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## **ANNUAL REPORT** 2014 Year ended March 31, 2014



The cover illustration is from Amekun Debut, a picturebook published through the fifth Nippon Shinyaku Children's Literary Awards contest. For more information about the contest, please refer to page 26 of this report.



ANNUAL REPORT 201















#### **Editorial Policy**

#### Period Covered

- Fiscal 2013 (April 1, 2013 to March 31, 2014). Some sections of the report also discuss initiatives since April 2014
- Companies Covered

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

Note: Figures presented in this report are taken from Nippon Shinyaku's Financial Report for the year ended March 31, 2014. As figures have been rounded, totals may not exactly equal the sum of their composite statistics

#### Forward-looking statements:

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

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Nippon Shinyaku Launches Zalutia<sup>®</sup>, a Breakthrough New Drug for Urinary Disorders Caused by Benign Prostatic Hypertrophy

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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 urological diseases

Drugs for pain, inflammation, and allergies

Drugs for hematologic malignancies





 Zalutia<sup>®</sup> Eviprostat<sup>®</sup> Bladderon<sup>®</sup> Estracyt<sup>®</sup> Cialis<sup>®</sup>

 Erizas<sup>®</sup> Bavnas<sup>6</sup> Azunol<sup>®</sup> Gargle Liquid Livostin<sup>®</sup>

 Vidaza Cvlocide Trisenox<sup>®</sup> Amnolake<sup>®</sup>

Launched in April 2014. Zalutia® offers a new mechanism of action that is expected to make it a first-in-class drug for the treatment of symptoms related to benign prostatic spray dispenser. hypertrophy.

 Hypen<sup>®</sup> Erizas<sup>®</sup> Nasal Powder 200µg 28 metered spray is a treatment for allergic rhinitis that features a 14-day supply of steroid powder filled in a nasal

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 prolone survival in MDS patients. This has helped it penetrate the market

Protein preparations and

nutritional ingredients

## **Functional Food**

### **Health food**





 Hvaluronic acid 3000 NSCP aqua Garcinia Powder Mangosteen agua NS Amla extract powder Morus leaves extract powde

We leverage expertise in

provide health food

human health based on

assured quality and

evidence of efficacy

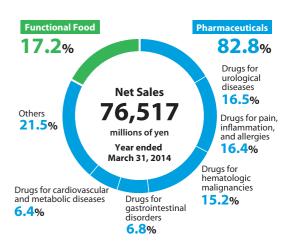


We supply preservatives of consistent quality that both safety and guality control practices developed in our extend the shelf life of pharmaceuticals business to various foods and minimize the impact on flavor by ingredients beneficial to using proprietary maintaining and improving formulation techniques.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

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

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





Drugs for gastrointestinal disorders



Gaslon N<sup>e</sup> Portolac<sup>6</sup>

#### Drugs for cardiovascular and metabolic diseases



 Adcirca<sup>®</sup> Selectol<sup>®</sup>

#### Others



Regtect

Lunabell<sup>6</sup>

Cephadol<sup>®</sup>

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.

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

Launched in May 2013 Regtect<sup>®</sup>, which supports the maintenance of abstinence in patients with alcohol dependence, is the only pharmaceutical in Japan that works on the central nervous system to reduce the urge to drink alcohol.

#### Spices and condiments



- 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 pharmaceuticals business to make spices hot chili extracts, onion concentrate, as well as juice extracts from haskap and cantaloupe melon produced in Hokkaido.

#### Others



 Suncircle H Nineace S

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

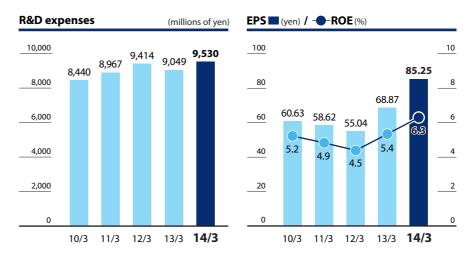
#### Summary of consolidated financial indicators

