Ended** March 31, 2013

### Sales of innovative new drug products have grown, bringing along increased revenue and profit

The Nippon Shinyaku Group recorded net sales of ¥69,941 million (up 3.9% year-on-year), operating profits of ¥6,901 million (up 14.8% year-on-year), ordinary income of ¥7,209 million (up 16.4% year-on-year), and net income was ¥4,647 million (up 25.1% year-on-year).

In the pharmaceuticals segment, competition from other pharmaceuticals and generic drugs led to lower sales of existing core drugs such as Hypen® non-steroidal analgesic and anti-inflammatory agent, and Eviprostat®, a treatment for benign prostatic hypertrophy. Sales from six products that we released to the market starting in 2008 contributed significantly to an overall increase in net sales. We recorded significant increases in sales of products including Vidaza®, a remedy for myelodysplastic syndrome, and Erizas®, used to treat allergic rhinitis, and achieved growth with Lunabell<sup>®</sup>, a dysmenorrhea remedy, and Adcirca® treatment agent for pulmonary arterial hypertension, as well. As a result, net sales amounted to ¥58,318 million (up 4.6% year-on-year).

In the functional food segment, both the processed food and health food sectors continued to be marked by challenging business conditions. However, while sales of health food ingredients dropped, sales increased for nutritional ingredients and preservatives, and sales of protein preparations stayed nearly flat. As a result, net sales in the functional food segment were ¥11,622 million (up 0.6% year-on-year).

### Helping People Lead Healthier, Happier Lives

#### **Business Philosophy**

## **Helping People** Lead Healthier, **Happier Lives**

Our corporate slogan is to build a healthier future, so that people can live longer and enjoy more fruitful and more energetic lives.

### **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 for 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.

## **Financial Position**

#### Assets, Debts, and Net Assets

For the year ended March 31, 2013, total assets increased by ¥7,426 million year-on-year to ¥113,730 million. Total debts increased by ¥2,462 million year-on-year to ¥24,201 million. Net assets increased by ¥4,963 million year-on-year to ¥89,529 million.

#### **Cash Flows**

For the year ended March 31, 2013, cash and cash equivalents increased by ¥379 million year-on-year to ¥20,044 million. Net cash from operating activities amounted to ¥3,767 million, while net cash used in investing activities amounted to ¥2,026 million. Net cash expended for financing activities amounted to ¥1,413 million.

### Medium- and Long-Term Business Strategy

The business segments we operate in have been marked by increasingly tougher business conditions due to factors such as the continuing emphasis on measures to limit medical costs, and sluggish consumption owing to uncertainty over the global financial situation. Under the circumstances, we must accelerate our efforts to implement innovations in order to realize our corporate vision and achieve growth as a corporation. To guide our efforts, we formulated our 4th Medium-term Management Plan for achieving innovation and growth, covering the five-year period starting from the year ended March 31, 2010.

In the pharmaceuticals business, we have been focusing on developing and supplying unique and high-quality

#### Management Policy

#### **Code of Conduct**

#### **Challenge: Meet Challenges**

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

#### **Speed: Speedy Action**

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

#### Investigation: Spirit of Investigation

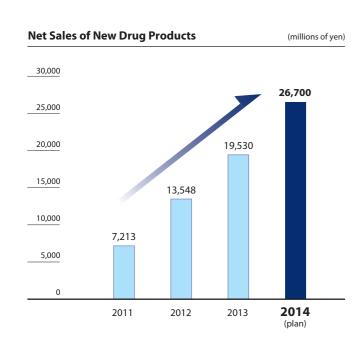
We will carefully investigate and analyze information that we have broadly gathered, and carefully plan to achieve our goals, and make certain to implement plan-do-check-action (PDCA) cycles.

pharmaceuticals that are safe and highly effective relative to other drugs, and that in some way contribute to a better quality of life for patients, first and foremost for patients who suffer from illnesses and targeting the fields of urology and hematology that we specialize in. By focusing on the three pillars of drug discovery research, in-licensing, and product life cycle management, we strive to expand the pipeline of product development to consistently bring new pharmaceuticals to market. In terms of sales, we are seeking to achieve balanced growth between our new and existing products. For marketing and informational activities, we are employing efficient and scientific approaches to managing our products and improving productivity among our medical representatives.

In the area of production, we seek to earn the trust of society by ensuring that we consistently supply high-quality active pharmaceutical ingredients and pharmaceuticals. In addition, we are pursuing low-cost management in an effort to enhance our cost competitiveness and improve profitability.

In the functional food business, we supply high-quality products that leverage our advanced technology as a pharmaceuticals company. We are developing products that meet customer needs, and identifying priority products and marketing strategies to expand sales, for the efficient and systematic pursuit of the functional food business. Furthermore, we are striving to position the business to achieve growth and generate consistent profits by expanding the scope of the business.

Nippon Shinyaku embraces a code of conduct: Meet Challenges, Speedy Action, and Spirit of Investigation. By making rapid and correct business decisions based on careful investigation and analysis, we will appropriately allocate our business resources to priority areas, while expanding our human resource development so that all



employees can positively approach their work with pride and motivation. At the same time, we are renewing our personnel policies in an effort to boost employee motivation and facilitate their growth.

We will also be putting together and announcing the next Medium-term Management Plan, starting in the year ending March 31, 2015.

### **Corporate Social Responsibility Initiatives**

### **Executing Our Management Policy to Achieve** Sustainable Growth Together with Society

The Nippon Shinyaku Group is committed to achieving our business philosophy of "Helping people lead healthier, happier lives." We will achieve sustainable growth together with society and fulfill our corporate social responsibility (CSR) through our management policy to supply unique and high-quality products, and earn the trust of society while developing each employee.

In our CSR initiatives (see page 21), we endeavor to strike a balance between social contributions through our business activities, and social contributions outside of business. Our non-business activities include sponsorship of the Nippon Shinyaku Children's Literary Awards contest and the Shining Future for Children Fund, which organizes a fundraising drive to provide vaccines for needy children in developing countries. We send employees to teach workshops for elementary school students in the community, are involved in initiatives to preserve and maintain Kyoto culture, and arrange for our corporate baseball team to conduct baseball clinics for youth. We also run the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project, a new activity we launched recently (see page 24).

#### Results in the year ended March 31, 2013 and Forecast in the year endin

March 31, 2014 for New Drug Products								
New Drug	2013	2014						

New Drug Products	2013 (Results)	2014 (Forecast)	ΥοΥ
Vidaza®	7,015	10,000	+42.5%
Lunabell®	4,627	5,200	+12.4%
Cialis®	3,371	3,600	+6.8%
Erizas®	2,145	3,000	+39.8%
Adcirca®	1,913	2,700	+41.1%
Tramal®	456	2,200	+382.3%
Total	19,530	26,700	+36.7%

(millions of yen)



**Projected Business Results for the Year Ending** March 31, 2014

#### Increased Sales and Profits

In the pharmaceuticals segment, the major drivers of increased sales are the further growth of new drug products such as Vidaza<sup>®</sup> remedy for myelodysplastic syndrome and Erizas<sup>®</sup> treatment for allergic rhinitis. We also expect increased revenue from newly launched Regtect<sup>®</sup>, an aid for maintaining alcohol abstinence, and Lunabell® Compound Tablet ULD, a treatment for dysmenorrhea. Tramal®, a treatment for cancer pain, has been approved for an additional indication of chronic pain and will also contribute to revenue growth.

In the functional food segment, we forecast increased sales from our strengthened initiatives toward priority products.

With the above in mind, we expect net sales of ¥74,300 million, operating profits of ¥7,600 million, ordinary income of ¥7,900 million, and net income of ¥5,400 million.

## Dividends

#### **Returning Profits to Shareholders**

Under our strategy to maximize corporate value, we strive to strengthen our business foundations by bolstering R&D to expand the pipeline for product development, and retain sufficient earnings to enable us to maintain a corporate position to withstand increasingly competitive conditions. Our policy on returning profits to shareholders is to issue dividends linked to earnings and maintain a consolidated payout ratio of around 30%.

For the year ended March 31, 2013, we issued an annual cash dividend of ¥21 per share, comprising an interim dividend of ¥10 per share and year-end dividend of ¥11 per share.

For the year ending March 31, 2014, we are projecting an annual cash dividend of ¥23 per share, comprising an interim dividend of ¥11 per share and year-end dividend of ¥12 per share.

Moving forward, we will continue our efforts to meet the expectations of stakeholders, and we welcome their continued feedback and support.

President S. machawa

**Regtect® Aid for Maintaining Alcohol Abstinence** 

## Helping with recovery from alcohol dependence This long-awaited drug launched

Alcohol dependence obstructs the everyday lives of those it affects and can drive them to suicide and depression. Alcohol dependence is becoming a social problem due to difficulty in treating it and increasing numbers of female and elderly sufferers. To help, we acquired in March 2013 approval to manufacture and sell Regtect<sup>®</sup> aid for maintaining alcohol abstinence, and put it on the market in May.



### Female and elderly sufferers on the rise in recent years

Alcohol dependence is a condition where habitual consumption of alcohol causes a person to become unable to control their consumption. While this condition has long been suffered by middle-aged males, recent statistics show that the percentage of female sufferers has risen to 20% in recent years, up from 10% of all sufferers in 1980, and the percentage of elderly sufferers aged 60 or over has increased from 10% to 30%.\*1

A society that is now more accepting of alcohol consumption by women coupled with everyday worries has contributed to this increase in female sufferers. Psychiatric disorders are also common in sufferers, and many turn to alcohol to take their minds off their condition. Others drink heavily due to eating disorders. Relieved of work responsibilities, retirees can also turn to excessive drinking, and some also begin drinking due to a sense of loss after the death of a family member or friend, a divorce, or from losing a job. Still others are unable to control their drinking due to dementia.

\*1 Data from the National Hospital Organization Kurihama Medical and Addiction Center, This center is the first public medical care provider to feature a special ward for those with alcoholi

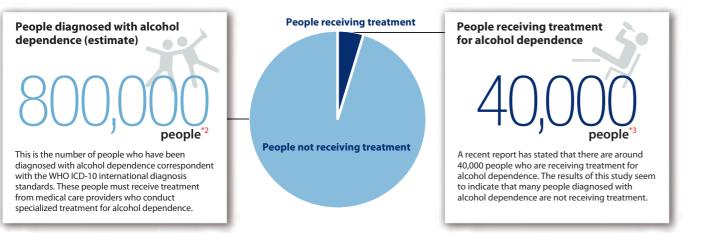
## A serious and difficult-to-treat illness that affects others

Alcohol dependence is a condition that hurts the patients as well as those around them. Families in particular tend to encounter serious hardships such as financial problems, domestic violence, spousal estrangement, divorce, and disorders involving children's mental development. Employees being chronically late or absent for work or working drunk and causing trouble can become problems for their company. Society also suffers when those under the influence of alcohol cause serious incidents or accidents. People who drink habitually may become incapable of avoiding driving while drunk or may turn to drink as the only way to stop their shaky hands, which can increase the risk of causing major accidents.

While it is important to take care of right away, alcohol dependence is difficult to treat and involves an arduous path to recovery. In many cases, people reach for a bottle impulsively and symptoms return. When this happens, some people may experience feelings of self-loathing and become depressed, eventually taking their own life.

### A lack of pharmaceutical options to aid psychosocial treatment

The ultimate aim of alcohol dependence treatment is to prevent situations like this and make it so that people can live



\*3 Patient survey conducted by the Ministry of Health, Labour and Welfare in 201

healthy lives together with family and society without alcohol. Treatment is centered on "psychosocial treatment" aimed at achieving abstinence through a combination of different methods including participation in self-help groups and psychological treatment involving counseling with doctors and medical staff, but pharmaceutical-based assistive therapy is also used.

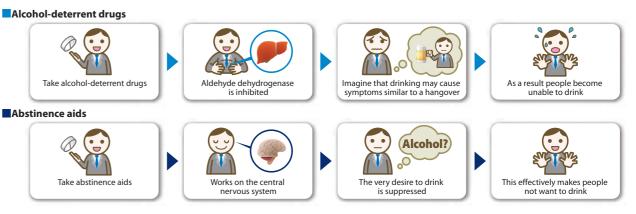
Pharmaceutical treatment options have been limited in Japan so far, with only alcohol-deterrent drugs\*4 available. Alcohol-deterrent drugs work by temporarily making the body unable to drink alcohol. Caution is a must due to their ability to, if alcohol is consumed after taking them, cause serious palpitations, nausea, headaches, and drops in blood pressure, among other symptoms.

\*4 The two kinds of alcohol-deterrent drugs, disulfiram and cyanamide, work by blocking aldehyde dehydrogenase. These drugs inhibit the degradation of a primary degradation product of alcohol, acetaldehyde, which is the cause of hangovers

## Approval of long-awaited Regtect®

Regtect® has been offered up as a possible new option in treating alcohol dependence. It works by acting on the central nervous system to reduce the craving for alcohol, and has been shown to be significantly more effective than placebos in helping people abstain from alcohol.\*5 Though much effort has gone into treating alcohol dependence, not much improvement has been seen in the abstinence rate. That is why Regtect®'s test

#### Difference between alcohol-deterrent drugs and abstinence aids





results are so significant.

The three academic societies related to alcohol filed a petition with the Ministry of Health, Labour and Welfare regarding the clinical usage of this medication and we were asked to develop the drug by this Ministry in May 2010. Having always seen major social significance in the development of a medication for treating alcohol dependence, we acquired the drug from the French company Merck Santé S.A.S.\*6 in 2003 for development in Japan. We then applied with the Ministry of Health, Labour and Welfare for approval to manufacture and sell the drug in March, 2012 and gained approval in March, 2013.

\*5 We compared the rate of complete abstinence at the end of 24-week administration period between a group of patients who took placebo (tablets with no active ingredient) and a group of patients who took Regtect®

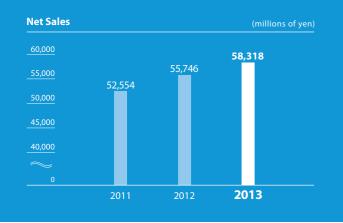
\*6 Currently Merck Serono S.A. (headquarters: Germany)

## Making the drug useful in treating alcohol dependence

It is important to use Regtect® properly in order to maximize its benefit and make it useful in treating alcohol dependence. We are therefore providing accurate information to medical settings to ensure that this medication is used properly by patients who have been diagnosed with alcohol dependence, are undergoing psychosocial therapy, and have a desire to achieve abstinence.

## **Pharmaceuticals**

Nippon Shinyaku's core business is pharmaceuticals. This business mainly targets Japan's prescription drug market through development and sales of therapeutic agents for intractable diseases that have yet to find an effective cure as well as for diseases where patients strongly require improved quality of life during treatment.





#### **Market Conditions**

### Market conditions remain challenging

In fiscal 2012, Japan's prescription drug market was valued at some ¥9.5 trillion on a NHI price basis. However, the market grew by only 0.25% year–on-year in fiscal 2012 due to the impact of revision of the medical payment system that included measures to promote the greater use of generics, indicating that challenging market environment conditions continue to persist in Japan.

Nevertheless, new drugs such as anti-cancer agents, diabetic medicine with a new mechanism of action, and combination preparations of antihypertensive compounds are being released one after another, thereby invigorating the prescription drug market. In addition, demand for disease areas such as cancer and osteoporosis has risen for the market as a whole.

Meanwhile, in response to aging society and changes in disease composition, key growth drivers are gradually shifting from existing products for lifestyle diseases to specialty drugs aimed at addressing unmet medical needs.

#### Sales Conditions

## Sales of new drug products have grown, resulting in increased revenues

Nippon Shinyaku is further accelerating its R&D in order to release a steady stream of new drug products with greater added value in a speedy manner. We are also committed to enhancing the value of our existing drug products by considering new possibilities from a product life cycle perspective, based on an evaluation of their status in meeting current market needs, and if needed, we modify the drug's formulation.

Our pharmaceuticals business saw a decline in sales for existing core drugs due to the influence of generics and competitor drugs. However, our new lineup of drug products that have been brought to market in a steady stream and our allergy-related drug products have seen a significant increase in sales.

Current fiscal year sales of Vidaza®, a treatment for myelodysplastic syndrome (MDS), increased, driving strong sales of Lunabell®, combination tablets for dysmenorrhea, Adcirca®, a pulmonary arterial hypertension treatment, and Erizas®, a treatment of allergic rhinitis. As a result, pharmaceutical business net sales rose 4.6% year-on-year to ¥58,318 million.

#### Prospects for Fiscal 2013

## Sales of new drug products expected to grow and result in increased revenues

Although the environment surrounding the pharmaceutical industry is becoming more challenging, we are implementing strategies with a focus on our new drug product lineup based on strategic R&D management defined in our 4th Medium-term Management Plan.

In fiscal 2013, we will further promote market penetration of therapeutic agent Vidaza<sup>®</sup>, a treatment for MDS, which contributed significantly to sales growth in fiscal 2012. A non-narcotic analgesic Tramal<sup>®</sup> is now approved for an additional indication of chronic pain. Moreover, we launched Regtect<sup>®</sup>, a drug for supporting maintenance of abstinence in patients with alcohol dependence, and Lunabell<sup>®</sup> Compound Tablet ULD, a treatment for dysmenorrhea that contains the



smallest amount of ethinyl estradiol in Japan. We expect to increase our revenues from new drug products, including the three noted above, by about 40%.

The growth in sales of our new drug products is expected to increase net sales of our pharmaceuticals business by 7.0% year-on-year to ¥62,400 million.

Moreover, we aim to conduct a phase III trial of long-acting oral analgesic NS-24, a phase III trial of ACT-064992 (Macitentan) and a phase II trial of NS-304, which are therapeutic agents for pulmonary arterial hypertension, in hopes of marketing drug products from our pipeline in a prompt and steady manner. In fiscal 2013, we plan to begin phase IIa trials (POC trials) of a new antipruritic drug NS-141 and NS-986, a therapeutic agent for nocturia.

In this manner, we will continue to bring new drug products with specialized functions to market in order to boost our competitiveness and earnings power, and maximize corporate value.

## **Research & Development**

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

Nippon Shinyaku has determined five fields of medicine on which to focus its primary R&D efforts and that align with its sales strategy: urology, hematology, obstetrics and gynecology, otorhinolaryngology, and orthopedics. With an emphasis on these specialty fields, we aim to provide breakthrough products to address patient needs through in-house drug discovery and manufacturing, licensing from other companies, and product life cycle management (PLCM). In particular, we are driven by a sense of responsibility to meet the challenges of developing treatments for unmet medical needs such as rare diseases and intractable diseases.

#### **Drug Discovery Research**

With a focus on our core medical specialty of urological and hematological diseases, and through elucidating the causes of new ailments, our drug discovery research focuses on the development of unique and proprietary drugs with an emphasis on speed.

#### Licensing-in Activity

We work actively to license in both marketed products and development candidates within our core medical specialty, in order to enhance our product pipeline.

#### Product Life Cycle Management

We examine possibilities for adding new indications or new formulations for our products on the market and under development, in order to maximize product value.

#### **Development of New Technology**

Nippon Shinyaku is actively engaged in advanced research centered on genomic drug discovery<sup>\*1</sup> and nucleic acid drugs<sup>\*2</sup> at its Discovery Research Laboratories in Tsukuba.

In particular, we are focused on the development of pharmaceuticals based on a new therapeutic principle which emphasizes the relationship between gene functions and mutations with disease.

- \*1 To analyze the connection between a disease and genes as a way of defining the target for drug discovery
- \*2 Pharmaceuticals that control the function of a specific gene. A portion of the structure includes the structural component of genes, nucleic acid.

### Development of the R&D Pipeline

In fiscal 2012, we pushed forward with development on a variety of drug products, while also expanding our development pipeline, including the number of new in-licensed products.

We obtained marketing approval for Regtect<sup>®</sup> Tablet 333mg, a drug for supporting abstinence in patients with alcohol dependence in March 2013 and launched in May 2013.

We filed an application for an additional indication of chronic pain for NS-315 (Tramal®), a non-narcotic analgesic, in September 2012, and received approval in June 2013. Our licenser Eli Lilly Japan K.K. filed an application for new drug approval for LY450190 (Tadalafil), a therapeutic agent used to treat urinary disorder caused by benign prostatic hypertrophy (BPH), in February 2013.

We began phase III clinical trials for NS-24, a sustained release preparation of tramadol hydrochloride, in April 2012 and for ACT-064992 (Macitentan), a therapeutic agent for pulmonary arterial hypertension (PAH), in October 2012.

As for new in-licensed products, there were GA101 (obinutuzumab), a therapeutic agent for indolent and aggressive Non-Hodgkin's Lymphoma (jointly developed and marketed with Chugai Pharmaceutical Co., Ltd.), and NS-986, a therapeutic agent for nocturia (licensed from Dainippon Sumitomo Pharma Co., Ltd.). Both of these drug products are in the specialty fields where we focus, and going forward, we plan on continuing development.



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

## We are working on expanding our development pipeline including in-licensed products, and also obtaining approval for promising new drugs

We strive for the development of high quality products through appropriate allocation of management resources for drug discovery research, licensing-in activities, and PLCM, with a clear definition of R&D targets. As a result, in fiscal 2012 we obtained marketing approval for Regtect<sup>®</sup>, a drug for supporting abstinence in patients with alcohol dependence. In addition, progress was made with many promising drugs currently under development, including approval for an additional indication of chronic pain for NS-315 (Tramal<sup>®</sup>). We also licensed promising products in our specialty fields of urology and hematology as part of our efforts to expand our development pipeline further.

In the future, we will engage actively in the development of therapeutics for diseases that have yet to see an established cure. In order to provide therapeutic products for patients as quickly as possible, we aim to achieve early approval by accelerating our clinical development process and improving success rates of clinical trials.

#### **Pipeline: Domestic**

Co

ode No. (Generic name)	Development phase	Therapeutic field	Indications	Ori				
NS-11	Launch	Other	Support maintenance of abstinence from alcohol in patients with alcohol dependence	Licensed-in from International S./				
(Acamprosate calcium)			lutamatergic nerve system induced b ırope and North America.	y alcohol depe				
NS-315	Launch	Pain, inflammation, and allergies	Chronic pain	Licensed-in fro Grünenthal Gn				
(Tramadol hydrochloride)	Additional indi	cations of Trama	al®. In addition to cancer pain, approv	al was received				
LY450190	Application	Urology	Urinary disorder caused by BPH	Licensed-in fi Eli Lilly Japan				
(Tadalafil)	As a therapeut Japan K.K. in Fe		ign prostatic hypertrophy (BPH), it po	ssesses a new r				
NS-24	PIII	Pain, inflammation, and allergies	Cancer pain Chronic pain	Licensed-in fr Paladin Labs				
(Tramadol hydrochloride)	Long-acting form of Tramadol hydrochloride, which has the same degree of efficad started in Japan in April 2012.							
	PIII	Cardiovascular and metabolic system	Pulmonary arterial hypertension	Licensed-in from: Actelion Pharmaceuti				
<b>ACT-064992</b> (Macitentan)	A highly active, tissue-specific dual endothelin receptor antagonist that shows effe and obtained positive results. Phase III trial started in Japan in October 2012.							
GA101	PIII	Hematologic malignancies	Indolent non-Hodgkin's lymphoma Aggressive non-Hodgkin's lymphoma	Licensed-in fror Chugai Pharma				
(Obinutuzumab)	A humanized anti-CD20 monoclonal antibody which targets CD20 on B cells. Chu Japan in October 2008. A joint development and marketing agreement was signe							
NS-304	PII	Cardiovascular and metabolic system	Pulmonary arterial hypertension/Chronic thromboembolic pulmonary hypertension	Nippon Shiny				
(Selexipag)	Orally-available, long-acting PGI2 receptor agonist, currently in phase II trial conduc							
	PII	Pain, inflammation, and allergies	Pruritus associated with cutaneous disease	Nippon Shiny				
NS-141			new mechanism of action that has n dditional Plla trial for indication of atc					
	PII (Preparation)	Urology	Nocturia	Licensed-in fro Sumitomo Pha				
NS-986			carinic effect and ability to block sodi e development, manufacturing, and r					

#### **Pipeline: Overseas**

Code No. (Generic name)	Development phase	Therapeutic field	Indications	Orio
<b>NM441</b> (Prulifloxacin)	Launch preparation PIII (Preparation)	Infectious diseases	Synthetic antibacterial	Nippon Shiny
NC 204	PIII	Cardiovascular and metabolic system	Pulmonary arterial hypertension	Nippon Shiny
NS-304 (Selexipag) Actelion is conducting a phase III trial worldwide, except in Japan.				
<b>NS-187</b> (Bafetinib)	PII	Hematologic malignancies	B-cell chronic lymphoid leukemia Chronic myeloid leukemia (PII preparation)	Nippon Shiny
	Potent inhibito	r of Bcr-Abl and	Lyn tyrosine kinases. Possibly effectiv	ve in imatinib-re
NS-018	PI/II	Hematologic malignancies	Myelofibrosis	Nippon Shiny
	JAK2 tyrosine k	inase inhibitor. [	Due to its high selectivity to activated	I JAK2, it can be

gin	Development	Phase I	Phase II	Phase III	Application	Launch			
n: Merck Serono A. (Germany)	Nippon Shinyaku								
ndence, which is considered to lead to reduce desire of drinking in patients with alcohol dependence.									
m: ibH (Germany)	Nippon Shinyaku								
for chronic pai	ns such as osteoarthritis, lowe	r back pain,	and posthe	erpetic neur	algia.				
om: K.K.	Eli Lilly Japan K.K.								
nechanism of a	ction to inhibit phosphodieste	erase-5. An a	application	was submit	ted in Japan	by Eli Lilly			
om: nc. (Canada)	Nippon Shinyaku								
y and safety as	Tramal® with one dose a day.	Available in	19 countrie	es around th	ne world. Ph	ase III trial			
als Ltd. (Switzerland)	Co-development: Actelion Pharmaceuticals Japan Ltd.								
ct with one dos	e a day. Actelion conducted a	n internatio	nal phase II	l trial, excep	ot in Japan,				
n: ceutical Co., Ltd.	Co-development: Chugai Pharmaceutical Co., Ltd.								
	cal Co., Ltd. began its develop 'harmaceutical Co., Ltd. in Nov								
aku	Co-development: Actelion Pharmaceuticals Japan Ltd.								
ted together with Actelion Pharmaceuticals Japan Ltd.									
aku	Nippon Shinyaku								
activity. Has an effect on intractable pruritus that does not respond to existing treatments. ssociated pruritus.									
m:Dainippon rma Co., Ltd.	Nippon Shinyaku		Preparation						
afferent nerve	fibers. Signed a licensing agr	eement wit	h Dainippoi	n Sumitomo	o Pharma Co	o., Ltd.			

gin	Development	Phase I	Phase II	Phase III	Application	Launch
	Licensed-out to: Yuhan Corporation (Korea)					Preparation
yaku	Licensed-out to:Lee's Pharmaceutical Holdings Ltd (Hong Kong)			Preparation		
yaku	Licensed-out to:Actelion Pharmaceuticals Ltd. (Switzerland)					
yaku	Licensed-out to: CytRx Corporation (USA)					
esistant and/or	recurrent leukemia.					
yaku	Nippon Shinyaku					

## Sales

#### Core Measures

## Each division working closely together to execute action plans

As part of our marketing strategy, the emphasis of marketing activities has been placed on our new lineup of drug products. The Marketing Division combines its marketing, academic, and logistics capabilities to formulate and implement our marketing action plan. This refers to the streamlined integration of each strategy by providing each department with a specific direction to follow, which together leads to one solid action.

### For new drug products, we have established a system to respond promptly to the needs of medical professionals

A product manager has been assigned to each of our four new products: Lunabell<sup>®</sup>, Vidaza<sup>®</sup>, Adcirca<sup>®</sup> and Tramal<sup>®</sup>, to enhance promotional campaigns targeting key opinion leaders (KOL)\*1 throughout Japan, and to formulate strategies for the future of the drug as well as maximize its value, based on which specific action plans are implemented.

For the field of hematology, which is covered by Vidaza® and our other drug products, we have established a system to promptly respond to the needs of medical professionals by stationing 10 Area Product Managers (aPM) at four departments and seven offices across Japan. This enables our MRs and aPMs in charge of medical institutions throughout Japan treating blood cancers to work together to provide information on the proper use of our drug products. Also, we provide information to hematologists and pharmacists through hematological malignancy KOLs at academic seminars, etc. In MR activities, we will continue to strive for timely dissemination of information that matches the needs of medical experts as well as improve the quality and quantity of information provided.

## Undertaking sales and marketing with an added awareness of compliance

We are strongly aware of compliance and are committed to its thorough implementation. We conduct compliance training within each division every month on an ongoing basis, covering the Nippon Shinyaku Group Charter of Business Conduct, the Nippon Shinyaku Group Code of Practice, the Prescription Drug Promotion Code and the Fair Competition Code.

In fiscal 2012, we formulated our own transparency guideline based on the Transparency Guideline addressing the relationship between company activities and medical institutions established by the Japan Pharmaceutical Manufacturers Association. We are currently making preparations for disclosure of information starting in fiscal 2013.

Furthermore, as measures against counterfeit pharmaceutical drug products, we work to educate medical professionals by exhibiting counterfeit ED drugs at events co-sponsored with the Japanese Society for Sexual Medicine.

\*1 Physicians with the power to influence other physicians in their treatment decisions and the prescription trend within their medical specialty

## TOPICS

#### Provided high quality information on proper drug use in a more timely manner

In order to provide information in line with medical professional needs, we are working to enhance the quality of our MR detail and as part of these efforts we will launch an in-house MR gualification test program in fiscal 2013 that is separated into three stages (basic, advanced and specialist). Our information provision activities will focus in particular on Vidaza®, Adcirca® and other specialty drug products.

## **Production**

#### **Core Measures**

### We boosted inventories of anti-cancer drugs and implemented BCP\*2 activities at our Odawara Central Factory

The single greatest mission of Resource Procurement, Production & Assurance Division is to provide stable supplies of high quality active pharmaceutical ingredients and drug products to society. Therefore, we source raw materials from two separate suppliers for pharmaceutical products used to treat rare diseases as well as anti-cancer agents that have no substitution and possess a great influence on society, ensure the stable operation of production equipment, and pursue a rigorous approach to GMP\*3 controls.

As part of our efforts to ensure a stable supply of drug products, in fiscal 2012 we boosted inventories of anti-cancer drugs, which have a great impact on society, and systematically upgraded aging production equipment at our Odawara Central Factory in accordance with its BCP.

We also set up a production system to ensure stable supplies of new products planned for launch in fiscal 2013. \*2 Business Continuity Plan

\*3 Good Manufacturing Practice: Production management and quality management standards for pharmaceutical products

### Leveraging our strength as a novel drug manufacturer to focus on the consignment manufacturing

We are implementing cost reduction efforts within each division in order to enhance our profit margin.

In fiscal 2012, our Procurement Division reduced procurement costs by closely evaluating new suppliers and obtaining competitive bids, while the Manufacturing Division introduced measures, including expanding staggered work schedules, that have greatly reduced overtime hours, thereby reducing personnel costs. Our Logistics Division also cut costs by re-evaluating its shipping providers.



Tetsuyasu Yuno Director, General Manager, Sales and Marketing Division

#### Further expanding our information dissemination activities aimed at the sales growth of our new drug product lineup

We are making great efforts toward maximizing the potential of our new products launched since fiscal 2008. We assign Product Managers to each new drug product, have stepped up our lobbying efforts toward KOLs across Japan, and are creating and promoting strategies aimed at maximizing drug value and enhancing the future development of new drugs. In fiscal 2012, we established a system to provide important information to medical institutions on myelodysplastic syndrome treatment Vidaza®

In fiscal 2013, we will bring three new preparations to market, including an additional indication of chronic pain for Tramal®, Regtect®, a drug for supporting maintenance of abstinence in patients with alcohol dependence, and Lunabell® Compound Tablet ULD, a dysmenorrhea remedy. We will combine our marketing, academic and logistics capabilities to bolster our marketing activities and pursue sales activities that fulfill demand for more diverse academic information with the increase in the number of new drugs as well as demand for wholesale measures on the distribution side.

Going forward, we will reinforce our collection system for information on the proper use of our drug products and strive to enhance the quality of our MR detail. This will help us reach our goal of becoming a company that is trusted by both patients and medical professionals alike.

#### Enhancing our stable supply system and expanding our Consignment Manufacturing Business

Our most important mission is to provide a steady stream of high quality drug products to society. For this reason, we are strengthening our supply chain, procuring raw materials used in our pharmaceutical drug products from two different suppliers, ensuring the steady operation of production equipment, and implementing high standards of GMP. Furthermore, in the 4th Medium-term Management Plan (2009-2013), we established a BCP for the Odawara Central Factory and systematically implemented risk aversion strategies for the entire supply chain. In fiscal 2012, we increased inventories of drug products considered to have a great influence over society to ensure stable inventory, as well as established a production system to ensure the stable supply of new drug products planned for launch in fiscal 2013. Whereas, from a profitability standpoint, we transferred our ownership of the Chitose Synthesis Plant to a manufacturer of active pharmaceutical ingredients and intermediates. In the Consignment Manufacturing Business, which forms part of our efforts to generate new profits, we have been steadily increasing the number of consigned products thanks to highly positive assessments of our technological

prowess as a novel drug manufacturer.

In fiscal 2013, we will work to enhance our stable product supply system further, cut procurement, production and logistics costs, expand the Consignment Manufacturing Business including investigational new drugs, and make contributions to local communities.

Meanwhile, in addition to current drug products being manufactured on consignment, we began newly manufacturing one drug and two items on consignment. We are now focused on developing our Consignment Manufacturing Business, including investigational new drugs, by utilizing one of Japan's largest microparticle coating machines used to manufacture orally-disintegrating tablets which we installed at the Odawara Central Factory.

### Striving to advance quality assurance and safety management

As a pharmaceutical products business, it is essential for us to ensure the quality and safety of our products. To that end, our Assurance Division is mainly in charge of quality assurance and safety management.

The division performs audits of trials for obtaining new drug marketing approval and application documents at an appropriate stage to ensure the reliability of research data. In addition, it also implements scheduled and spontaneous audits at sites that manufacture active pharmaceutical ingredients and formulations to verify their compliance status with GQP\*4 and GMP.

As for managing the safety of our pharmaceutical products, in addition to adhering to GVP\*5, we also collect, analyze, and evaluate data on side effects via medical institutions, medical professionals, and related companies within Japan and abroad, as well as from patients, their family, articles, and conference reports. If an issue arises, we determine a response and report to the regulating authorities as well as provide feedback to medical professionals and patients.