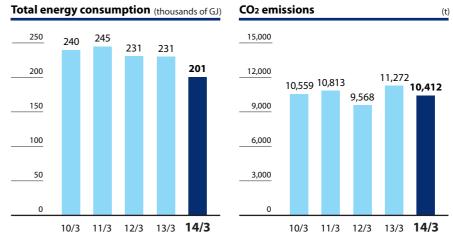
	2010/3	2011/3	2012/3	2013/3	2014/3	2014/3
For the year					millions of yen	Thousands of U.S. Dollars
Net sales	62,932	63,525	67,304	69,941	76,517	742,891
Pharmaceuticals	52,165	52,554	55,746	58,318	63,345	615,003
Drugs for urological diseases	13,541	13,741	13,189	12,334	12,609	122,425
Drugs for pain, inflammation, and allergies	12,866	13,766	12,760	13,499	12,524	121,595
Drugs for hematologic malignancies	2,825	3,092	6,600	8,965	11,668	113,290
Drugs for gastrointestinal disorders	5,051	5,111	5,324	5,325	5,188	50,368
Drugs for cardiovascular and metabolic diseases	4,575	4,601	4,330	4,410	4,902	47,596
Functional food	10,767	10,970	11,558	11,622	13,172	127,887
Cost of sales	29,018	30,218	32,702	34,776	39,033	378,970
Gross income on sales	33,914	33,307	34,601	35,165	37,483	363,920
Selling, general and administrative expenses	27,475	28,151	28,588	28,263	29,445	285,874
Operating income	6,461	5,181	6,012	6,901	8,038	78,046
Net income	4,096	3,958	3,715	4,647	5,750	55,829
Depreciation and amortization	3,078	3,116	2,948	2,759	2,704	26,253
Capital investment	1,859	1,185	967	1,332	1,072	10,417
R&D expenses	8,440	8,967	9,414	9,049	9,530	92,529
End of the year					millions of yen	Thousands of U.S. Dollars
Total assets	103,575	102,737	106,304	113,730	118,188	1,147,465
Net assets	80,370	81,692	84,566	89,529	93,186	904,726
Financial information per share					yen	U.S. Dollars
Book value per share	1,187.42	1,207.43	1,250.11	1,323.87	1,378.93	13.38
Earnings per share	60.63	58.62	55.04	68.87	85.25	0.82
Dividend per share	19	19	19	21	23	0.22
Principal financial indicators						
Ratio of net worth	77.4	79.3	79.4	78.5	78.7	_
Return on equity	5.2	4.9	4.5	5.4	6.3	_
Pay-out ratio	31.3	32.4	34.5	30.5	27.0	_

#### ESG indices<sup>\*1</sup> summary

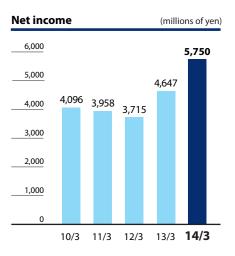
Total energy consumption (thousands of GJ)*2	240	245	231	231	201	_
CO <sub>2</sub> emissions (t) <sup>*2</sup>	10,559	10,813	9,568	11,272	10,412	_
CO <sub>2</sub> per unit of revenue (t/million yen)*2	0.168	0.171	0.143	0.162	0.136	-
Number of employees (people)	1,818	1,882	1,898	1,895	1,899	_

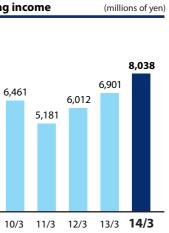
\*1 Indices related to environment, social, and corporate governance initiatives \*2 Applies to main business locations (excluding our sales offices) Net sales (millions of yen) Operating income 80,000 10,000 76,517 8,000 69,941 70,000 67,304 6,461 62,932 63,525 6,000 5,181 60,000 4,000 50,000 2,000  $\sim$ 0 10/3 11/3 12/3 13/3 **14/3** 

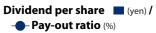


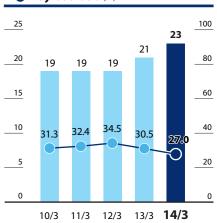


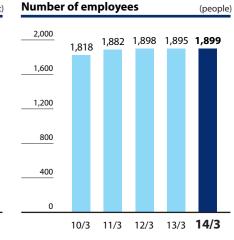
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The Nippon Shinyaku Group's business environment during the year ended March 31, 2014 proved to be quite difficult because of the headwinds against R&D-focused pharmaceuticals companies, and the pharmaceutical sector in general, caused by the continuing emphasis on measures to limit medical costs, including the greater promotion of generics, coupled with Japan's declining birthrate and aging population. Additionally, despite surging costs for imported raw materials in the functional food segment, consumers' inclination toward low priced products remains unchanged and competition in the market has grown more intense, resulting in challenging conditions.

Amid this environment, the Nippon Shinyaku Group proactively engaged in the sales and marketing of its innovative new drug products, achieving record highs in terms of net sales, operating income, ordinary income and net income. Our new product launches included Regtect® and Lunabell<sup>®</sup> Compound Tablet ULD. We also received approval for an additional indication for Tramal® to treat chronic pain. In terms of R&D, we received approval for Zalutia<sup>®</sup>, a drug for urinary disorders caused by benign prostatic hypertrophy, and we commenced phase II clinical trials of NS-304 for arteriosclerosis obliterans, demonstrating steady advances in our R&D pipeline.

### **Business Results for the Year Ended** March 31, 2014

#### **Record Highs Posted for Net Sales, Operating Income,** Ordinary Income and Net Income

The Nippon Shinyaku Group recorded net sales of ¥76,517 million (up 9.4% year-on-year), operating income of ¥8,038 million (up 16.5% year-on-year), ordinary income of ¥8,598 million (up 19.3% year-on-year), and net income of ¥5,750 million (up 23.7% year-on-year). Net sales, operating income, ordinary income and net income each set record highs.

In the pharmaceuticals segment, sales of Vidaza®, a remedy for myelodysplastic syndrome, Lunabell®, a dysmenorrhea remedy, Adcirca®, a treatment agent for pulmonary arterial hypertension, Tramal®, a treatment for cancer pain and chronic pain, and other drug products increased. As a result, net sales amounted to ¥63,345 million (up 8.6% year-on-year).

In the functional food segment, sales of health food ingredients declined slightly, but sales of preservatives, protein preparations and nutritional ingredients increased. As a result, net sales in the segment were ¥13,172 million (up 13.3% 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.