Furthermore, in fiscal 2013, we plan on developing and enhancing an integrated pharmaceutical drug product risk management system spanning from development to post-marketing in accordance with the revised GVP ministerial ordinance (issued in March 2013) and Risk Management Plan (RMP).

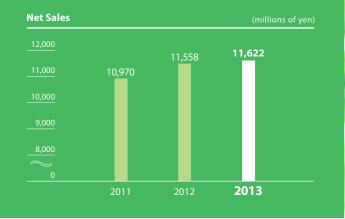
\*4 Good Quality Practice: Quality management standards for pharmaceutical products \*5 Good Vigilance Practice: Safety management standards for pharmaceutical products after marketing approva



**Tsugio Tanaka** Director, General Manager, **Resource Procurement, Production** & Assurance Division

# **Functional Food**

Nippon Shinyaku launched its functional food business in 1961 with the belief that "medicine and food have the same origin." We engage in the functional food business under the recognition that the functional food ingredients provided by Nippon Shinyaku must be at a higher standard of quality, functionality and safety because peoples' health directly correlates to the food they eat.





#### **Market Conditions**

## Consumers are saving more and needs for safety and security in food are rising

Japan's processed food market is facing its share of major challenges, including the emergence of lower priced private brands to match consumer's thrifty inclinations and pressure from distributors to lower prices, despite the rising price of raw materials. The size of the market, too, has continued to shrink on the back of Japan's aging population and declining birthrate. The time when simply making new products guaranteed sales has ended and today processed food manufacturers are fighting for their very survival.

Meanwhile, growth in the health foods market has stalled, despite supplements have shown steady growth as of late. The nutritional foods market for seniors and athletes continues to grow, but its overall size remains small.

Processed food manufacturers now face unprecedented consumer demand for information—including information about ingredient sources for better traceability and pesticide management information—to improve safety and security of food. At the same time, we have also faced an increase in costs and labor when it comes to ensuring food safety.

### **Sales Conditions**

## Revenue increased slightly on the back of an increase in sales of preservatives and nutritional ingredients

While difficult times persist, we are exploring new business opportunities by strengthening flagship products as we develop new ones in the Functional Food Company. As a result, despite the launch of new product "Amla Extract," sales of health food ingredients declined. Meanwhile, sales of preservatives grew steadily thanks to "Mikaku Fine Z." Nutritional ingredient sales also performed solidly thanks to an increase in revenue from caseinates and whey protein. Sales of protein preparations remained largely on par with the previous year, despite a drop in revenue from soy proteins. Based on the above, sales rose 0.6% year-on-year to ¥11.622 billion.

#### Main Strategy

## Develop functional food ingredients of enhanced quality, functionality and safety as well as expand sales

Functional Food Company's products include seasonings and spices, preservatives, protein preparations, health food ingredients, nutritional ingredients, sterilizers, cleansers, and wheat products. These are used as auxiliary ingredients in processed foods, health foods, and nutritional foods for seniors and hospitals, and are used in keeping factories sanitary. Created using a variety of techniques developed over many years through the pharmaceuticals business, these products undergo strict quality control and are well received and trusted by the food industry. In recent years, as the population ages and thinks more about its health, we are working on research and development and lineup enhancements for our functional food and ingredients for the nutraceutical<sup>\*</sup> and nutrition industries.

In terms of sales, we have regarded preservatives, protein preparations, health foods and nutritional ingredients as our flagship products and will expand sales of these products by narrowing the focus of target customers and markets. For preservatives, we will focus on growing sales of our proprietary preparations such as "Mikaku Fine Z" and the all-new "Glycine GX-2." As for protein preparations, our focus is on new product development for soy proteins and expanding sales of soy proteins and dried albumen. For health food ingredients, we will increase sales of hyaluronic acid, collagen peptide, and mangosteen extract, while also researching and collecting various data on working mechanisms to verify the specific

## We meet the needs of the times with precision, providing highly-original functional food and ingredients that benefit society

As a company dealing in functional food and ingredients under our philosophy "helping people lead healthier, happier lives," we make the most of our advanced manufacturing techniques, research and development capabilities, and quality control expertise honed through many years of the pharmaceutical business to provide high quality functional foods and ingredients that fulfill our customers' expectations. As a functional food manufacturer within Nippon Shinyaku, we make quality, functionality and safety a top priority as we conduct product development based on research into the functionality of food ingredients and promote our business efficiently and systematically. This will enable us to unlock growth and establish a stable earnings base through the expansion of our presence in the market place.

Consumer needs toward foods are growing more diverse and continue to change amid Japan's aging population and declining birthrate as well as changes in lifestyle and tastes. Going forward, we will adapt to these changes in needs and society to make contributions to society from the aspect of food by providing useful and proprietary functional food ingredients.



efficacy of products. As for nutritional ingredients, in addition to caseinates and whey protein for the medical and nursing care fields, we will increase sales in the fields of sports nutrition for training athletes as well as health foods for helping seniors to maintain and improve their health.

In order to satisfy consumers' increasing demands for safe and secure foods, we are reinforcing our product risk management and performing audits across the entire supply chain from Japan to sites overseas, strengthening our quality assurance system and providing accurate product information.

\*Nutraceutical is a new category situated between nutrition and pharmaceuticals that refers to foods and food ingredients that are beneficial to health maintenance and improvement.

#### Prospects for Fiscal 2013

### In addition to expanding sales of core products and bringing new products to market, we will be starting new business ventures overseas

Sales for fiscal 2013 are projected to be ¥11.9 billion, a 2.4% increase year-on-year.

Although hard times are expected to persist next year in Japan's food industry, we will expand sales of our core flagship products and bring at least one new product to market that fulfills the needs of users and the times in order to grow our functional food business.

In addition to the domestic market, we will also newly launch product exports for markets in Asia, including Taiwan and South Korea.



Hiroshi Adachi Director, COO, Functional Food Company

## **CSR** Management

## **Promoting CSR**

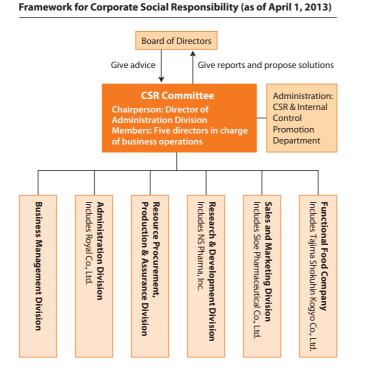
### **Our Approach to Corporate Social Responsibility**

The Nippon Shinyaku Group places great importance on meeting the expectations of diverse stakeholders who are connected with our business activities, in order to meet our corporate social responsibility (CSR).

To realize this approach, we have established codes of conduct each governing our relation to the environment and society, encompassing all stakeholders including patients, business partners, users, shareholders, investors, and our employees.

## Framework for CSR

The Nippon Shinyaku Group operates a CSR Committee that lays out the direction of CSR initiatives and works to confirm that corporate activities meet social standards and expectations, in seeking to expand the Group-wide implementation of CSR initiatives under the basic CSR policy. The committee engages in inter-departmental discussions regarding the direction of CSR initiatives and important related matters raised by business divisions, and reports to the Board of Directors and proposes solutions as the need arises.



#### **Our Approach to CSR**



## **Dialogue with Stakeholders**

### **Policy Regarding Dialogue with Stakeholders**

Nippon Shinyaku promotes CSR and we consider it important to listen to and engage in dialogue with all stakeholders —patients, business partners, users, shareholders, investors, and employees. Requests and feedback that we receive through dialogue help to shape our corporate activities, in aiming to fulfill our responsibilities to stakeholders and earn their confidence.

We believe that meeting the expectations of all stakeholders as the Nippon Shinyaku Group overall will enable us to grow as a corporation and in turn contribute to the sustainable growth of society.

## Nippon Shinyaku Group Charter of Business Conduct

#### **Creation of Charter of Business Conduct**

Nippon Shinyaku Group aims to continue expanding its pharmaceutical and functional food businesses following its philosophy of "helping people lead healthier, happier lives," while striving to be a company with a meaningful existence in healthcare.

For this reason, we believe it is of the utmost importance for each and every employee to implement our management policies of supplying unique and high-quality products, earning the trust of society, and developing each employee in our business activities.

In addition, we understand that in order to earn the trust of our stakeholders, we must strive to achieve regulatory compliance and adhere to internal rules, as well as conduct fair and honest business activities according to high ethical standards.

#### Continuing to strive to be a company with a meaningful existence

The Nippon Shinyaku Group believes its CSR should reflect its business philosophy of "helping people lead healthier, happier lives." We aim to achieve sustainable growth together with society as a company that is indispensable to our customers and society. As evidence of this, we responded to society's needs through the sale of Regtect®, which supports abstinence from alcohol in patients with alcohol dependence, and also launched the "Nippon Shinyaku & Seitaro Kuroda Smiles Art Project" which offers thoughtful artwork to cheer up people in hospitals and nursing care facilities. Moving forward, the Nippon Shinyaku Group as well as each and every one of its employees and executive officers will endeavor to sustainably develop the pharmaceuticals and functional food businesses, actively make social

contributions, and address global environmental issues, as part of our approach to address a wide range of social challenges. This approach forms our commitment to meeting our social responsibilities as a corporation.

As such, Nippon Shinyaku Group has developed the Charter of Business Conduct to serve as basic standards to put into practice within our business activities.

#### Nippon Shinyaku Group Charter of Business Conduct (revised in July 2011)

We will act with high ethical standards and in accordance with our business philosophy and management policy while always being conscious of our social responsibilities. We will also achieve regulatory compliance and adhere to internal rules in fostering a relationship of trust with society.
We, as employees of a company that deals with products that affect life, will strive to enhance our qualifications and quality of our work and act creatively.
We will maintain a safe and comfortable work environment by respecting each individual's rights and personality.
We will promote business activities that are environmentally friendly, and will aim to maintain and improve the global environment.
We will build a trusting relationship with our stakeholders through timely and adequate communication of company information.
We will implement unfettered competition that is fair and transparent by maintaining a healthy and adequate relationship with the politicians, governments, and business partners.
We fully recognize the values of our corporate assets including information asset, and will manage these appropriately.
We will not comply with inappropriate or unlawful requests from antisocial forces or organizations who threaten the safety and order of civil society.
As a member of society, we will take a proactive approach in social contribution activities.
We will comply with international rules and local regulations, as well as respect local culture and customs in our global business activities.



**Yoshiro Yura** Director, General Manager, Administration Division

Standing Alongside Patients and Medical Professionals



## In Pursuit of a Future Only Nippon Shinyaku Can Achieve

With a focus on patients with intractable conditions for which there is no effective treatment and on diseases where there is a strong desire to improve quality of life, Nippon Shinyaku is committed to making medicines with qualities only we can achieve. It's not just medicine we provide — as a pharmaceuticals company constantly concerned with what we can do for patients and those in the medical field, we also strive to do things like disseminate information about medicines, educate about medical conditions, and stamp out counterfeit medicines. Our highest mission is to continue our many efforts to ensure the safety of our patients.

### **Providing Information**

#### Educating Consumers about Ailments through Our Website

At Nippon Shinyaku, we distribute information helpful for resolving health concerns through our company website.

On our "Support Site for Alcohol Dependence" (http://alcoholic.navi.jp), created in March 2013, we provide a range of information about treatment for alcohol dependence that includes messages from medical specialists, abstinence success stories, and healthcare cost data.



Our Support Site for Alcohol Dependence

On our "ED Care Support" website (http://www.ed-care-support.jp/), we introduce medical institutions where individuals can receive consultations, and at the same time try to relieve any psychological resistance to seeking out help by dispelling some of the misunderstandings surrounding the issue of erectile dysfunction (ED). In addition, we are actively providing information and promoting awareness about counterfeit ED drugs.

We manage other websites as well, including our "Nose Care" site, which focuses on allergic rhinitis, and our "Talking about Menstrual Cramps" site, which encourages early checks for endometriosis and dysmenorrhea.

#### Public Lectures and Newspaper/Magazine Contributions

Every year since 1998, Nippon Shinyaku has invited physicians to give lectures open to public audiences. In January 2013, we held a medical symposium in Osaka with the theme "Experts Provide the Latest Information on and Appropriate Measures for Hay Fever". The symposium was attended by approximately 320 people.

We also contributed to a variety of media, such as our educational advertisements on ED in newspapers and in the magazine President. These contributions inform readers of accurate information on illnesses and up to date research developments in pharmaceutical treatments.

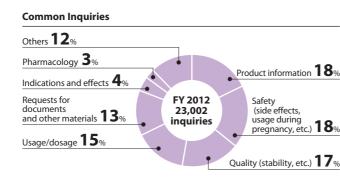
#### Providing Information about Nippon Shinyaku's Medicines

As pharmaceutical products have been described as "chemicals with directions attached," they are only effective when used properly based on accurate information. Consequently, Nippon Shinyaku has Drug Consultants who receive inquiries from physicians and pharmacists, and reply with advice on the proper usage of our products. Also, for patients and members of the general public, we respond to a broad range of inquiries with accurate, easy to understand information. Although the quantity of inquiries has been increasing year by year, introducing a CTI system<sup>\*1</sup> has allowed us to continue to provide prompt, accurate responses. Our system allows us to quickly convey valuable patients' and medical professionals' 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<sup>\*2</sup>, interview forms, package inserts, and updated usage warnings. Patients and general readers can find a pharmaceuticals guide and information aimed at improving wellness.

\*1 A system linking telephones and computers that routes calls to customer service representatives and provides information management and analysis functionality

\*2 Explanation sheets (in Japanese, English, and other languages) intended for patients



#### **Quality Assurance and Supply Stability**

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

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

At the R&D stage of product development, we carry out clinical and

non-clinical tests, and prepare application documents for manufacture and sales approval. Our Assurance Division audits these documents at the appropriate stage to assure the accuracy of non-clinical test data and the reliability of clinical trials.

After receiving manufacture and sales approval, we assure the quality of the product being manufactured and sold, affirm its safety, and work to manage and maintain manufacture and sales approval and license.

#### **Pharmaceutical Products Reliability Assurance**

R&D stage					
Nonclinical tes	ts	Clinical trials			
Test data reliability assur on GLP and reliability crit		Clinical trial reliability assurance based on GCP			
· · · · · · · · · · · · · · · · · · ·					
Pos	t-manufactur	e and marke	ting		
Manufacturing	Marketing		Approval, license maintenance, management		
Post-manufacture and marketing quality assurance based on GMP and GQP	Post-manufacture and marketing safety management based on GVP		Manufacture and marketing approval, manufacture and marketing license maintenance, management		

#### Framework for Supplying Products

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

Our diverse initiatives in this area include efforts to reduce lead times by enhancing the efficiency of our overall production process including quality control processes, and sourcing ingredients from more than one supplier to ensure stable procurement.

#### Framework for Supplying Products



#### Swift, Stable Product Supply

At our Odawara Central Factory, we have instituted a production framework dedicated to reducing manufacturing lead-time and ensuring swifter product supply. Multi-skill employee training<sup>\*3</sup> and a cell manufacturing system<sup>\*4</sup> have been introduced as part of this framework.

Also, we have adopted a Business Continuity Plan (BCP) in the event of any disasters, so that disruptions to the supply of products to patients may be avoided. In addition, we have diversified our storage locations for product inventory and are working with various partner companies to bolster our support framework. In fiscal 2012, with our continued focus on avoiding shortage risk, we have increased the inventory on hand of products with great importance in society.

\*3 Training and education that makes each employee proficient in multiple tasks \*4 A system where each production team is in charge of all manufacturing steps, in contrast to

\*4 A system where each production team is in charge of all manufacturing steps, in contrast to the standard model of separately dividing different manufacturing steps between teams

#### Close Collaboration between Three Management Chiefs

The Revised Japanese Pharmaceutical Affairs Law that took effect in 2005 stipulates that companies in the pharmaceutical products manufacturing

and marketing industry shall appoint "three chiefs": a marketing supervisor-general, a quality assurance manager, and a post-manufacturing-and-sales safety management supervisor. The marketing supervisor-general oversees the other two chiefs and is the official ultimately responsible for products placed on the market.

At Nippon Shinyaku, we follow these stipulations and appoint the three officials as a team of leaders that meets regularly to share information and ensure close, collaborative operations between all relevant departments.

### **Responding to Patient Needs**

#### Researching Market Needs

At Nippon Shinyaku, when we receive complaints from patients and medical professionals regarding product quality, we use the new information in assuring and improving product quality.

Nippon Shinyaku's Quality Assurance Division works under the supervision of the quality assurance manager to ensure the highest quality products. In close cooperation with domestic and overseas bulk substance and product manufacturing plants, audits of manufacturing facilities are performed regularly, or more often if necessary, with due compliance under the Pharmaceutical Affairs Law and related regulations.

Our Safety Management Division collects information on product side effects, etc. from a wide variety of sources, including domestic and overseas medical institutions, medical professionals, partner companies, patients, patient families, medical journals, and reports from academic associations. We analyze and evaluate this information, determine necessary response measures, issue reports to regulatory agencies, and supply feedback to patients and medical professionals.

#### Providing Pharmaceutical Products that Meet Patient Needs

Using information gathered from patients and medical institutions, we are developing products that are both easy to swallow and convenient to use.

For example, we are developing and providing medicines with less bitter aftertastes for patients who experience unpleasant tastes and orally dissolving medicines without any need for water for patients who have difficulty swallowing tablets.

#### Measures Against Counterfeit Drugs

Recent years have seen a health hazard caused by counterfeit medicines around the world.

Since 2009, we have been working with three companies involved in the manufacture and distribution of ED treatments on measures to combat the counterfeiting of ED medicines. Together we have investigated the authenticity of treatments and improved counterfeiting awareness through things like creating publications urging patient caution and holding press seminars for those in the media. Moreover, we have made the results of these investigations as well as other information related to ED pharmaceutical counterfeiting available through our ED Care Support website (see page 21).

We also established the anti-Counterfeiting Committee in June 2013 to inspect information related to counterfeit Nippon Shinyaku products and establish the proper countermeasures. The committee allows us to coordinate with our licensor and industry associations, and provide support for governmental initiatives.

## **CSR** Activities Report

## In Partnership with Employees



## Building Rewarding, Comfortable Workplaces

Individual growth is the soil of corporate growth. Based on this belief, we have created an array of education and training programs aimed at providing each of our employees with opportunities for growth. Another focus of ours is on promoting better work-life balance by creating corporate environments where individual human rights are respected, creating systems to ensure the health and safety of employees, and enhancing benefits programs, all with the goal of creating environments where people can work without worry.

#### Creating Productive, Employee-Friendly Workplaces

Nippon Shinyaku strives for appropriate work-life balance through an environment that harmonizes rewarding work and rewarding lifestyles for its employees. We promote the "Good Job Initiative" as part of this effort. Nippon Shinyaku defines the "Good Job Initiative" as: working productively, resting regularly, and leading a fruitful lifestyle that increases one's satisfaction and zest for life. Our policies for effecting this include identifying overloads, wastefulness, and inconsistencies in each work process, while advancing productivity and equality through incorporating appropriate rotation of duties. This prevents work from being disproportionately assigned only to certain individuals.

We have also implemented staggered work shifts beginning in fiscal 2012 that allow employees to set their start and finish times based on needs related to child raising, nursing care, or work. Fiscal 2013 plans call for improvement of our paid leave system.

#### Career Support System: "Growth For Each and Every Employee"

In fiscal 2010, we introduced a framework called CAST (Career Approach SysTem). As an in-house employee recruitment system, CAST makes information available about the types of workers each department is looking to acquire, with specific mention of desired skills and qualifications. Similarly, the aspirations of employees are also solicited so that the interests of both parties can be reflected in employee transfers and personnel changes. The system aims to foster autonomous, empowered employees and to help create the opportunity for them to proactively plan their future career paths. In addition to this, Nippon Shinyaku has established a Career Support Academy called CASA. This system is structured on the twin aspects of education and training for each level of employees, and elite education and training for core personnel. Support is also available for employees seeking to attain higher level degrees such as a doctorate or MBA. Our intention is to recognize the increased corporate value that comes from enhancements in the abilities of our employees, as well as to create a challenging and active organizational environment.

#### Promoting Women in the Workplace

In June 2011, we started the "Maruenu Supplement" project to provide support for women in the workplace.

By the end of fiscal 2012, we had come up with a list of support measures made possible by understanding women's work patterns through questionnaires to all employees and through interviews with individual departments. We will begin implementing these measures in fiscal 2013.

#### Hiring Employees with Disabilities

Operating on the belief that proactively hiring employees with disabilities is one of the social responsibilities incumbent upon us as a corporation, Nippon Shinyaku is focused on expanding employment and creating new job opportunities based on the principle of inclusion. Consequently, since fiscal 2007, we have carried out a dual system in collaboration with a special-needs support school. This system includes features such as involving a number of consultants for disabled workers. The consultants are stationed in the workplace to help promote an environment where disabled workers will be able to productively work side by side with non-disabled workers. This is one example of how we are working to create comfortable work environments for the disabled.

#### 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 at each of our facilities to identify potential risks and hazards in our workplaces and establish measures to prevent them. In connection with this, the Odawara Central Factory has operated an occupational health and safety management system (OHSMS). The system adheres to occupational health and safety system (OHSAS) 18001 and 18002 standards, and directs the plant to implement risk assessments. The

research laboratories also put an emphasis on conducting risk assessments for chemical substances, which is another effort towards preventing occupational accidents.



Poster promoting occupational safety

## Joining with Society and Local Communities

# Acting as a Member of Society to Bring About a Better World

In addition to supplying the world with high-quality drugs as a pharmaceuticals manufacturer, our other role is contributing to the development of communities as a member of society. As examples of means to achieve these goals, we strive to put the knowledge we have to use in making the world healthier and conduct awareness campaigns for medical conditions. In addition, we are also engaged in revitalizing communities and preserving the culture unique to our home region of Kyoto through initiatives that include helping organizations conduct public-interest activities, holding and sponsoring sports and culture events, and making our facilities such as Botanical Research Institute open to the public.

#### Disease Education Activities

Cancer is the most common cause of death in Japan, responsible for 1 out of 3 deaths. As part of cancer treatment, it is important to find ways for patients to avoid enduring excessive pain. In our efforts to see even one fewer person suffering from cancer-related pain, we have become part of the Cancer Pain Relief Consortium that strives to spread information and educate patients on therapies for pain relief. Similarly, we support the Ministry of Health, Labour and Welfare's Orange Balloon Project for increasing awareness of palliative care.

Also, a significant number of women endure menstrual cramps, though relatively few of them are aware that endometriosis or other disorders are possible causes. Nippon Shinyaku promotes a public education campaign symbolized by yellow ribbons in order to disseminate accurate information on menstrual cramps and endometriosis. We also publish and update relevant information on our "Talking About Menstrual Cramps" website (http://seiritsu.jp/). In addition, we continue to hold seminars on menstrua pain mainly during women's health week (March 1-8). In fiscal 2012, we





Our "Talking About Menstrual Cramps" website

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held our first menstrual pain seminar for occupational health nurses, general nurses, and obstetric nurses.

#### Nippon Shinyaku & Seitaro Kuroda Smiles Art Project

Beginning in March 2013, we 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 paintings at hospitals and nursing care facilities.

For the first event, on March 31 2013 we visited Ono District General Hospital (Ono-machi, Tamura-gun, Fukushima Prefecture) and drew murals on walls with some 70 people comprised of local elementary school students, hospital staff, and others from the community.

"Hospitals are where you go when you get injured or sick. Let us cover the walls with flowers and make hospital-goers smile." In about an hour, children driven by this appeal from Kuroda-san used crayons in a rainbow of colors to draw things like flowers, birds, and butterflies in any way they liked to make vivid hospital art<sup>\*</sup>.

We will continue to implement Nippon Shinyaku & Seitaro Kuroda Smiles Art Project and visit local hospitals and other facilities to strengthen the bond among doctors, patients, the elderly, children, students, and all people in society, and put a smile on their faces by making art together.

\* A method of setting patients' minds at ease through art by, for example, displaying sculptures and drawing pictures on hospital walls and pillars





At the project's first event

#### The Nippon Shinyaku Children's Literary Awards

Nippon Shinyaku wants to nurture the spirited growth and future dreams of the children who will inherit our world. With this hope in mind, we instituted the Nippon Shinyaku Children's Literary Awards in 2009 to mark 90 years since our founding. The Nippon Shinyaku Children's Literary Awards work with the support of the Japan Juvenile Writers Association to call for works of art as either stories or illustrations. **CSR** 

A winning submission is selected in each category and both works of art are made into picture books. Approximately 30,000 of these books are then distributed nation-wide to places like medical institutions and public libraries, as well as education boards in Kyoto (the site of our head offices) and Odawara (the site of our Central Factory) to reach a wide range of children. Also, visitors to our website are able to see electronic versions of the books and hear them read aloud as they browse the pages.

With support from The Kyoto Children's Center NPO, we conducted an awards ceremony in October where we invited the recipients of the Literary Awards. Participants at the event including local children took part in a workshop where they drew "important things" on a piece of paper 10 meters long. The fourth Literary Awards

contest saw the creation of the book Koguma and Mikazuki (Bear Cub and Crescent Moon), which tells the story of a black bear cub who realizes the importance of things close to him when the crescent moon mark on his chest suddenly disappears. Drawing in a free and easy manner, the children came up with two large pictures to express their "important things".



Furthermore, through our Shining Future for Children Fund, we collect donations from employees to support the Japan Committee – Vaccines for the World's Children, which strives to protect children in developing countries from infectious disease. The books printed through our Literary Awards contest are not intended for sale, but we have devised a scheme where people outside the company who donate 500 yen to the Shining Future for Children Fund may receive a free copy of one of the books.

Going forward, we would like to continue to expand the scope of the Nippon Shinyaku Children's Literary Awards to nurture the spirited growth of children, while supporting the creation of picture books that encourage the development of gentle, resilient youth.

#### Initiatives to Preserve Biodiversity

Nippon Shinyaku's Yamashina Botanical Research Institute was founded in 1934 as the Yamashina Pilot Farm and is an important part of our R&D efforts. The facility stores and cultivates nearly 3,000 varieties of medicinal and therapeutic plants gathered from across the globe. One of the products from the Institute, mibuyomogi, was used as an ingredient in our Santonin vermicide and greatly contributed to the growth of Nippon Shinyaku.

Also among the plants preserved and cultivated at the Institute are Tree tumbo (Welwitschia mirabilis) and many other species that are facing global extinction. The Institute preserves these, and carries out its horticultural research, as a way of contributing to the protection of

our natural biodiversity. Close collaboration is also promoted with professionals active at universities and horticulture centers within Kyoto, which allows for joint research symposiums and other opportunities to exchange information about environmental issues, and



Yamashina Botanical Research Institute

cultivating and preserving endangered plants.

Fiscal 2012 saw the continued appeal of the Institute, as approximately 110 groups (1,300 visitors in all) made time to stop by the facility and express their interest in learning about the connection between plants and medicine, and studying the valuable plants we preserve and cultivate. These visitors included plant enthusiast groups and local residents, groups from pharmacist associations and teachers and students at universities studying pharmacology and pharmacognosy, and doctors and pharmacists from across Japan interested in medicinal plants. We also held an indigo dyeing event during summer break for local elementary students.

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

Nippon Shinyaku is engaged in various activities to spread the historical heritage and traditional culture of Kyoto to a wide audience. Over the half-century, we have produced an annual calendar of Kataezome prints made using dyeing stencils and a traditional dyeing technique. The calendar images introduce a variety of aspects of Kyoto, including

seasonal landscapes and sights as well 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.



The Kataezome calendar and other items

#### Supporting Education through Sports

The Nippon Shinyaku amateur baseball team provides practical coaching guidance to elementary and senior high school students to promote sports in the local community.

The team also held the Japan High School Baseball Federation Kyoto Skills Development Clinic in November 2012 at Wakasa Stadium. Approximately 300 attendees from 73 high schools received hands-on instruction in baseball techniques as part of the team's effort to contribute to high schoolers' baseball skill development in the greater Kyoto community. Also in January 2013, we held our 3rd Youth Baseball Workshop for 27 teams and approximately 310 youngsters. The workshop was organized by the Kyoto City Amateur Sports Association and Kyoto Baseball Association, with support from the City of Kyoto. Similarly, in the same month, we collaborated with the Odawara Sports Association to hold the 5th Odawara Youth Baseball Clinic for 6 teams and approximately 70 players from local clubs in the city of Odawara. The baseball clinic held for the players from the Kushimoto Koza High School baseball team in February in Kushimoto, Wakayama Prefecture, where we hold our own annual spring training camps, is another example of these efforts.

These various clinics and events were intended to improve youths' baseball skills and physical strength, and create opportunities for exchange with the communities near our business locations.

Players receiving instruction at the 3rd Kyoto Youth Baseball Workshop



## Environmental Conservation Activities

# To Be a Company That Is Kind to the Environment

In order to pass on nature's bounty to future generations, Nippon Shinyaku is fully aware that its pursuits are closely tied with nature and recognizes the importance of practicing business activities that are in harmony with the environment. Based on this philosophy, we have set targets to reduce environmental burden while complying with environment-related laws and internal regulations.

#### Basic Environmental Policy

#### Nippon Shinyaku Basic Environmental Policy

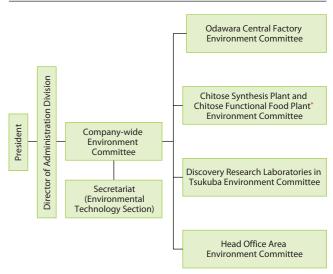
As a corporate citizen and to help people lead healthier and happier lives, Nippon Shinyaku will work to enrich society by establishing a policy for sustainable conservation of the environment, and settings goals for the entire company to pursue.

- We will establish and operate an internal organization responsible for environmental issues, for the collective pursuit of environmental conservation initiatives. We will also expand our self-management for the sustainable pursuit of environmental conservation initiatives.
- We will comply with environmental regulations and prepare internal rules and manuals to enhance our environmental conservation initiatives.
- We will predict and assess environmental impacts starting from the planning and development phases, to reduce environmental impacts at all phases in the product life cycle.
- 4. We will enhance our efforts in the areas of resource and energy conservation, waste reduction, recycling, chemical substances management, and green procurement.
- 5. We will train and educate all employees to recognize the importance of environmental conservation and act in a responsible manner.
- 6. We will actively communicate with local communities and share information, in an effort to enhance the quality of our environmental conservation initiatives.

#### Environmental Management System

In 1998, we formulated the Nippon Shinyaku Basic Environmental Policy as the guideline for our environmental conservation activities. The Company-wide Environment Committee, chaired by the director of Administration Division, was established to put this policy into practice and deliberates on the direction of environmental preservation activities and targets. This committee confirms the progress towards achieving the Nippon Shinyaku Environmental Targets Plan (see page 27), which is set every three years.

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#### **Environmental Management Structure**

\*Ownership of the Chitose Synthesis Plant and Chitose Functional Food Plant was transferred to a manufacturer of active pharmaceutical ingredients and intermediates in April 2013.

#### Applying Environmental Management Certification

Nippon Shinyaku has acquired external environmental management certification in implementing environmental activities, which helps with strict management of environmental burden.

We have attained ISO 14001 certification, an international standard in environmental management systems, at production facilities with significant environmental burden (Chitose Synthesis Plant, Chitose Functional Food Plant and Odawara Central Factory).

The head office area was certified by KES Environmental Management System Standard Step 2 (KES Step 2) in June 2012 once the introduction of an environmental management system became mandatory following a revision to the Kyoto City Global Warming Countermeasures Ordinance in April 2011.

#### Environmental Audits

Nippon Shinyaku regularly conducts audits through an internal organization or external institution in order to confirm the effectiveness of its environmental management.

#### Audits at Sites with Environmental Management Certification

For production facilities that have acquired ISO 14001 certification, namely the Chitose Synthesis Plant, Chitose Functional Food Plant, and Odawara Central Factory, Nippon Shinyaku conducts internal audits and undergoes third-party audits by outside organization every year.

The audit by the outside organization in fiscal 2012 merely pointed out certain items of observation, but none of the indications were considered a major environmental risk. We will continue working to enhance our environmental management system by further promoting low-cost management in consideration of the environment as a tool to bolster ongoing environment improvement activities and management efficiency.

## **CSR** Activities Report

#### Audits at Other Sites

The department that oversees environmental management for head office conducts environmental audits every three years for business locations (including consolidated subsidiaries) that engage in manufacturing and R&D activities but are not presently certified by

#### **Results of ISO 14001 Review**

Business Location		"Chitose Synthesis Plant, Chitose Functional Food Plant	Odawara Central Factory	
Time of IS	O 14001 acquisition	December 2002	August 2004	
Last third-party audit		October 2012 (regular audit)	February 2013 (renewal audit)	
Nonconformities	No. of minor nonconformities	0	0	
Noncomornities	No. of observations	1	3	

\*1 ISO 14001 certification for the Chitose Synthesis Plant and Chitose Functional Food Plant was taken over by Chitose Hamari Yakuhin K.K. after the transfer of these facilities to said company (on April 1, 2013).

**3rd Nippon Shinyaku Environmental Targets Plan and Results** 

Nippon Shinyaku has pursued continuous environmental preservation activities along clear medium-term goals that we have set for ourselves. Since fiscal 2011, we have centered our activities around the 3rd Nippon Shinyaku Environmental Targets Plan (Fiscal 2011-2013).