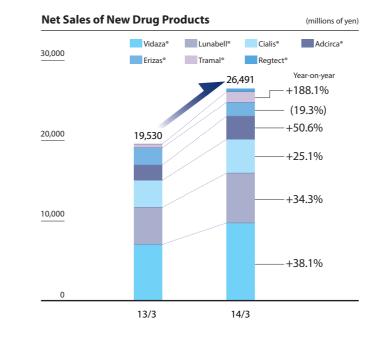
illnesses. We will develop and supply high-quality functional food that meets the needs of customers.

## Society: Earn the Trust of Society

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.



#### **Management Policy**

#### **Customers: Supply Unique and High-quality Products**

We will develop and supply pharmaceuticals that are safe and highly effective relative to other drugs, and that in some way contribute to a better quality of life for patients, first and foremost for patients who suffer from

We will achieve regulatory compliance and

#### **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.

### **Financial Position**

#### Assets, Debts, and Net Assets

For the year ended March 31, 2014, total assets increased by ¥4,458 million year-on-year to ¥118,188 million. Total debts increased by ¥801 million year-on-year to ¥25,002 million. Net assets increased by ¥3,657 million year-on-year to ¥93,186 million.

### **Cash Flows**

For the year ended March 31, 2014, cash and cash equivalents increased by ¥1,185 million year-on-year to ¥21,229 million. Net cash from operating activities amounted to ¥6,015 million, while net cash used in investing activities amounted to ¥3,357 million. Net cash expended for financing activities amounted to ¥1,606 million.

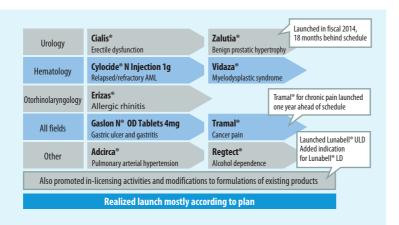
#### Achievements and Issues from the 4th Five-year Medium-term Management Plan (Fiscal 2009 to Fiscal 2013)

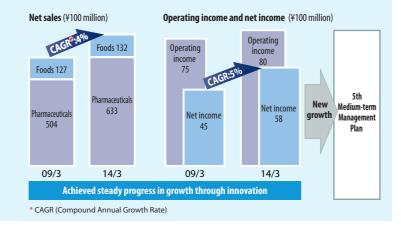
#### Close to fully achieving our plan for the development and market launch of new drug products

In the pharmaceuticals segment, we actively worked on new drug products and net sales of our new drug product lineup exceeded our initial plan. Our development and market launch schedule for new drug products was close to being fully achieved as planned.

#### Posted record highs in net sales and profits

Under the vision of innovation and growth, our company-wide efforts aimed at achieving targets enabled us to expand the R&D pipeline and build a management foundation not dependent on long-listed drugs. Thanks to these efforts, we were also able to realize record high net sales, operating income, ordinary income and net income for fiscal 2013, the final year of the plan.





#### Medium- and Long-Term Business Strategy

#### Review of the 4th Five-year Medium-term Management Plan

The 4th Five-year Medium-term Management Plan called for achieving innovation and growth and the entire company worked together toward becoming a company with a meaningful existence in healthcare.

As a result, sales of new products in the pharmaceuticals segment grew more than planned, but our existing core drugs were impacted more than initially anticipated by measures to promote the use of generics. The functional food segment also saw deflation and a drop in raw materials prices. Consequently, we were unable to achieve our numerical targets for the plan. Nevertheless, we were able to expand our R&D pipeline and carry out a reform to build a management base not dependent on long-listed drugs. Thanks to these achievements, we were able to realize record high net sales, operating income, ordinary income and net income for fiscal 2013, the final year of the plan.

#### Formulation of the 5th Five-year Medium-term Management Plan

In fiscal 2014, we drew up the 5th Five-year Medium-term Management Plan "Aiming for New Growth — Pursuit of Originality —" based on the foundation established under the 4th Five-year Medium-term Management Plan. Under this new Medium-term Management Plan, we will work to create our own unique foundation that can respond to changes in business climate by setting ourselves apart from peers and pursuing originality.

#### Summary of the 5th Five-year Medium-term Management Plan

Nippon Shinyaku's business environment is forecast to become even more challenging amid government efforts to rein in medical costs. In the pharmaceuticals segment, we will target niche domains within the five main fields of focus (urology, hematology, intractable/orphan diseases, gynecology and otorhinolaryngology) that have unmet medical needs, concentrating management resources to expand our pipeline and increase market share. In the functional food segment, we will capitalize on our advanced technologies as a pharmaceutical company to provide high value added products that meet market needs mainly in the three focus areas (health food ingredients, preservatives, and nutritional ingredients). Through these initiatives, we will become a company with a meaningful existence in healthcare that is trusted and appreciated by society.

Our numerical targets for fiscal 2018, the final year of the plan, are net sales of ¥110 billion and operating income of ¥18 billion.

### Projected Business Results for the Year Ending March 31, 2015

#### **Increased Sales and Profits**

In the pharmaceuticals segment, despite impacts from NHI drug price revisions, we anticipate increased sales from further growth in our new drug product lineup, including Vidaza<sup>®</sup>, a remedy for myelodysplastic syndrome, and Lunabell<sup>®</sup>, a treatment for dysmenorrhea, and contributions from Zalutia<sup>®</sup>, the new drug for urinary disorders caused by benign prostatic hypertrophy, which was launched in April 2014.