Objective	Targets	FY 2012 Results
CO2 Emissions Reductions (Global Warming Countermeasures)	<ul> <li>Hold FY 2013 CO<sub>2</sub> emissions at or below FY 1990 levels. (JPMA target: 23% reduction by FY 2020, as compared to FY 2005 levels)</li> </ul>	<ul> <li>Although total energy consumption was at the same level as FY 2011, CO<sub>2</sub> emissions in FY 2012 increased by 6.7% compared with FY 1990 levels to 11,272 tons<sup>-2</sup> due to an increase in the CO<sub>2</sub> emission coefficient resulting from a decline in operating ratio of nuclear power plants.</li> <li>96.5% of the 692 sales vehicles are now low-emission vehicles.</li> </ul>
Reduction of Waste	<ul> <li>Achieve zero emissions<sup>*3</sup> company-wide by FY 2013.</li> <li>Actively pursue the 3Rs (Reduce, Reuse, Recycle) and work to increase our usage ratio of recycled materials.</li> </ul>	<ul> <li>With a FY 2012 final landfill waste ratio of 0.5%, we were able to meet our zero emissions target.</li> <li>Waste volume increased to 471 tons at our main business locations, up from 462 tons in FY 2011.</li> </ul>
Promote Proper Management of Chemical Substances	<ul> <li>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.</li> </ul>	• The amount of chloroform handled in FY 2011 <sup>*4</sup> decreased by 24.4% compared with FY 2010 but the amount of dichloromethane and acetonitrile handled increased by 59.3% and 10.8%, respectively.
Promote an Environmental Management System (EMS)	<ul> <li>Continually improve the results of our environmental performance by maintaining ISO 14001 certification.</li> <li>Introduce an EMS tailored to the characteristics of our head office's area.</li> </ul>	<ul> <li>We completed the periodic inspection of ISO 14001 in October 2012 at the Chitose Synthesis Plant and the Chitose Functional Food Plant.</li> <li>The Odawara Central Factory completed renewal of ISO 14001 certification in April 2013.</li> <li>We acquired certification of KES Environmental Management System (KES Step 2) at our head office area in June 2012.</li> </ul>
Environmentally Conscious Product Upgrades and Materials Procurement	<ul> <li>Reduce product packaging materials as part of pharmaceutical product package simplification efforts.</li> <li>Promote green purchasing and procurement practices.</li> </ul>	<ul> <li>We employed a more environmentally friendly method of printing for printed materials used by medical professionals.</li> <li>We introduced green purchasing measures for office supplies at our main business locations (Green purchasing rate was 91% in FY 2012)</li> </ul>
Communication with Society and Local Neighbors	<ul> <li>Actively participate in activities to give back to the areas where we do business.</li> <li>Appropriately disclose information (through our corporate website and Annual Report) to society and to the local areas of our business offices.</li> </ul>	<ul> <li>Implemented beautification projects at our business offices and in surrounding local communities.</li> <li>Participated in volunteer tree-planting activities at the Chitose Synthesis Plant and the Chitose Functional Food Plant.</li> <li>Collected aluminum cans at our Odawara Central Factory and donated three wheel chairs to the Odawara-city Welfare for the Disabled Conference. Also started support activities to send vaccines through a movement to collect pet bottle caps.</li> <li>Held guest lectures at elementary schools in Kyoto.</li> </ul>
Promote Environmental Education	<ul> <li>Implement environmental preservation education for all of our employees.</li> </ul>	<ul> <li>Each of our main business locations decided on an environmental education theme and carried out employee instruction programs to raise awareness of these preservation topics.</li> </ul>
Providing an Environmental Organizational Structure	<ul> <li>Review and strengthen the organization of our Environment Committee in order to promote company-wide environmental preservation activities.</li> <li>Clearly identify environmental management responsibility and authority while promoting high quality environmental preservation activities.</li> </ul>	<ul> <li>Activities initiated by the Energy Efficiency and Conservation Promotion Committee in FY 2011 were incorporated into the activities of the Environment Committee at each Business Office in order to save electricity and energy across the board.</li> <li>KES Step 2 was introduced at our head office area to clarify the responsibility and authority of officers in EMS structures and promote environmental improvement activities.</li> </ul>

\*2 This figure is for the business locations to which the fiscal 1990 emission amounts are applicable (i.e., our main business locations apart from our sales offices, etc.); total emissions were 13,900 tons. Calculations are made using the CO2 real emissions coefficients from the Ministry of Economy, Trade and Industry

\*3 "Zero emissions" is defined as a final landfill waste ratio (final amount of landfilled waste/amount of waste generated x 100) of 1.0% or lower achieved by the recycling of waste generated during business activities. \*4 Due to compilation methods, data displayed extends up to fiscal 2011

environmental management systems, to confirm the status of environmental preservation activities and compliance with environmental laws and regulations. In fiscal 2012, there were no sites that were subject to audit. We plan to audit our consolidated subsidiary Sioe Pharmaceutical Co., Ltd. in fiscal 2013.

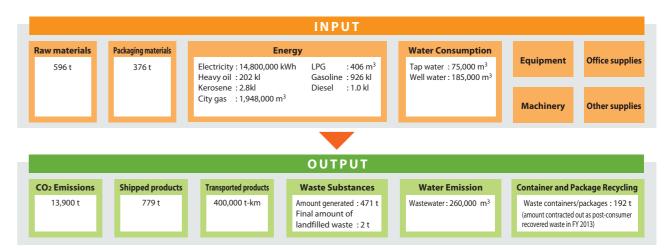
#### **Result of KES Step 2 Registration Review**

Busi	iness Location	Head Office Area
Time of certificate acquisition		June 2012
Last third-party audit		May 2012 (Review for certification)
Nonconformities	No. of minor nonconformities	1
NOTICOTTOTTTUES	No. of observations	1

#### Material Balance in Our Business Activities

Material balance refers to the amounts of input, in terms of resources and energy used in our business activities, and output, in terms of the environmental impact of manufactured and marketed products, waste substances, greenhouse gas emissions, wastewater, etc. Understanding the material balance offers a way to gain an overall picture of Nippon Shinyaku's effect on the environment.

environmentally detrimental outputs from its business activities.



#### Environmental Accounting

Nippon Shinyaku carries out environmental accounting, based on Company criteria, aimed at efficiently and effectively promoting our environmental preservation efforts. As part of this environmental accounting, we quantitatively assess environmental conservation costs and environmental conservation gains. The costs are categorized according to the connections between business activities and environmental impacts, and the gains are the result of efforts to lessen our burden on the environment. The environmental conservation gains are stated as year-on-year increases or decreases in environmental impact items in the material balance calculations.

\*Statistical methodology: refer to the Ministry of the Environment's Environmental Accounting Guidelines, 2005 ver.

#### . . . E

Environmental Conservation Cos	ts		(unit: thousands of yen)
Costs	Investments	Expenses	Primary Initiatives
Costs within our business areas	76,202	168,089	
Pollution prevention costs	4,994	31,083	Upgrading deodorizing/exhaust control apparatus; maintenance management of wastewater processing facilities
Global environmental conservation costs	70,368	70,808	Energy conservation activities
Resource recycling costs	840	66,198	Proper waste disposal efforts
Upstream and downstream costs	0	6,877	Contract costs for post-consumer container/packaging recovery efforts*5
Management activity costs	1,791	86,032	EMS maintenance and operation, green space conservation, environment-related personnel expenses
R&D costs	0	0	-
Social activity costs	0	5,282	Donations and funding for groups involved with our Elementary School lectures and environmental preservation initiatives
Environmental remediation costs	0	0	-
Total	77,993	266,280	

#### **Environmental Conservation Benefits**

Benefit verification	Units	FY 2011 Results	FY 2012 Results	Amount of Increase/Reduction	Rate of Increase/Reduction
CO <sub>2</sub> emissions	Tons	12,185	13,900	1,715	14.10%
Electricity usage	Thousand kWh	14,453	14,800	347	2.40%
Oil, kerosene usage	kl	217	205	▲12	▲ 5.5%
City gas, LPG usage	Thousand m <sup>3</sup>	1,986	1,948	▲ 38	▲ 1.9%
Gasoline, diesel usage	kl	942	927	▲15	▲ 1.6%
Water consumption (main business locations)	Thousand m <sup>3</sup>	273	260	▲13	4.8%
Waste substances generated (main business locations)	Tons	462	471	9	1.9%
Final amount of landfilled waste (main business locations)	Tons	2	2	0	0.0%

\*5 Nippon Shinyaku pays commission fees based on the amount of product containers and packaging generated in accordance with the Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging. The amount of payments in fiscal 2012 amounted to 6,342,000 yen.

Nippon Shinyaku uses the material balance information in its efforts to decrease the amounts of resource and energy inputs as well as

#### (excluding our sales offices)

## **CSR** Activities Report

### **Reducing CO<sub>2</sub> Emissions**

Targets	Hold fiscal 2013 CO <sub>2</sub> emissions at or below fiscal 1990 levels.
FY 2012 Results	Increased by 6.7% to 11,272 tons <sup>*1</sup> compared with fiscal 1990 (10,569 tons).

#### Energy Conservation Efforts

Nippon Shinyaku is continuously endeavoring to conserve energy and reduce emissions of CO<sub>2</sub>. These efforts include switching boilers and air conditioning equipment to energy efficient models when they reach the end of their life span, and reassessing how and when the equipment is operated.

In fiscal 2012, although energy consumption increased at the Odawara Central Factory due to expanded production, total energy consumption was roughly on par with fiscal 2011 thanks to across-the-board efforts to save electricity and energy coupled with the upgrade of air conditioning units in the Research Laboratories Kvoto and the administration building in the head office area to more efficient equipment. Despite this, CO2 emissions for fiscal 2012 increased by 6.7% to 11,272 tons compared with the targeted 1990 level (10,569 tons) as a result of an increase in the CO<sub>2</sub> emission coefficient caused by a decline in the operating rate of nuclear power plants.

\*1 This figure is for the business locations to which the fiscal 1990 emission amounts are applicable (i.e. our main business locations apart from our sales offices, etc.): total emissions were 13,900 tons Calculations are made using the CO<sub>2</sub> real emissions coefficients from the Ministry of Economy, Trade and Industry

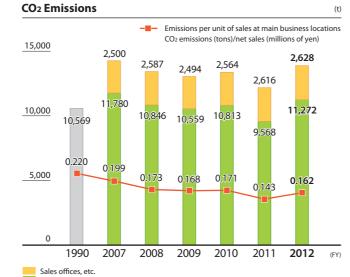
#### Introducing Environmental Friendly Vehicles in Our Sales Fleet

Our policy is to use low emissions models (with 4 star ratings for 75% emissions reduction based on 2005 criteria) for our fleet of sales force vehicles, and since fiscal 2008 we have been gradually phasing in high gas mileage, low CO<sub>2</sub> hybrid models. As of the end of fiscal 2012, 96.5% of the 692 vehicles used by our sales force were low emissions vehicles.

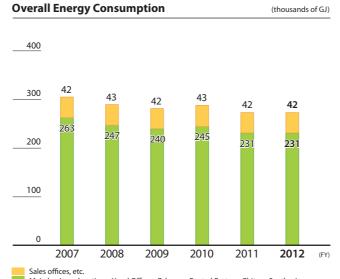
In addition, we stepped up our environmental preservation activities by promoting use of public transport in Tokyo. At the same time, we are promoting awareness of eco-driving throughout the Company.



Sales force hybrid vehicle

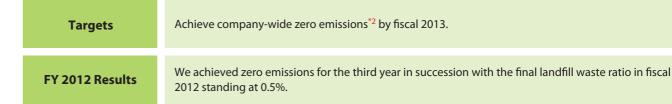


Main business locations: Head Offices, Odawara Central Factory, Chitose Synthesis Plant & Functional Food Plant, Discovery Research Laboratories in Tsukuba



Main business locations: Head Offices, Odawara Central Factory, Chitose Synthesis Plant & Functional Food Plant, Discovery Research Laboratories in Tsukuba

### **Reducing Volume of Waste**



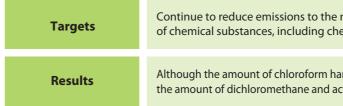
#### Results of Initiatives

The amount of waste generated in fiscal 2012 was 471 tons—a 9-ton increase over fiscal 2011's amount. However, we achieved zero emissions for the third year in succession with the final landfill waste ratio standing at 0.5%.

Also, in accord with the PCB Special Measures Act, we are stringently following storage protocol for PCB waste in the head office area and the Odawara Central Factory. In addition, two ballasts and one transformer unit were removed from the Sapporo Business Office and the Yamashina Botanical Garden, respectively, and taken to the head office area for storage pursuant to the law.

\*2 Nippon Shinyaku is targeting zero emission, which is a final landfill waste ratio (Amount of final waste/Amount of waste generated x 100) of under 1.0% by reusing waste generated in business activities

### **Proper Management of Chemical Substances**

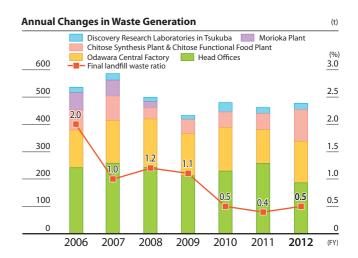


#### Results of Initiatives

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

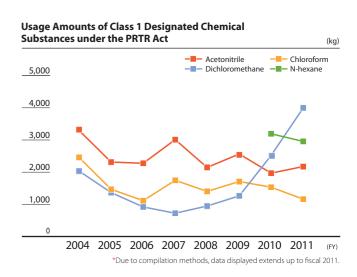
The amount of chloroform and n-hexane handled in fiscal 2011 decreased by 24.4% and 7.4%, respectively, compared with fiscal 2010, whereas the amount of dichloromethane and acetonitrile handled increased by 59.3% and 10.8%, respectively. In particular, the amount of dichloromethane handled has continued to increase significantly since fiscal 2010. We will work to reduce the amount of these substances handled, with this marked as an area of focus under our environmental management system (KES Step 2) for fiscal 2013. In the same manner, we promoted establishment of an SDS (Safety Data Sheet) and understanding among employees of the harmful effects of chemical substances within risk assessments related to occupational safety and health as areas of focus under KES Step 2 for fiscal 2012.

\*3 Act on confirmation, etc. of release amounts of specific chemical substances in the environment and promotion of improvements to the management thereof



Continue to reduce emissions to the natural environment by promoting appropriate management of chemical substances, including chemical substances designated under the PRTR Act<sup>\*3</sup>.

Although the amount of chloroform handled in fiscal 2011 decreased by 24.4% compared with fiscal 2010, the amount of dichloromethane and acetonitrile handled increased by 59.3% and 10.8%, respectively.



## **Corporate Governance**

# **Corporate Governance and Internal Control**

#### **Our Approach to 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 we are committed to further expanding the framework for internal control, compliance, and risk management.

#### Framework for Corporate Governance

Nippon Shinyaku employs a system of auditors, with the general meeting of shareholders, Board of Directors, and Board of Auditors serving as internal bodies.

Outside directors have been elected since fiscal 2012 to further strengthen the supervisory function related to the execution of duties by directors and to further boost transparency and objectivity in management. In line with this, two outside directors were elected at the general meeting of shareholders held in June 2013.

The Board of Directors is comprised of nine directors, including two outside directors, and convenes in principle once a month. The Board of Directors makes decisions and reports on important matters related to management. Each director is responsible for executing separate areas of work in order to efficiently manage the Company.

The Board of Auditors is comprised of four auditors including two outside auditors. These auditors attend meetings of the Board of

Directors and other important meetings, in addition to reviewing documents and periodically meeting with the President, and work closely with the Internal Audit Department to provide an effective framework for audits.

#### Internal Control System

The internal control system is stipulated under the Companies Act and prescribes the fundamental policies of the Board of Directors, while establishing a framework to ensure the proper execution of the business. Through internal control, we strive to secure regulatory compliance and raise the effectiveness and efficiency of our business.

In addition, we have Compliance Operating Rules in place to secure the proper execution of business activities and employee duties, and have assigned a dedicated department to encourage compliance, while having a system in place for internal reporting. At the same time, we have assigned a dedicated department for risk management, to variously manage risks that could have a critical impact on the management of the Company.

Since fiscal 2008, internal control reporting has been obligated under the Financial Instruments and Exchange Act, and to comply with these requirements we develop and operate a framework to secure the appropriateness of financial reporting and evaluate internal controls for financial reporting on a timely basis. Nippon Shinyaku employs Deloitte Touche Tohmatsu LLC as its accounting auditor, to help ensure the observance of proper accounting procedures and secure the transparency of management.

We operate the Internal Audit Department that reports directly to the President and is responsible for verifying that these frameworks are properly operating. The Internal Audit Department works with the Board of Auditors and accounting auditor to audit the effectiveness of internal controls as well as compliance efforts and risk management.

## Compliance

#### Framework for Compliance

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

#### **Compliance Initiatives**

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

In fiscal 2012, we implemented the training and education activities outlined below, and the President and compliance officer issued messages to employees in April and October 2012 to stress the need for compliance.

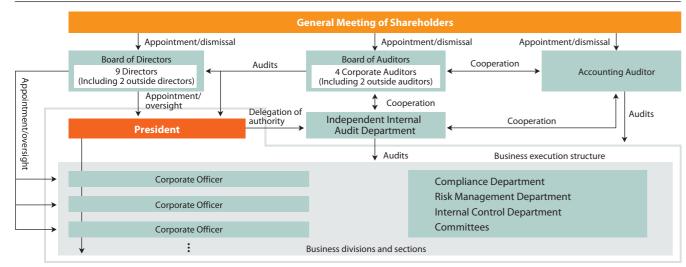
#### **Compliance Training in Fiscal 2012**

Type of Training Description	Description
Departmental compliance training (monthly)	Conducted departmental training incorporating company-wide content and department-specific content.
Training for new employees (April)	Training that focuses on teaching new employees about compliance concepts and approaches, and stressing the importance of compliance.
Training for newly promoted managers (April, October)	Training that focuses on teaching compliance to newly promoted managers.
Direct training (October-January)	Employees of dedicated departments are sent to Head Office, Business Offices nationwide and Group companies to provide training. Training was focused on the importance of case studies in compliance in fiscal 2012.
Training on compliance for management (January)	Training that focuses on promoting compliance in the Nippon Shinyaku Group.
Training on the Charter of Business Conduct for new employees (As needed)	Request to enhance understanding of and compliance with the Charter of Business Conduct.

#### **Education Initiatives**

- Conducted e-learning education for compliance for employees in the 2<sup>nd</sup> year of employment.
- · Prepared a compliance education poster with a slogan and design
- applied by employees, and put up posters in each department.
- Distributed a compliance reference card to all employees.
- Conducted a survey on compliance-related awareness.

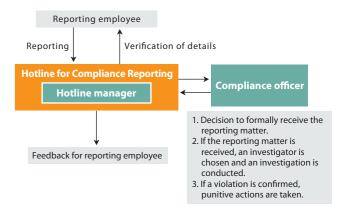
#### Organization for Corporate Governance (As of June 27, 2013)



## **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. The hotline can be reached through a dedicated phone number or e-mail address, and guidelines are 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. Employees are briefed on the hotline in training, and all employees receive a card that lists the hotline contact information, so that they are familiar with the system.



## **Risk Management**

### **Initiatives for Risk Management**

The Nippon Shinyaku Group has Basic Risk Management Rules in place that direct the Company to identify underlying risks and specify departments that are responsible for each risk. The Group also designates measures to prevent risks and crises as well as specifies countermeasures for when these situations arise.

Nippon Shinyaku positioned "information management," "disaster and accident response" and "power harassment" as priority areas of risks in fiscal 2012 based on a risk awareness survey conducted in fiscal 2011, and worked to strengthen the management system.

First, in terms of "information management," we specified important electronic data in each division and reinforced password control in order to strengthen measures against leaks of confidential information. To prevent employees from making inappropriate posts on social media, we had outside lecturers give presentations to management and also provided an e-learning course. Management was then given the responsibility of passing on what they had learned to employees in the workplace, which helped enlighten people on the proper way to use social media.

In terms of "disaster and accident response," Nippon Shinyaku conducted Company-wide drills for ensuring employee safety and earthquake and fire response exercises for each Business Office with an

## **Corporate Governance**

emphasis on improving response capabilities. In particular, we held experience-based fire extinguishing and emergency life-saving drills for all employees in the head office area, in which they learned how to use a fire extinguisher and AED as well as the procedure for cardiopulmonary resuscitation.

Finally, in terms of "power harassment," we held training in each workplace and had outside instructors give presentations, which helped boost awareness of the need for prevention.

Nippon Shinyaku also implemented a risk awareness survey for management in fiscal 2012 as in fiscal 2011 to help identify key areas of risk to be addressed in fiscal 2013. These survey results and the results from previously implemented initiatives were discussed by the directors in charge of various departments and it was decided that the key areas of risk to focus on in fiscal 2013 were "information management" and "general workplace harassment."

### Framework for Risk Management

The Nippon Shinyaku Group has a contact system and response procedures in place if a risk or crisis arises, under Basic Risk Management Rules.

If an employee has information that a risk has or may have occurred, he or she notifies the supervising manager, who in turn notifies the risk management department and the director in charge of risk management. If the employee determines that there is a particularly high level of urgency, he or she directly notifies the risk management department. The risk management department reports to the director in charge of risk management, and the director judges the degree of impact on business activities from the risk. If the risk is determined to have a minor impact, the supervising department for the particular risk is instructed to respond and take action. However, if the risk is determined to have a major impact signifying a crisis, the

situation is immediately reported to the President and a temporary crisis management office is assembled headed by the Company directors. At the same time, a working group in charge of practical response is assembled to summarily report to the crisis management office with information that is needed to help in decision making, and to report on proposed countermeasures. The working group also establishes a framework to enable rapid response according to instructions from the crisis management office.

### **Initiatives for Information Security**

In today's rapidly shifting business conditions, the information risks that affect corporations are continually changing, while the spread of new and convenient information technologies is also giving rise to new risks. To secure and maintain information security, corporations must continually implement measures under a security policy.

Nippon Shinyaku implements a basic policy and rules to guide our initiatives for information security. We operate an information security management system (ISMS) committee that implements specific rules for information security, guided by the basic policy and rules.

We also formulated new guidelines for the handling of social media and distributed them to all employees in light of the increasing pervasiveness of social media and the growing number of users.

In fiscal 2012, we once again reviewed our handling of confidential information and examined the handling of e-mails that are sent outside the company.

In addition, we study and analyze IT risks and examine countermeasures for the damage and loss of electronic data as well as data falsification and leakage as needed. Moving forward, Nippon Shinyaku will continue to address information security concerns with an emphasis on preventing the leakage of confidential information.



From left: Yuno, Matsuura, Adachi, Tanaka, Yura, Maekawa, Fukushima, Sugiura, Sakata

riesident
Shigenobu Maekawa

Ducaldand

Hiroshi Adachi (General Manager, Functional Food Div.)

Directors

Yoshiro Yura

#### **Managing Director**

Kazuo Fukushima (General Manager, Business Management)

Tsugio Tanaka (General Manager, Resource Procurement Production & Assurance Div.)

(General Manager, Administration Div.)

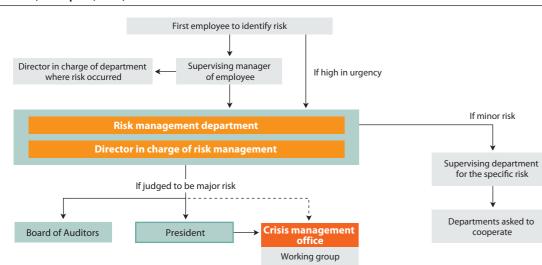
Akira Matsuura (General Manager, Research & Development Div.)

Tetsuyasu Yuno (General Manager, Sales and Marketing Div.)

Yukio Sugiura (External Director

Hitoshi Sakata (External Director)

## Path of Risk Notification (as of April 1, 2013)





From left: Tanabe, Toriyama, Kameyama, Suzuma

**Corporate Auditors** 

Yoichi Toriyama (Standing Corporate Auditor)

Kenji Kameyama (Standing Corporate Auditor)

#### **Corporate Officers**

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

Kiyotaka Konno (General Manager, Clinical Development Div.)

Yoshitaka Fukuda (General Manager, Personnel Dept.)

Shigeki Sonoda (General Manager, Odawara Central Factory)

Hironori Ninomiya (General Manager, Regulatory Affairs Supervision & Assurance Div.)

Hitoshi Saito (General Manager, Research & Development Administration Div.)

Kenro Kobayashi (General Manager, Kinki-Tokai Div.)

Yasuo Tanabe (Outside Auditor

Yoshishige Suzuma (Outside Auditor)

Hideya Mukai (General Manager, Discovery Research Labs.)

Shouzou Sano (General Manager, Syutoken Div.)

Seiichiro Morimura (General Manager, Business Development Div.)

Tomoyuki Ota (General Manager, Kitanihon Div.)

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

Hiranori Edamitsu (General Manager, Business Management)

As of June 27, 2013

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**Tokyo Business Office** 8-4, Nihonbashi 3-chome, Chuo-ku, Tokyo 103-0027, Japan Phone: +81-3-3241-2151 Facsimile: +81-3-3241-2262

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#### **Business Branch**

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**Odawara Central Factory** 676-1, Kuwabara, Odawara 250-0861, Japan Phone: +81-465-36-4111 Facsimile: +81-465-37-1033

#### **Overseas Offices**

**Beijing Representative Office** 3015, Changfugong Office Building, No.26, Jian Guo Men Wai street, Chaoyang District, Beijing, 100022, China

London Office Building 3, Chiswick Park 566, Chiswick High Road, Chiswick, London, W4 5YA, UK

#### **Subsidiaries**

Phone: +81-6-6499-2601

#### NS Pharma, Inc.



#### **Overseas Offices/Subsidiaries**





Beijing Representative Office



NS Pharma, Inc.

# **Financial Section**

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Business Risks	- P38
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Consolidated Statement of Comprehensive	e Income
Consolidated Statement of Changes in Equ	ity
Consolidated Statement of Cash Flows	

## **Operating Results**

#### **1. Fundamental Policy Regarding Profit Sharing**

Under our strategy to maximize corporate value, we strive to strengthen our business foundations by bolstering R&D to expand the pipeline for product development, and retaining sufficient earnings to enable us to maintain a corporate position to withstand increasingly competitive conditions.

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

For the year ended March 31, 2013, we issued an annual cash dividend of ¥21 per share, comprising an interim dividend of ¥10 per share and year-end dividend of ¥11 per share.

For the year ending March 31, 2014, we are projecting an annual dividend of ¥23 per share, comprising an interim dividend of ¥11 per share and year-end dividend of ¥12 per share.

#### 2. Financial Condition

With notes and accounts receivable as well as inventory assets increasing since March 31, 2012, current assets rose by ¥4,599 million. Due in part to a year–on-year increase in investment securities, fixed assets rose by ¥2,827 million. Total assets consequently rose by ¥7,426 million to ¥113,730 million.

Liabilities increased year-on-year by ¥2,462 million to ¥24,201 million. Accounts payable, income taxes payable, and other account payables increased and current debts increased by ¥1,716 million. Deferred tax liability etc. increased and fixed debts rose by ¥746 million since March 31, 2012.

Net assets increased by ¥4,963 million year-on-year to ¥89,529 million. Equity increased by ¥3,280 million year-on-year to ¥84,366 million. Accumulated other comprehensive income rose by ¥1,675 million to ¥4,964 million.

The equity ratio was 78.5%.

Net cash from operating activities amounted to ¥3,767 million. The main cash inflows were income before income taxes of ¥7,286 million and depreciation costs of ¥2,759 million, while the main outflows were an increase in income tax paid of ¥2,341 million, an increase in account receivables of ¥2,278 million, and a rise in inventory assets of ¥1,341 million.

Net cash used in investing activities amounted to ¥2,026 million. The main cash outflows were expenditure of ¥1,020 million for acquisition of tangible fixed assets and ¥677 million for long-term prepaid expenses.

Net cash expended for financing activities amounted to ¥1,413 million, primarily comprising cash payment of dividends. As a result, cash and cash equivalents as of March 31, 2013

increased by ¥379 million year-on-year, to ¥20,044 million. Nippon Shinyaku takes care to maintain a sound balance

sheet and secure appropriate levels of liquidity and access to capital necessary to carry out our business activities.

#### 3. Summary of Consolidated Business Results

#### 1. Pharmaceuticals

In the pharmaceuticals segment, sales of products such as Hypen® non-steroidal analgesic and anti-inflammatory agent and Eviprostat®, a treatment for benign prostatic hypertrophy were down due to competing and generic drugs. However, sales of Vidaza®, a remedy for myelodysplastic syndrome, and the allergic rhinitis remedy Erizas® showed considerable growth, and the sales of Lunabell® dysmenorrhea remedy and Adcirca® treatment agent for pulmonary arterial hypertension also increased. Sales consequently increased 4.6% year-on-year to ¥58,318 million.

#### 2. Functional Food

In the functional foods segment, both the processed food and health food sectors continued to be marked by challenging business conditions. Although sales of health food ingredients dropped, we increased our sales of nutritional ingredients and preservatives. Sales of protein preparations stayed mostly level. As a result, net sales in the functional foods segment were ¥11,622 million, a year-on-year increase of 0.6%.

## **Business Risks**

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

#### **1. Regulatory Control Risks**

The core pharmaceuticals and functional food businesses of the Nippon Shinyaku Group are strictly regulated under the Pharmaceutical Affairs Act and Food Sanitation Act. In the event that regulatory changes require the Group to recall or cease the sale of products, it could impact our business results. In addition, there are intellectual property theft risks and product liability risks, that in some cases could impact our business results.



#### 2. R&D Risks

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

#### 3. Side Effect Risks

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

#### 4. Drug Price Revision Risks

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

#### 5. Manufacturing and Procurement Risks

The Nippon Shinyaku Group is improving its production efficiency by concentrating its manufacturing facilities. At the same time, if operations at manufacturing facilities cease due to a natural disaster or other circumstance, it could interrupt the supply of products and impact our business results. In addition, we procure certain products and important ingredients from specific suppliers. If the supply is interrupted, it could impact our business results.

## Consolidated Balance Sheet

ippon Shinyaku Co., Ltd. and Consolidated Subsidiaries arch 31, 2013	Millior	ns of Yen	Thousands of U.S. Dollar (Note 1)		
SSETS	2013	2012	2013		
CURRENT ASSETS:					
Cash and cash equivalents (Note 11)	¥ 20,044	¥ 19,665	\$ 213,234		
Time deposits (Note 11)	242	322	2,574		
Notes and accounts receivables (Note 11):					
Trade notes	274	240	2,914		
Trade accounts	33,992	31,747	361,617		
Other	234	82	2,489		
Total notes and accounts receivables	34,501	32,070	367,031		
Inventories (Note 5)	13,266	11,925	141,127		
Deferred tax assets (Note 10)	1,637	1,635	17,414		
Other current assets	1,239	714	13,180		
Total current assets	70,932	66,333	754,595		
PROPERTY, PLANT, AND EQUIPMENT:					
Land	7,888	8,030	83,914		
Buildings and structures	26,215	26,146	278,882		
Machinery, equipment, and vehicles	12,505	12,577	133,031		
Tools, furniture, and fixtures	9,138	9,184	97,212		
Construction in progress	62	1	659		
Total	55,811	55,940	593,734		
Accumulated depreciation	(38,672)	(38,105)	(411,404)		
Net property, plant, and equipment	17,138	17,835	182,319		
INVESTMENTS AND OTHER ASSETS:					
Investment securities (Notes 4 and 11)	13,873	11,170	147,585		
Long-term prepaid expenses	8,829	8,111	93,925		
Deferred tax assets (Note 10)	62	199	659		
Other assets	2,895	2,653	30,797		
Total investments and other assets	25,659	22,135	272,968		
TOTAL	¥ 113,730	¥ 106,304	\$ 1,209,893		

	Mill	Thousands of U.S. Dolla (Note 1)		
IABILITIES AND EQUITY	2013	2012	2013	
CURRENT LIABILITIES:				
Notes and accounts payables (Note 11):				
Trade notes	¥ 1,682	¥ 1,413	\$ 17,893	
Trade accounts	3,345	3,605	35,585	
Other	3,061	2,710	32,563	
Total notes and accounts payables	8,089	7,729	86,053	
Income taxes payable (Note 11)	1,665	1,294	17,712	
Accrued expenses	3,587	3,530	38,159	
Deposits from customers	315	305	3,351	
Other current liabilities	2,019	1,101	21,478	
Total current liabilities	15,677	13,961	166,776	
LONG-TERM LIABILITIES:				
Liability for retirement benefits (Note 6)	7,418	7,357	78,914	
Deferred tax liability (Note 10)	715		7,606	
Other long-term liabilities	389	418	4,138	
Total long-term liabilities	8,523	7,776	90,670	
EQUITY (Notes 7 and 14):				
Common stock, authorized, 200,000,000 shares;				
issued 70,251,484 shares	5,174	5,174	55,042	
Capital surplus	4,445	4,445	47,287	
Retained earnings	76,839	73,541	817,436	
Treasury stock - at cost, 2,774,507 shares in 2013 and				
2,757,573 shares in 2012	(2,092)	(2,075)	(22,255)	
Accumulated other comprehensive income:				
Unrealized gain on available-for-sale securities	4,989	3,328	53,074	
Deferred gain on derivatives under hedge accounting	4	1	42	
Foreign currency translation adjustments	(30)	(41)	(319)	
Total	89,330	84,374	950,319	
Minority interests	198	191	2,106	
Total equity	89,529	84,566	952,436	
TOTAL	¥ 113,730	¥ 106,304	\$ 1,209,893	

5.41	1	Thousands of U.S. Dollars
		(Note 1) 2013
¥ 69,941	¥ 67,304	\$ 744,053
	_	_
34,776	32,702	369,957
28,263	28,588	300,670
63,040	61,291	670,638
6,901	6,012	73,414
287	289	3,053
(8)	(9)	(85)
105	(99)	1,117
385	180	4,095
7,286	6,193	77,510
2,715	2,229	28,882
(90)	230	(957)
2,625	2,459	27,925
4,660	3,734	49,574
13	18	138
¥ 4.647	¥ 3,715	\$ 49,436
	2013 ¥ 69,941 34,776 28,263 63,040 6,901 287 (8) 105 385 7,286 2,715 (90) 2,625 4,660	¥         69,941         ¥         67,304           34,776         32,702           28,263         28,588           63,040         61,291           63,040         61,291           6,901         6,012           287         289           (8)         (9)           105         (99)           385         180           7,286         6,193           2,715         2,229           (90)         230           2         2,625           2,625         2,459           4,660         3,734           13         18

		Y	en		U.S	. Dollars
AMOUNTS PER COMMON SHARE (Notes 2.p and 13):						
Basic net income	¥	68.87	¥	55.04	\$	0.73
Cash dividends applicable to the year		21.00		19.00		0.22

See notes to consolidated financial statements.

#### Consolidated Statement of Comprehensive Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Year Ended March 31, 2013

### NET INCOME BEFORE MINORITY INTERESTS

#### OTHER COMPREHENSIVE INCOME (Note 12):

Unrealized gain on available-for-sale securities

Deferred gain on derivatives under hedge accounting

Foreign currency translation adjustments

Total other comprehensive income

#### **COMPREHENSIVE INCOME**

Owr	ners	of	the parent	

Minority interests

See notes to consolidated financial statements.