In the functional food segment, we forecast increased sales from our greater emphasis on new product development and launches as well as our strengthened initiatives toward priority products.

With the above in mind, we expect net sales of ¥84,000 million, operating income of ¥8,500 million, ordinary income of ¥8,700 million, and net income of ¥6,000 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, 2014, we issued an annual cash dividend of ¥23 per share, comprising an interim dividend of ¥11 per share and year-end dividend of ¥12 per share. For the year ending March 31, 2015, we are projecting an annual cash dividend of ¥25 per share, comprising an interim dividend of ¥12 per share and year-end dividend of ¥13 per share.



#### **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 23), 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, which creates heartwarming hospital art (see page 27).

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

S. maehawa President

## Aiming for New Growth — Pursuit of Originality —

#### Overview

## We will set ourselves apart from our peers and achieve growth through the launch of new products and improved profitability.

Nippon Shinyaku's business environment is expected to become even more challenging in the future given additional focus on measures to limit medical costs and Japan's declining birthrate and aging population. To achieve sustainable growth in this changing environment, we will need to clearly set ourselves apart from peers and establish our own unique foundation.

Based on our awareness of this environment and our long-term vision of becoming a company with a meaningful existence in healthcare, we will leverage our management foundation to pursue greater originality and we have established our 5th Five-year Medium-term Management Plan (fiscal 2014 to fiscal 2018) as a unique foundation aimed at unlocking new growth.

We will achieve growth by differentiating ourselves from other companies while also launching new products and improving profitability. Our ultimate goal will be to achieve net sales of ¥110 billion and operating income of ¥18 billion in fiscal 2018, the final year of our Medium-term Management Plan.

#### Numerical targets for fiscal 2018

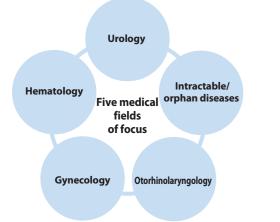
	Fiscal 2013 results	Fiscal 2018 plan	CAGR
Net sales	¥76.5 billion	¥110 billion	8%
Pharmaceuticals	¥63.3 billion	¥95 billion	8%
Functional food	¥13.2 billion	¥15 billion	3%
Operating income	¥8.0 billion	¥18 billion	17%
Net income	¥5.8 billion	¥12 billion	16%
ROE*1	6.3%	10%	—
EPS*2	¥85	¥180	16%
*1 ROE (Return On Equity)			

\*2 EPS (Earnings Per Share)

#### **Business Strategy for Pharmaceuticals**

### We will concentrate management resources on core domains while expanding our R&D pipeline and market share.

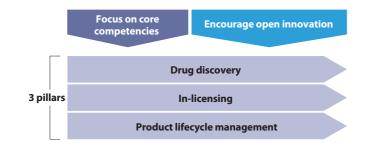
Pharmaceuticals will focus specifically on the medical fields of urology, hematology, intractable/orphan diseases, gynecology, and otorhinolaryngology. Management resources will be committed to these areas in order to expand our R&D pipeline and market share.



#### **R&D Strategy**

We will target niche domains within the five main fields of focus that have unmet medical needs, concentrating management resources and also utilizing external resources to reinforce our drug discovery. We will expand our pipeline around the three pillars of drug discovery, in-licensing and product lifecycle management to continually develop products that will drive the next stage of our growth.

Additionally, using our long-standing fundamental technology of nucleic acid synthesis, we will aim to launch Japan's first-ever antisense nucleic acid pharmaceutical (for the treatment of muscular dystrophy).



### **Marketing Strategy**

By committing management resources to the main fields, we will maximize the value of pharmaceuticals and develop the three product groups (Zalutia<sup>®</sup>, Vidaza<sup>®</sup> and PAH<sup>\*3</sup> treatments) as growth drivers.

To this end, we will increase the number of hospital MRs covering specialty pharmaceuticals such as those to treat hematological disorders or PAH, among other conditions. We will also utilize our internal certification and testing program to improve MRs' academic knowledge and enhance the quality of the information we provide. \*3 Pulmonary Arterial Hypertension

> Urology Zalutia® Hematology

Vidaza<sup>®</sup>/GA101

Adcirca® ACT-064992 NS-304

### **Supply Chain Strategy**

We will pursue business process efficiencies and cost management in every phase of the supply chain, from delivering a stable supply of products to procurement, manufacturing, and logistics.

Additionally, we will construct a manufacturing facility for highly active pharmaceuticals to expand our production of NS-304 and other novel drugs from our drug discovery as well as to increase contract manufacturing capabilities, which will in turn enhance productivity.

## **Overseas Business Strategy**

The overseas expansion of our proprietary novel drugs, including NS-304 for PAH and hematological cancer drugs and nucleic acid pharmaceuticals yet to be launched, will be carried out through out-licensing, in principle. In the US, Europe, and Asia, however, we will select the most appropriate means to rolling these drugs out and expand our business accordingly.



#### **Business Strategy for Functional Food**

## We will supply unique materials that are of high quality and added value.

The functional food segment will be transformed into a high margin business by supplying unique materials that are of high quality and added value and contribute to healthy longevity, active lifestyles, food safety, and food waste reduction.

In terms of R&D, management resources will be committed to the research and development of the segment's focus areas that include health food ingredients, preservatives, and nutritional ingredients. This will enable us to supply high quality and high added-value functional food ingredients that set us apart from peers.

As for marketing, again management resources will be allocated to focus fields to maximize product value and make marketing activities which avoid price competition.

In the supply chain, the segment will reinforce quality management and review costs related to procurement, manufacturing and logistics to reduce cost price.

#### Value for society

#### **Focus fields**





Health food ingredients Preservatives Nutritional ingredients

### **Human Resources Management**

Based on the recognition that our people create our originality, we will strive to increase hiring and training opportunities as well as improve employee motivation.

We will increase the Nippon Shinyaku Group's workforce from around 1,900 currently to around 2,000. This will be achieved by increasing the number of non-regular employees and keeping the number of regular employees in charge of core operations unchanged. We will actively utilize our female workers and also re-employ seniors to capitalize on their experience and technological expertise, with an eye on improving productivity.

## Nippon Shinyaku Launches Zalutia<sup>®</sup>, a Breakthrough New Drug for Urinary Disorders Caused by Benign Prostatic Hypertrophy

Benign prostatic hypertrophy, or BPH, negatively affects a patient's quality of life (QOL) because of the various clinical conditions such as frequent urination.

Amid calls for a new remedy to treat these different clinical conditions, Nippon Shinyaku launched Zalutia<sup>®</sup> in April 2014. This much-anticipated new drug in Nippon Shinyaku's target field, urology, helps to improve patient QOL.

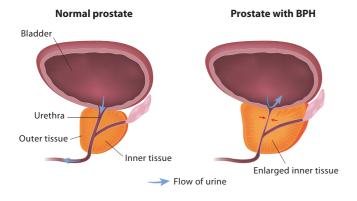


## Rising Number of BPH Patients as the Population Ages

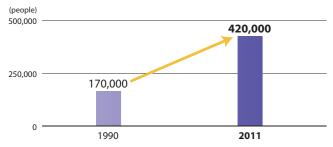
BPH is a medical condition that affects only men. The prostate, which is located below the bladder surrounding the urethra and forms part of the male reproductive system, expands as the body ages and results in various symptoms, such as a weak stream when urinating or difficulty urinating. The cause of these symptoms is not only attributed to pressure on the urethra from an enlarged prostate, but also the narrowing of the urethra caused by excessive tension on the sympathetic nerve or reduced activity of the nitroxidergic nerve. A specific treatment for each clinical condition is required.

With the recent arrival of an aging society, the number of patients seen for BPH has risen exponentially from 170,000 in 1990 to 420,000 in 2011<sup>\*</sup>. The number of potential patients with BPH is said to be four million.

\* Statistics and Information Department, Minister's Secretariat, Ministry of Health, Labour and Welfare: FY2011 Patient Survey



The number of patients seen for BPH



### The Objective of Treatment Is Improving QOL

The primary goal of BPH treatment is to improve the patient's QOL.

Our goal is to free patients from having to wake up frequently at night to urinate, worrying about where the bathroom is when away from home, enduring long meetings, trouble urinating, or the constant urge to urinate, and help them regain a more active lifestyle.



### Conventional Treatments Not Fully Effective on All BPH Patients

The method of BPH treatment, whether it is simple observation, medical treatment or surgery, depends on the condition of the patient and severity of the symptoms. Alpha-1 blockers, though they cannot shrink the enlarged prostate, are used as the drug of the first choice for BPH because they can quickly alleviate excessive tension on the sympathetic nerve, which will loosen the urethra and prostate, and allow urine to flow better.

It is said, however, about one-third of BPH patients do not obtain a sufficient treatment effect from alpha-1 blockers. Other drugs, such as 5-alpha reductase inhibitors which can shrink the enlarged prostate and plant preparations like Eviprostat<sup>®</sup> that can reduce swelling or inflammation of the prostate, are also prescribed. Nevertheless, the existing medical treatments of BPH lack sufficient efficacy, which has required the development of a drug with a new mechanism of action.

### Breakthrough New Drug Zalutia® Offers a New Choice for Patients

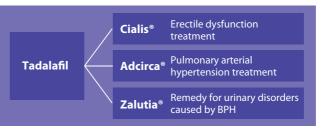
Zalutia® represents a new choice for patients with BPH, offering a completely different mechanism of action compared to conventional drugs because it inhibits phosphodiesterase type 5 (PDE5).

Nitric oxide that is released from the nerve endings when a man urinates produces cyclic guanosine monophosphate (cGMP), which loosens the urethra and prostate, enabling smooth urination. Zalutia<sup>®</sup>'s mechanism of action is to increase the concentration of cGMP by inhibiting PDE5 which degrades cGMP and to improve any problems in urinating. Also, cGMP dilates blood vessels and improves blood flow in the prostate and the bladder. Furthermore, Zalutia<sup>®</sup> is understood to be effective at reducing excessive activity of the afferent nerve from the bladder.