## Consolidated Statement of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Year Ended March 31, 2013

	Thousands					Millio	ns of Yen				
					Ac	cumulated (	Other Compreh	ensive 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 on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Total	Minority Interests	Total Equity
BALANCE, APRIL 1, 2011	67,510 ¥	5,174 ¥	4,444 ¥	71,108 ¥	(2,058)¥	2,880	¥ 2	¥ (36) ¥	<b>81,515</b> ¥	177 ¥	81,692
Net income				3,715					3,715		3,715
Cash dividends, ¥19.00 per sh	are			(1,282)					(1,282)		(1,282)
Purchase of treasury stock	(17)				(17)				(17)		(17)
Disposal of treasury stock											
Net change during the year						448		(4)	443	13	457
BALANCE, MARCH 31, 2012	67,493	5,174	4,445	73,541	(2,075)	3,328	1	(41)	84,374	191	84,566
Net income				4,647					4,647		4,647
Cash dividends, ¥20.00 per sh	are			(1,349)					(1,349)		(1,349)
Purchase of treasury stock	(18)				(18)				(18)		(18)
Disposal of treasury stock	1				1				1		1
Net change during the year						1,660	3	10	1,675	7	1,682
BALANCE, MARCH 31, 2013	67,476 ¥	5,174 ¥	4,445 ¥	76,839 ¥	(2,092)¥	4,989	¥ 4	¥ (30) ¥	89,330 ¥	198 ¥	89,529

	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available- for-sale Securities	Deferred Gain on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Total	Minority Interests	Total Equity
BALANCE, MARCH 31, 2012	\$ 55,042	\$ 47,287	\$ 782,351	\$ (22,074) \$	35,404	\$ 10	\$ (436)	\$ 897,595 \$	2,031	\$ 899,638
Net income			49,436					49,436		49,436
Cash dividends, \$0.21 per share			(14,351)					(14,351)		(14,351)
Purchase of treasury stock				(191)				(191)		(191)
Disposal of treasury stock				10				10		10
Net change during the year					17,659	31	106	17,819	74	17,893
BALANCE, MARCH 31, 2013	\$ 55,042	\$ 47,287	\$817,436	\$ (22,255) \$	53,074	\$ 42	\$ (319)	\$ 950,319 \$	2,106	\$ 952,436

See notes to consolidated financial statements.

	Million	s of Yen		Thousa	nds of U.S. Dollars (Note 1)
	2013		2012		2013
¥	4,660	¥	3,734	\$	49,574
	1,660		448		17,659
	3				31
	10		(4)		106
	1,675		443		17,819
¥	6,335	¥	4,177	\$	67,393
¥	6,322	¥	4,158	\$	67,255
	13		18		138

-	Thousands	of U.S.	Dollars	(Note 1)	

Accumulated Other Comprehensive Income

lippon Shinyaku Co., Ltd. and Consolidated Subsidiaries ear Ended March 31, 2013					Thousar	nds of U.S. Dollar
	201		s of Yen	2012		(Note 1)
	201	13		2012		2013
OPERATING ACTIVITIES:		7.200		6 102		77 510
Income before income taxes and minority interests	¥	7,286	¥	6,193	\$	77,510
Adjustments for:		(2.2.44)		(4.524)		(24.004)
Income taxes - paid		(2,341)		(1,531)	-	(24,904)
Depreciation and amortization		2,759		2,948		29,351
Changes in assets and liabilities:		( )			_	(0.0.00.0)
Increase in trade notes and trade accounts receivables		(2,278)		(4,414)	_	(24,234)
Increase in inventories		(1,341)		(377)	_	(14,265)
(Increase) decrease in other current assets		(527)		730	_	(5,606)
Increase (decrease) in trade notes and trade accounts payables		8		(278)	_	85
Increase (decrease) in other current liabilities		(97)		128		(1,031)
Increase (decrease) in liability for retirement benefits		60		(360)		638
Other - net		239		620		2,542
Total adjustments		(3,518)		(2,535)		(37,425)
Net cash provided by operating activities		3,767		3,658	_	40,074
INVESTING ACTIVITIES:					-	
Proceeds from redemption of marketable securities				240		
Capital expenditures		(1,020)		(988)		(10,851)
Purchases of investment securities		(104)		(5)		(1,106)
Proceeds from redemption and sales of investment securities		3		171		31
Purchases of software		(359)		(128)		(3,819)
Acquisition of license rights		(677)				(7,202)
Other - net		133		(48)		1,414
Net cash used in investing activities		(2,026)		(759)		(21,553)
FINANCING ACTIVITIES:					_	
		(1.250)		(1.201)	-	(14 261)
Cash dividends paid		(1,350)		(1,281)		(14,361)
Increase of treasury stock		(18)		(17)	-	(191)
Other - net		(44)		(42)		(468)
Net cash used in financing activities		(1,413)		(1,341)		(15,031)
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON						
CASH AND CASH EQUIVALENTS		51		(34)		542
NET INCREASE IN CASH AND CASH EQUIVALENTS		379		1,523		4,031
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR		19,665		18,142		209,202
CASH AND CASH EQUIVALENTS, END OF YEAR	¥	20,044	¥	19,665	\$	213,234

See notes to consolidated financial statements.

#### 1. BASIS OF PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

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

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form that is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2012 consolidated financial statements to conform to the classifications used in 2013.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Nippon Shinyaku Co., Ltd. (the "Company") is incorporated and operates. Japanese yen figures less than a million yen are rounded down to the nearest million yen, except for per share data. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥94 to \$1, the approximate rate of exchange at March 31, 2013. U.S. dollar figures less than a thousand dollars are rounded down to the nearest thousand dollars, except for per share data. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### a. Consolidation

The consolidated financial statements as of March 31, 2013 and 2012, include the accounts of the Company and its significant two domestic and one overseas subsidiaries (together, the "Companies"). Consolidation of the remaining subsidiary would not have a material effect on the accompanying consolidated financial statements.

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

Investment in one unconsolidated subsidiary is stated at cost. If the equity method of accounting had been applied to the investment in this company, the effect on

the accompanying consolidated financial statements would not be material.

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

#### **b.** Cash Equivalents

Cash equivalents are short-term investments that are readily convertible into cash and that are exposed to insignificant risk of changes in value. Cash equivalents include time deposits, certificates of deposit, and commercial paper, all of which mature or become due within three months of the date of acquisition.

#### c. Investment Securities

Investment securities are classified and accounted for, depending on management's intent, as follows: i) held-to-maturity debt securities, which management has the positive intent and ability to hold to maturity, are reported at amortized cost; and ii) available-for-sale securities that are not classified as held-to-maturity securities and are reported at fair value, with unrealized gains and losses, net of applicable taxes, are reported as a separate component of equity. Realized gains and losses on available-for-sale securities are included in earnings and are calculated by using the moving-average method to determine the cost of securities sold. Nonmarketable available-for-sale securities are stated at cost, cost being determined principally by the moving-average method. Write-downs are recorded in earnings for securities with a significant decline in value that is considered to be other than temporary.

#### d. Inventories

Inventories held for sale in the ordinary course of business are measured at the lower of cost, determined by the average cost method, or net selling value, which is defined as the selling price less additional estimated manufacturing costs and estimated direct selling expenses. The replacement cost may be used in place of the net selling value, if appropriate.

#### e. Property, Plant, and Equipment

Property, plant, and equipment are stated at cost. Depreciation is principally computed by the declining-balance method while the straight-line method is applied to buildings acquired after April 1, 1998. The range of useful lives is principally from 10 to 50 years for buildings and structures; from eight to 10 years for machinery, equipment, and vehicles; and from four to six years for tools, furniture, and fixtures.

#### 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

Employees of the Company and domestic subsidiaries terminating their employment are entitled to lump-sum severance payments based on their salaries at the time of termination, length of service, and certain other factors. If the termination is involuntary or caused by death, the employees are entitled to greater payments than in the case of voluntary termination.

The Company has a cash balance pension plan, under which each participant has an account on which a fixed amount is contributed and interests added. Interests are calculated yearly based on a market-related interest rate with a certain minimum interest rate secured. The Company also has an unfunded retirement benefit plan for employees and a defined contribution pension plan to allow qualified persons aged from 60 to 64 years to receive postretirement benefits at their discretion. Consolidated domestic subsidiaries have unfunded retirement benefit plans.

#### h. Asset Retirement Obligations

In March 2008, the Accounting Standards Board of Japan (ASBJ) published the accounting standard for asset retirement obligations, ASBJ Statement No. 18, "Accounting Standard for Asset Retirement Obligations," and ASBJ Guidance No. 21, "Guidance on Accounting Standard for Asset Retirement Obligations." Under this accounting standard, an asset retirement obligation is defined as a legal obligation imposed either by law or contract that results from the acquisition, construction, development, and the normal operation of a tangible fixed asset and is associated with the retirement of such tangible fixed asset. The asset retirement obligation is recognized as the sum of the discounted cash flows required for the future asset retirement and is recorded in the period in which the obligation is incurred if a reasonable estimate can be made. If a reasonable

estimate of the asset retirement obligation cannot be made in the period the asset retirement obligation is incurred, the liability should be recognized when a reasonable estimate of asset retirement obligation can be made. Upon initial recognition of a liability for an asset retirement obligation, an asset retirement cost is capitalized by increasing the carrying amount of the related fixed asset by the amount of the liability. The asset retirement cost is subsequently allocated to expense through depreciation over the remaining useful life of the asset. Over time, the liability is accreted to its present value each period. Any subsequent revisions to the timing or the amount of the original estimate of undiscounted cash flows are reflected as an adjustment to the carrying amount of the liability and the capitalized amount of the related asset retirement cost.

#### i. Allowance for Doubtful Accounts

The allowance for doubtful accounts is stated at an amount considered to be appropriate based on the Companies' past credit loss experience and an evaluation of potential losses in receivables outstanding.

#### j. Leases

In March 2007, the ASBJ issued ASBJ Statement No. 13, "Accounting Standard for Lease Transactions," which revised the previous accounting standard for lease transactions issued. The revised accounting standard for lease transactions was effective for fiscal years beginning on or after April 1, 2008.

Under the previous accounting standard, finance leases that were deemed to transfer ownership of the leased property to the lessee were capitalized. However, other finance leases were permitted to be accounted for as operating lease transactions if certain "as if capitalized" information was disclosed in the notes to the lessee's financial statements. The revised accounting standard requires that all finance lease transactions be capitalized by recognizing lease assets and lease obligations in the balance sheet. In addition, the accounting standard permits leases that existed at the transition date and do not transfer ownership of the leased property to the lessee to continue to be accounted for as operating lease transactions.

The Company applied the revised accounting standard effective April 1, 2008. In addition, the Company continues to account for leases that existed at the transition date and did not transfer ownership of the leased property to the lessee as operating lease transactions. All other leases are accounted for as operating leases.

#### k. Bonuses to Directors and Audit & Supervisory Board Members

Bonuses to directors and Audit & Supervisory Board members are accrued at the end of the year to which such bonuses are attributable.

#### I. 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 tax laws to the temporary differences.

#### m. Foreign Currency Transactions

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

#### n. Foreign Currency Financial Statements

The balance sheet accounts and revenue and expense accounts of the overseas consolidated subsidiary are translated into Japanese yen at the current exchange rates as of the balance sheet date except for equity, which is translated at historical rates. Differences arising from such translation are shown as "Foreign currency translation adjustments" under accumulated other comprehensive income in a separate component of equity.

#### o. Derivative Financial Instruments

The Company uses foreign currency forward contracts as a means of hedging exposure to foreign currency risks related to the procurement of merchandise from overseas suppliers. The Company does not enter into derivatives for trading or speculative purposes. Derivative financial instruments and foreign currency transactions are classified and accounted for as follows: a) all derivatives are recognized as either assets or liabilities and measured at fair value, and gains or losses on derivative transactions are recognized in the consolidated statement of income and b) for derivatives used for hedging purposes, if such derivatives qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, gains or losses on derivatives are deferred until maturity of the hedged transactions. The foreign

currency forward contracts are utilized to hedge foreign currency exposures in procurement of raw materials from overseas suppliers. Trade payables denominated in foreign currencies are translated at the contracted rates if the forward contracts qualify for hedge accounting.

#### p. Per Share Information

Basic net income per share (EPS) is computed by dividing net income available 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 years, including dividends to be paid after the end of the year.

#### q. Accounting Changes and Error Corrections

In December 2009, the ASBJ issued ASBJ Statement No. 24, "Accounting Standard for Accounting Changes and Error Corrections" and ASBJ Guidance No. 24, "Guidance on Accounting Standard for Accounting Changes and Error Corrections." Accounting treatments under this standard and guidance are as follows: (1) Changes in Accounting Policies - When a new accounting policy is applied following revision of an accounting standard, the new policy is applied retrospectively unless the revised accounting standard includes specific transitional provisions, in which case the entity shall comply with the specific transitional provisions. (2) Changes in Presentation - When the presentation of financial statements is changed, prior-period financial statements are reclassified in accordance with the new presentation. (3) Changes in Accounting Estimates - A change in an accounting estimate is accounted for in the period of the change if the change affects that period only and is accounted for prospectively if the change affects both the period of the change and future periods. (4) Corrections of Prior-Period Errors - When an error in prior-period financial statements is discovered, those financial statements are restated.

#### r. New Accounting Pronouncements

Accounting Standard for Retirement Benefits - On May 17, 2012, the ASBJ issued ASBJ Statement No. 26, "Accounting Standard for Retirement Benefits" and ASBJ Guidance No. 25, "Guidance on Accounting Standard for Retirement Benefits," which replaced the Accounting Standard for Retirement Benefits that had been issued by the Business Accounting Council in 1998 with an effective date of April 1, 2000, and the other related practical guidance, and followed by partial amendments from time to time through 2009.

#### Major changes are as follows: (a) Treatment in the balance sheet

Under the current requirements, actuarial gains and losses and past service costs that are yet to be recognized in profit or loss are not recognized in the balance sheet, and the difference between retirement benefit obligations and plan assets (hereinafter, "deficit or surplus"), adjusted by such unrecognized amounts, is recognized as a liability or asset.

Under the revised accounting standard, actuarial gains and losses and past service costs that are yet to be recognized in profit or loss shall be recognized within equity (accumulated other comprehensive income), after adjusting for tax effects, and any resulting deficit or surplus shall be recognized as a liability (liability for retirement benefits) or asset (asset for retirement benefits).

## (b) Treatment in the statement of income and the statement of comprehensive income

The revised accounting standard does not change how to recognize actuarial gains and losses and past service costs in profit or loss. Those amounts would be recognized in profit or loss over a certain period no longer than the expected average remaining working lives of the employees. However, actuarial gains and losses and past service costs that arose in the current period and have not yet been recognized in profit or loss shall be included in other comprehensive income and actuarial gains and losses and past service costs that were recognized in other comprehensive income in prior periods and then recognized in profit or loss in the current period shall be treated as reclassification adjustments.

#### (c) Amendments relating to the method of attributing expected benefit to periods and relating to the discount rate and expected future salary increases

The revised accounting standard also made certain amendments relating to the method of attributing expected benefit to periods and relating to the discount rate and expected future salary increases. This accounting standard and the guidance for (a) and (b) above are effective for the end of annual periods beginning on or after April 1, 2013, and for (c) above are effective for the beginning of annual periods beginning on or after April 1, 2014, or for the beginning of annual periods beginning on or after April 1, 2015, subject to certain disclosure in March 2015, both with earlier application being permitted from the beginning of annual periods beginning on or after April 1, 2013. However, no retrospective application of this accounting standard to consolidated financial statements in prior periods is required.

The Company expects to apply the revised accounting standard for (a) and (b) above from the end of the annual period beginning on April 1, 2013, and for (c) above from the beginning of the annual period beginning on April 1, 2014, and is in the process of measuring the effects of applying the revised accounting standard in future applicable periods.

#### 3. ACCOUNTING CHANGE

Change in accounting policies that are difficult to distinguish from changes in accounting estimates -

Starting from the current fiscal year, the Company has changed the method of depreciation due to the revision of Corporation Tax Act. Accordingly, property, plant, and equipment acquired on or after April 1, 2012, are depreciated according to the revised act.

This change has minor impact on the consolidated statement of income.