## Tadalafil – PDE5 Inhibitor

Nippon Shinyaku has already commenced marketing for Cialis<sup>®</sup>, an erectile dysfunction treatment, and Adcirca<sup>®</sup>, a pulmonary arterial hypertension treatment. Both products contain the same long-acting PDE5 inhibitor called tadalafil as an active ingredient. Since PDE5 inhibitors can be effective against BPH, tadalafil was newly developed as a treatment to improve urological disorders associated with BPH and launched under the trade name Zalutia<sup>®</sup> in April 2014.

With this release, Nippon Shinyaku now has a lineup of three tadalafil products for different indications.



## Zalutia®'s Strong Reputation

Clinical trials carried out to date, including those in Japan, found that Zalutia<sup>®</sup> significantly improved lower urinary tract symptoms compared to placebo. Research papers in Japan and overseas have reported that Zalutia<sup>®</sup> has a very high treatment satisfaction rate among patients.

In Europe, where tadalafil is already used to treat BPH, PDE5 inhibitors were assigned the same grade as alpha-1 blockers in the guidelines revised in 2013. Treatment guidelines in Japan left the recommendation grade of tadalafil pending because tadalafil was unapproved in 2011 when the guidelines were issued. As for evidence level, tadalafil received the same high appreciation as alpha-1 blockers.

## Initiatives for Ensuring Proper Drug Usage

The proper use of Zalutia<sup>®</sup> is extremely important for achieving the greatest efficacy and treating BPH effectively. This is why Nippon Shinyaku provides proper information to medical care professionals in the field to ensure the drug is used correctly by patients diagnosed with BPH.

Additionally, through our website (http://www.nippon-shinyaku.co.jp/) we provide a wide range of information, including easy-to-understand explanations about the mechanisms behind urination for patients and their

families, and also share messages from specialist physicians. Going forward we will continue with these activities to raise awareness among consumers.

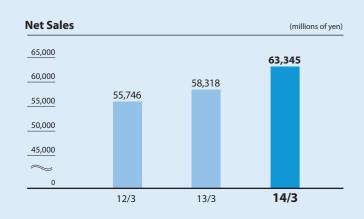
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"For Patients/Healthcare Professionals" page

## **Pharmaceuticals**



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



#### **Market Conditions**

### Market conditions remain challenging

In fiscal 2013, Japan's prescription drug market was valued at some ¥10.16 trillion on a NHI price basis. However, challenging market conditions continue to persist in Japan. For example, it has been decided in the NHI price system reform of 2014 that prices of long-listed drugs<sup>\*1</sup> for which generics have yet to reach a 60% share after five years from the initial listing<sup>\*2</sup> will be reduced further every time NHI price revisions are made until the share reaches 60%.

Nevertheless, a number of new drugs have been released, including therapeutic agents for diabetes and osteoporosis as well as narcotic analgesic agents, as overall demand in the market has grown for pharmaceuticals to treat conditions such as cancer, osteoporosis, and rheumatoid arthritis.

\*1 Long-listed drug: An original drug for which the patent has expired and generic versions are available
\*2 Listing: Approved as a prescription drug covered by NHI

#### Sales Conditions

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

Nippon Shinyaku is shortening its R&D lead time in order to deliver new unique and high quality drug products to patients as soon as possible, and continues to bring new drug products to market. We are also committed to enhancing the value of our existing pharmaceuticals by modifying drug formulations and applying for additional indications, so as to accommodate the needs of both patients and medical professionals alike.

Our pharmaceuticals business saw a decline in sales for existing core drugs due to the influence of generics and competitor drugs, but overall sales increased robustly thanks to the growth of new drug product lines and approvals of additional indications for our existing pharmaceuticals.

Current fiscal year sales rose for Vidaza®, a myelodysplastic syndrome treatment, Lunabell®, combination tablets for dysmenorrhea, Adcirca®, a pulmonary arterial hypertension treatment, Tramal®, a treatment for cancer pain and chronic pain, and Regtect®, a drug for supporting maintenance of abstinence in patients with alcohol dependence. As a result, pharmaceuticals business net sales rose 8.6% year-on-year to ¥63,345 million.

#### Prospects for Fiscal 2014

## 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 5th Five-year Medium-term Management Plan.

In fiscal 2014, we will focus efforts on promoting the further market penetration of our new drug product lines, including Zalutia<sup>®</sup>, a drug for urinary disorders caused by Benign Prostatic Hypertrophy (BPH) that was launched in April 2014. We will also make efforts to increase the market penetration of 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, both released last year, following a lifting of the dosing period restrictions.<sup>\*3</sup> We expect to increase our revenues from new drug products by 35.9% year-on-year in 2014.



The growth in sales of our new drug products is expected to increase net sales of our pharmaceuticals business by 11.5% year-on-year to ¥70,600 million.

With regard to R&D, an application for new drug approval of ACT-064992 (Macitentan), a therapeutic agent for pulmonary arterial hypertension, was filed. In addition, we applied for the new drug approval of long-acting oral analgesic NS-24 (Tramadol hydrochloride). We are moving forward with phase II trials for NS-304 (Selexipag), antipruritic drug NS-141 and NS-986, a therapeutic agent for nocturia, and are aiming to commercialize these drugs as soon as possible. Additionally, an investigator-initiated early-stage and exploratory clinical trial recently began for NS-065, a therapeutic agent for Duchenne muscular dystrophy. NS-065 is the first Japanese-made nucleic acid drug<sup>\*4</sup> to enter this stage.

In this manner, we will continue to bring unique drug products to market in order to boost our competitiveness and earning power, and maximize corporate value.

\*4 Nucleic acid drug: A collective name given to pharmaceuticals which contain linear nucleic acid or modified nucleic acid as the active ingredient and control the functions of a specific gene

<sup>\*3</sup> Dosing period restriction: A rule whereby new drugs can only be administered for a 14-day period for one prescription during the first year after their listing

## **Research & Development**

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

### Aiming to steadily and continually bring new drug products to market in specialty fields where we focus

We have determined five fields of medicine on which we strategically focus our medium- to long-term R&D efforts: urology, hematology, intractable/orphan diseases (pulmonary arterial hypertension, muscular dystrophy, and dependency), gynecology, and otorhinolaryngology. Targeting these specialty fields, we aim to build our development pipeline around in-house drug discovery, licensing from other companies, and product life cycle management (PLCM) in order to steadily and continually bring new drug products to market.

#### In-house Drug Discovery

With a focus on our core medical specialty of urological and hematological diseases, in-house drug discovery focuses on the development of highly competitive, unique and proprietary drugs. In-licensing

We work actively to license in both marketed products and development candidates 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** 

## Focusing on the development of nucleic acid drugs

Nippon Shinyaku is actively engaged in the advanced research of nucleic acid drugs at its Discovery Research Laboratories in

Tsukuba. Nucleic acid drugs, which directly target a specific disease-causing gene, offer great possibilities as a new treatment of diseases. We are focusing drug discovery efforts on nucleic acid drugs in order to quickly deliver these drugs to the frontlines of medicine to treat rare and intractable diseases that have proven difficult to treat until now.

#### Development of the R&D Pipeline

## Progress being made on many development candidates

We have seen progress on a number of development candidates since April 2013. First, we launched Zalutia®, a drug for urinary disorders caused by BPH in April 2014. We anticipate that this drug represents a new treatment option in our specialty field of urology and will contribute to improved patient QOL.

With regard to the status of applications, in May 2014 our licenser Actelion Pharmaceuticals Japan Ltd. filed an application for new drug approval of ACT-064992 (Macitentan), a therapeutic agent for pulmonary arterial hypertension that we have been jointly developing together. Also, we applied for new drug approval for NS-24 (Tramadol hydrochloride), a long-acting oral analgesic, in June 2014.

As for development candidates, we began phase II clinical trials for NS-141 (our original drug), an anti-pruritic agent, in September 2013, and NS-986 (in-licensed product from Dainippon Sumitomo Pharma Co., Ltd.), a treatment for nocturia, in December 2013. In addition, we began a phase II clinical trial in August 2013 for arteriosclerosis obliterans (ASO) patients as part of PLCM activities for our original drug NS-304 (Selexipag) currently under development as a therapeutic agent for pulmonary arterial hypertension.



#### We are working on expanding and advancing our development pipeline with a focus on diseases without an established treatment method

We have properly allocated management resources to in-house drug discovery, in-licensing, and PLCM after identifying our R&D specialty fields and we are now aiming to further expand our development pipeline and steadily bring new products to market. An example of our success was the April 2014 release of Zalutia®, a drug for urinary disorders caused by BPH. We have also made solid progress with many promising development candidates, including applying for new drug approval of long-acting oral analgesic NS-24 (Tramadol hydrochloride).

In the future, we will engage actively in the development of novel drugs primarily for patients with conditions that have no established treatment while also leveraging nucleic acid drugs and other emerging technologies. In order to provide effective pharmaceuticals for patients as quickly as possible to the frontlines of medicine and help people lead healthier, happier lives, we will expand and make further progress with our development pipeline in the future.

#### Akira Matsuura

Director, General Manager, Research & Development Division

#### **Pipeline: Domestic**

-						
ode No. (Generic name)	Development phase	Therapeutic field	Indications	Orig		
	Application	Cardiovascular and metabolic system	Pulmonary arterial hypertension	Licensed-in from: A Pharmaceuticals Lt		
ACT-064992 (Macitentan)			dual endothelin receptor antagonist t ined positive results. A joint phase III t			
NS-24	Application	Pain, inflammation, and allergies	Cancer pain Chronic pain	Licensed-in fro Paladin Labs In		
(Tramadol hydrochloride)			hydrochloride, which has the same c An application was submitted in Japa			
	PIII	Hematologic malignancies	Indolent non-Hodgkin's lymphoma Aggressive non-Hodgkin's lymphoma	Licensed-in from Chugai Pharmac		
GA101 (Obinutuzumab)	A humanized anti-CD20 monoclonal antibody which targets CD20 on B cells. Chuga Japan in October 2008. A joint development and marketing agreement was signed v					
	PII	Cardiovascular and metabolic system	Pulmonary arterial hypertension/Chronic thromboembolic pulmonary hypertension	Nippon Shinya		
NS-304	Orally-available, long-acting PGI2 receptor agonist, currently in phase II trial conduct					
(Selexipag)	PII	Cardiovascular and metabolic system	Arteriosclerosis obliterans	Nippon Shinya		
	Initiated phase IIa trial in August 2013.					
	PII	Pain, inflammation, and allergies	Pruritus associated with cutaneous disease	Nippon Shinya		
NS-141	An external preparation with a new mechanism of action that has no antihistaminic additional phase lla trial for the indication of atopic dermatitis associated pruritus in					
	PII	Urology	Nocturia	Licensed-in from Sumitomo Pha		
NS-986	Has a combination of antimuscarinic effect and ability to block sodium channels on March 2013 for the exclusive development, manufacturing, and marketing of the pro					