#### 4. INVESTMENT SECURITIES

Investment securities as of March 31, 2013 and 2012, consisted of the following:

		Million	/en	Thousands of U.S. Dollars	
		2013		2012	2013
Noncurrent:					
Equity securities	¥	13,873	¥	11,170	\$ 147,585
Total	¥	13,873	¥	11,170	\$ 147,585

The costs and aggregate fair values of investment securities at March 31, 2013 and 2012, were as follows:

				Millions	of Yen		
March 31, 2013		Cost	I	Unrealized Gains	Unrealized Losses		Fair Value
Securities classified as: Available-for-sale:							
Equity securities	¥	6,053	¥	7,486		¥	13,54
				Millions	of Yen		
March 31, 2012		Cost	l	Jnrealized Gains	Unrealized Losses		Fair Value
Securities classified as: Available-for-sale:							
Equity securities	¥	5,948	¥	4,886		¥	10,83
<u></u>			Т	housands of	U.S. Dollars		
March 31, 2013		Cost	ι	Jnrealized Gains	Unrealized Losses		Fair Value
Securities classified as: Available-for-sale:							
Equity securities	\$	64,393	\$	79,638		\$	144,04

### **5. INVENTORIES**

Inventories at March 31, 2013 and 2012, consisted of the following:

	Millio	ons of	Yen	 ousands of I.S. Dollars
	2013		2012	2013
Finished products and merchandise ¥	8,019	¥	6,843	\$ 85,308
Work in process	1,842		1,436	19,595
Raw materials	3,404		3,644	36,212
Total ¥	13,266	¥	11,925	\$ 141,127

#### **6. RETIREMENT BENEFITS**

The liability for employees' retirement benefits at March 31, 2013 and 2012, consisted of the following:

		Millions of Yen				iousands of J.S. Dollars
		2013		2012		2013
Projected benefit obligation	¥	26,554	¥	26,146	\$	282,489
Fair value of plan assets		(15,140)		(12,990)	(	161,063)
Unrecognized actuarial loss		(3,748)		(5,506)		(39,872)
Unrecognized prior service cost		(246)		(291)		(2,617)
Net liability	¥	7,418	¥	7,357	\$	78,914

The components of net periodic benefit costs for the years ended March 31, 2013 and 2012, are as follows:

		Millions of Yen			Thousands of U.S. Dollars	
		2013		2012		2013
Service cost	¥	862	¥	856	\$	9,170
Interest cost		518		530		5,510
Expected return on plan assets		(516)		(506)		(5,489)
Recognized actuarial loss		691		677		7,351
Amortization of prior service cost		45		45		478
Premiums for defined contribution	۱					
pension plan and other		62		55		659
Net periodic benefit costs	¥	1,663	¥	1,659	\$	17,691

Assumptions used for the years ended March 31, 2013 and 2012, are set forth as follows:

	2013	2012
Discount rate	2.0%	2.0%
Expected rate of return on plan assets	4.0%	4.0%
Recognition period of actuarial gain/loss	15 years	15 years
Amortization period of prior service cost	15 years	15 years

#### 7. 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 dividend upon resolution at the shareholders meeting. For companies that meet certain criteria, such as: (1) having a Board of Directors, (2) having independent auditors, (3) having an Audit & Supervisory Board, and (4) the term of service of the directors is prescribed as one year rather than two years of normal term by its articles of incorporation; the Board of Directors may declare dividends (except for dividends in kind) at any time during the fiscal year if the company has prescribed so in its articles of incorporation. However, the Company cannot do so because it does not meet all the above criteria.

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

Semiannual interim dividends may also be paid once a year upon resolution by the Board of Directors if the

articles of incorporation of the company so stipulate. The Companies Act provides certain limitations on the amounts available for dividends or the purchase of treasury stock. The limitation is defined as the amount available for distribution to the shareholders, but the amount of net assets after dividends must be maintained at no less than ¥3 million.

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

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

#### 8. RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥9,049 million (\$96,265 thousand) and ¥9,414 million for the years ended March 31, 2013 and 2012, respectively.

#### 9. LEASES

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

Total rental expenses for the years ended March 31, 2013 and 2012, were ¥1,227 million (\$13,053 thousand) and ¥1,206 million, respectively.

Future minimum payments under noncancelable operating leases was as follows:

		Operating Leases				
		20	13			
	Millions	Millions of Yen				
Due within one year Due after one year	¥	7 16	\$	74 170		
Total	¥	24	\$	255		

## Pro forma information of leased property whose lease inception was before March 31, 2008

ASBJ Statement No. 13, "Accounting Standard for Lease Transactions," requires that all finance lease transactions be capitalized to recognize lease assets and lease obligations in the balance sheet. However, ASBJ Statement No. 13 permits leases, without ownership transfer of the leased property to the lessee and whose lease inception was before March 31, 2008, to continue to be accounted for as operating lease transactions if certain "as if capitalized" information is disclosed in the notes to the financial statements. The Company applied ASBJ Statement No. 13 effective April 1, 2008, and accounted for such leases as operating lease transactions. Pro forma information of leased property whose lease inception was before March 31, 2008, was as follows:

Tools, furniture, and fixtures:

		Millio	ons of Yer	ı		usands of 5. Dollars
	2	013	2	012	:	2013
Acquisition cost	¥	5	¥	11	\$	53
Accumulated depreciation		5		11		53
Net leased property	¥		¥		\$	

#### Depreciation expense and other information under finance leases:

	Mill	ions of Yen	
		2012	
Depreciation expense	¥	1	
Lease payments	¥	1	

Depreciation expense, which is not reflected in the accompanying consolidated statement of income, is computed by the straight-line method.

#### **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 38% for the year ended March 31, 2013, and 41% for the year ended March 31, 2012. The overseas subsidiary is subject to the income tax of the country in which it operates.

The tax effects of significant temporary differences that resulted in deferred tax assets and liabilities at March 31, 2013 and 2012, are as follows:

	Millions of Yen			Thousands of U.S. Dollars		
		2013		2012		2013
Deferred tax assets:						
Retirement benefits	¥	2,674	¥	2,652	\$	28,446
Accrued expenses		1,100		1,095		11,702
Property, plant, and equipment		71		68		755
Other		1,225		1,174		13,031
Less valuation allowance		(367)		(373)		(3,904)
Deferred tax assets		4,704		4,617		50,042
Deferred tax liabilities:						
Unrealized gain on available-						
for-sale securities		2,496		1,557		26,553
Deferred gains on sales of						
property		1,186		1,195		12,617
Other		37		28		393
Deferred tax liabilities		3,720		2,782		39,574
Net deferred tax assets	¥	984	¥	1,835	\$	10,468

A reconciliation between the normal effective statutory tax rates and the actual effective tax rates reflected in the accompanying consolidated statements of income for the years ended March 31, 2013 and 2012, is as follows:

	2013	2012
Normal effective statutory tax rate	38.0%	41.0%
Expenses not deductible for income tax purposes	2.5	4.3
Income not taxable for income tax purposes	(1.1)	(1.4)
Increase in valuation allowance	(0.1)	(2.0)
Tax credits for research and development costs	(5.3)	(8.8)
Effect of tax rate reduction		6.0
Flat rate municipal tax	0.8	1.0
Other - net	1.2	(0.4)
Actual effective tax rate	36.0%	39.7%

On December 2, 2011, new tax reform laws were enacted in Japan, which changed the normal effective statutory tax rate from approximately 41% to 38% effective for the fiscal years beginning on or after April 1, 2012 through March 31, 2015, and to 36% afterwards.

#### 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 used, not for speculative purposes, but to manage exposure to financial risks as described in (2) below.

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

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

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

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

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

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

Because the counterparties to derivatives are limited to major financial institutions, the Company does not anticipate any losses from credit risk. Market risk management (foreign exchange risk and interest rate risk) Foreign currency trade payables are exposed to fluctuations in foreign currency exchange rates. Such foreign exchange risk is hedged principally by forward foreign currency contracts. The Companies have internal policies that restrict the use of derivatives only for the purpose of reducing market risks.

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

#### Liquidity risk management

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

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

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

(a) Fair value of financial instruments

	Millions of Yen						
March 31, 2013		Carrying Amount		Fair Value	Unrealized Gain/ Loss		
Cash and cash equivalents	¥	20,044	¥	20,044			
Time deposits		242		242			
Notes and accounts receivables		34,266		34,266			
Investment securities		13,540		13,540			
Total	¥	68,094	¥	68,094			
Notes and accounts payables	¥	8.089	¥	8.089			
Income taxes payable	Ŧ	1,665	Ŧ	1,665			
income taxes payable		1,005		1,005			
Total	¥	9,755	¥	9,755			
			Mi	llions of Yen			
March 31, 2012		Carrying Amount		Fair Value	Unrealized Gain/ Loss		
Cash and cash equivalents	¥	19,665	¥	19,665			
Time deposits		322		322			
Notes and accounts receivables		31,988		31,988			
Investment securities		10,835		10,835			
Total	¥	62,811	¥	62,811			
Notes and accounts payables	¥	7,729	¥	7,729			
Income taxes payable	Ŧ	1,294	т	1,294			
income taxes payable		1,294		1,294			
Total	¥	9,023	¥	9,023			

	Thousands of U.S. Dollars					
March 31, 2013	Carrying Amount	Fair Value	Unrealized Gain/ Loss			
Cash and cash equivalents	\$ 213,234	\$ 213,234				
Time deposits	2,574	2,574				
Notes and accounts receivables	364,531	364,531				
Investment securities	144,042	144,042				
Total	\$ 724,404	\$ 724,404				
Notes and accounts payables	\$ 86,053	\$ 86,053				
Income taxes payable	17,712	17,712				
Total	\$ 103,776	\$ 103,776				

#### Cash and cash equivalents, notes, and accounts receivable

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

#### Investment securities

The fair values of 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 investment securities by classification is included in Note 3.

## Notes and accounts payables, other payables, and income taxes payable

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

#### Derivatives

Fair value information for derivatives is omitted from disclosure because fair values and unrealized gains were immaterial for the years ended March 31, 2013 and 2012.

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

	Carrying Amount							
		Million	Thousands o U.S. Dollars					
		2013		2012	2013			
vestments in equity instruments								
that do not have a quoted market								
price in an active market	¥	332	¥	334	\$	3,531		

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

			Million	s of Yen	
March 31, 2013	Du	e in One Year or Less		Due after Five Years through Ten Years	Due after Ten Years
Cash and cash equivalents Time deposits Notes and account	¥	20,044 242			
receivables	5	34,266			
Total	¥	54,553			
			Million	s of Yen	
March 31, 2012	Du	e in One Year or Less	Due after One Year through Five Years	Due after Five Years through Ten Years	Due after Ten Years
Cash and cash equivalents Time deposits	¥	19,665 322			
Notes and account receivables	S	31,988			
Total	¥	51,975			
			Thousands o	of U.S. Dollars	
March 31, 2013	Du	e in One Year or Less		Due after Five Years through Ten Years	Due after Ten Years
Cash and cash equivalents	\$	213,234			
Time deposits		2,574			
Notes and account receivables	S	364,531			
Total	\$	580,351			

### **12. COMPREHENSIVE INCOME**

The components of other comprehensive income for the years ended March 31, 2013 and 2012, were as follows:

		Million	s of Ye	n		isands of . Dollars
Unrealized gain (loss) on available-for-sale securities:	2	013	ź	2012	2	013
Gains arising during the year Reclassification adjustments	¥	2,599	¥	232	\$2	7,648
to profit or loss Amount before income tax				119		
effect	:	2,599		352	2	7,648
Income tax effect		(939)		96	(	9,989)
Total	¥ 1,660		¥	448	\$1	7,659
Deferred gain (loss) on derivatives under hedge accounting: Gains (loss) arising during						
the year	¥	5	¥	(1)	\$	53
Income tax effect		(2)				(21)
Total	¥	3	¥		\$	31
Foreign currency translation adjustments: Adjustments arising during						
the year	¥	10	¥	(4)	\$	106
Total	¥	10	¥	(4)	\$	106
Total other comprehensive income	¥	1,675	¥	443	\$1	7,819

#### **13. NET INCOME PER SHARE**

Net EPS for the years ended March 31, 2013 and 2012, was as follows:

	Milli	ons of Yen	Thousands of Shares		Yen		Dollars
	Net Income		Weighted-Average Shares		E	PS	
For the year ended							
March 31, 2013 -							
Basic EPS							
Net income availabl	e						
to common							
shareholders	¥	4,647	67,485	¥	68.87	\$	0.73
For the year ended							
March 31, 2012 -							
Basic EPS							
Net income availabl	e						
to common							
shareholders	¥	3,715	67,502	¥	55.04		

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

#### 14. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 27, 2013, the Company's shareholders approved the following:

Payment of a year-end cash dividend of ¥11 (\$0.11) per share to holders of record at March 31, 2013, for a total of ¥742 million (\$7,893 thousand).

#### **15. SEGMENT INFORMATION**

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

#### 1. Description of reportable segments

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

- 2. Methods of measurement for the amounts of sales, profit, assets, and other items for each reportable segment The accounting policies of each reportable segment are consistent with those disclosed in Note 2, "Summary of Significant Accounting Policies."
- 3. Information about sales, profit, assets, and other items is as follows.

	Millions of Yen								
	2013								
		F	Repor	rtable Segme	ent		_		
	Pharm	aceuticals		Functional Food		Total	Re	econciliations	Consolidated
Sales:									
Sales to external customers	¥ 5	8,318	¥	11,622	¥	69,941			¥ 69,941
Intersegment sales or transfers									
Total	5	8,318		11,622		69,941			69,941
Segment profit		6,812		89		6,901			6,901
Segment assets	7	1,001		8,530		79,531	¥	34,199	113,730
Other:									
Depreciation		2,586		142		2,728		30	2,759
Increase in property, plant, and equipment and intangible assets		1,185		147		1,332			1,332

					M	llions of Yen			
						2012			
		F	Repor	rtable Segme	ent				
	Pha	armaceuticals	Functional Food Total		- Reconciliations		Consolidated		
Sales:									
Sales to external customers	¥	55,746	¥	11,558	¥	67,304			¥ 67,304
Intersegment sales or transfers									
Total		55,746		11,558		67,304			67,304
Segment profit		5,571		441		6,012			6,012
Segment assets		66,298		8,067		74,366	¥	31,937	106,304
Other:									
Depreciation		2,758		155		2,914		33	2,948
Increase in property, plant, and equipment and intangible assets		885		82		967			967

Sales: Sales to external customers Intersegment sales or transfers Total Segment profit Segment assets Other: Depreciation Increase in property, plant, and equipment and intar

Notes: Unallocated corporate assets included under "Reconciliations" for 2013 and 2012 are ¥34,199 million (\$363,819 thousand) and ¥31,937 million, respectively, and consist primarily of funds, such as cash equivalents, investment securities, assets for administrative functions, and deferred tax assets.

#### **Related Information**

1. Information about products and services

	Millions of Yen						
		2013					
	Pharmaceuticals	Functional Food	Total				
Sales to external customers	¥ 58,318	¥ 11,622	¥ 69,941				
	Tho	usands of U.S. Do	ollars				
	2013						
	Pharmaceuticals	Functional Food	Total				

#### 2. Information about geographical areas

#### (1) Sales

Information about geographic area is omitted, as sales to external customers located in Japan accounted for more than 90% of net sales presented in the consolidated statement of income for the year ended March 31, 2013.

(2) Property, plant, and equipment

Information about geographic area is omitted, as property, plant, and equipment located in Japan accounted for more than 90% of property, plant, and equipment presented in the consolidated balance sheet as of March 31, 2013.

		In	ousands of U.S. Do 2013	bilars	
		eportable Segme			
		sponable degrine	n it		
	Pharmaceuticals	Functional Food	Total	Reconciliations	Consolidated
	\$ 620,404	\$ 123,638	\$ 744,053		\$ 744,053
	620,404	123,638	744,053		744,053
	72,468	946	73,414		73,414
	755,329	90,744	846,074	\$ 363,819	1,209,893
	27,510	1,510	29,021	319	29,351
angible assets	12,606	1,563	14,170		14,170

#### 3. Information about major customers

			2013	
-	Sales			
- Name of Customers	Mi	llions of Yen	Thousands of U.S. Dollars	Related Segment Name
MEDICEO CORPORATION	¥	13,910	\$ 147,978	Pharmaceuticals
Alfresa Corporation		12,315	131,010	Pharmaceuticals
Suzuken Co., Ltd.		11,686	124,319	Pharmaceuticals
Toho Pharmaceutical Co., Ltd.		7,564	80,468	Pharmaceuticals

#### **Corporate Data/Investor Information**

As of March 31, 2013

#### **Corporate Data**

November 20, 1911

October 1, 1919

**Paid-in Capital** 

¥5,174 million

President

Employees

1,806

**Date of Incorporation** 

**Representative Director** 

Shigenobu Maekawa

Founded

#### Corporate Name Nippon Shinyaku Co., Ltd.

#### Head Office

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

Independent and Certified Public Acco

Deloitte Touche Tohmatsu Shijokarasuma FT Square 20, Naginataboko-cho, Karasuma-hio Shijo-dori Shimogyo-ku, Kyoto 600-8 Japan

#### Share Register

Mitsubishi UFJ Trust and Banking Cor 6-3, Fushimimachi 3-chome, Chuo-ku Osaka 541-8502, Japan

0

6,000

5,000

4,000

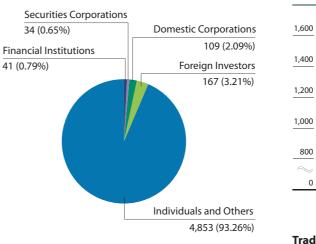
3,000

2,000

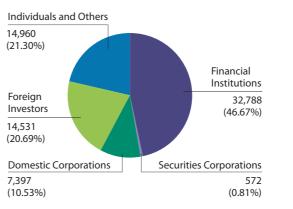
1,000

#### **Investor Information**

#### **Distribution of Shareholders**



Distribution of Shares Issued (Thousands of shares)



Deloitte Touche Tohmatsu LLC Shijokarasuma FT Square 20. Naginataboko-cho Karasuma-higashliru, Shijo-dori Shimogyo-ku, Kyoto 600-8608 Tel: +81 (75) 222 0181

Fax: +81 (75) 231 2703 www.delarte.com/jp.

INDEPENDENT AUDITOR'S REPORT

**Deloitte.** 

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, 2013, and the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

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

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

#### Auditor's Responsibility

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

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

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

#### Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its consolidated subsidiaries as of March 31, 2013, 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 Jouche Johnatsu LLC

June 27, 2013

Member of **Deloitte Touche Tohmatsu Limited** 

55

<b>Issued and Outstanding Number of Shares</b> 70,251,484
Number of Shareholders
5,204
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
PERSHING-DIV. OF DLJ SECS. CORP.
Japan Trustee Services Bank, Ltd. (Trust account 9)
Tokio Marine & Nichido Fire Insurance Co.,Ltd.
Mitsubishi Corporation