#### Pipeline: Overseas

Code No. (Generic name)	Development phase	Therapeutic field	Indications	Ori		
NM441 (Prulifloxacin)	PIII	Infectious diseases	Synthetic antibacterial	Nippon Shiny		
	PIII	Cardiovascular and metabolic system	Pulmonary arterial hypertension	Nippon Shiny		
NS-304 (Selexipag)	Actelion Pharmaceuticals Ltd. (Switzerland) conducted a phase III trial worldwide, e					
NS-187 (Bafetinib)	PII	Hematologic malignancies	B-cell chronic lymphoid leukemia	Nippon Shiny		
	Potent inhibitor of Bcr-Abl and Lyn tyrosine kinases. Possibly effective in imatinib-					
	PI/II	Hematologic malignancies	Myelofibrosis	Nippon Shiny		
NS-018	JAK2 tyrosine k	kinase inhibitor.	Due to its high selectivity to activated	d JAK2, it can be		

				A	s of Augu	st 8, 2014
igin	Development	Phase I	Phase II	Phase III	Application	Launch
n: Actelion 5 Ltd. (Switzerland)	Co-development: Actelion Pharmaceuticals Japan Ltd.					
	e a day. Actelion Pharmaceutic 2012. In May 2014, Acetlion Ph					
rom: Inc. (Canada)	Nippon Shinyaku					
acy and safety as I.	Tramal® with one dose a day.	Available in	17 countrie	es around tl	ne world. Ph	ase III trial
om: aceutical Co., Ltd.	Co-development: Chugai Pharmaceutical Co., Ltd.					
gai Pharmaceutical Co., Ltd. began its development as a therapeutic for non-Hodgkin's lymphoma in d with Chugai Pharmaceutical Co., Ltd. in November 2012, and joint development is being conducted.						
yaku	Co-development: Actelion Pharmaceuticals Japan Ltd.					
ucted together w	vith Actelion Pharmaceuticals	Japan Ltd.				
yaku	Nippon Shinyaku					
yaku	Nippon Shinyaku					
iic activity. Has a in September 20	n effect on intractable pruritu 113.	s that does 1	not respond	l to existing	treatments	. Initiated
rom: Dainippon harma Co., Ltd.	Nippon Shinyaku					
	e fibers. Signed a licensing agr			n Sumitomo	) Pharma Co	., Ltd. in

igin	Development	Phase I	Phase II	Phase III	Application	Launch
vaku	Licensed-out to: Lee's Pharmaceutical Holdings Ltd. (Hong Kong)					
/aku	Licensed-out to: Actelion Pharmaceuticals Ltd. (Switzerland)					
except in Japan,	and is now preparing to appl	y for approv	val.			
vaku	Licensed-out to: CytRx Corporation (USA)					
esistant and/or recurrent leukemia.						
/aku	Nippon Shinyaku					
e a treatment for myelofibrosis with increased efficacy and reduced side effects.						

## Sales

#### Core Measures

### Aiming to enhance our presence in core fields and become a pharmaceutical treatment partner

As part of our marketing strategy, the emphasis of marketing activities has been placed on our new lineup of drug products. Among these, new products such as Vidaza<sup>®</sup> and Adcirca<sup>®</sup> are used by highly specialized physicians in specific fields of medicine. Our mission to ensure the proper usage of our drug products includes not only providing product information based on evidence, but also delivering related information required by medical professionals in a timely manner.

Starting in fiscal 2013 we established an in-house MR gualification test program as part of our efforts to foster a corporate culture focused on daily knowledge acquisition and continual self improvement. In the basic course held during the initial fiscal year we began testing academic knowledge on a basic level, and in fiscal 2014 we will roll out advanced (developmental) and specialist (applied knowledge) forms of this in-house certification system. Additionally, we will establish a prompt cycle where we quickly ascertain the ever changing needs of patients and medical professionals and use this information to respond to their needs. This will enable us to capture greater trust from medical professionals and society, enhance our existential value, and become a pharmaceutical treatment partner for patients and medical professionals.

### Established a system that can respond promptly to the needs of medical professionals

The Marketing Division combines its marketing, academic and logistics capabilities to formulate and implement an action plan that includes marketing guidelines and product strategy. In this manner, we are implementing a robust action plan that combines measures from each department and clearly defines our actions.

In fiscal 2014, we newly established the Product Marketing Department in order to promote and implement our marketing action plan, and a product manager has been assigned to each of our four new products: Zalutia®, Vidaza®, Adcirca® and Lunabell<sup>®</sup>. Through this arrangement, we are maximizing the value of our products by enhancing promotional campaigns targeting key opinion leaders (KOL)\*1 throughout Japan and formulating strategies for the future of the drug, based on which specific action plans are implemented.

To ensure information on the proper use of our specialized drug products such as Vidaza® and Adcirca® is provided in an efficient manner, we have made changes to the structure of our marketing organization and added hospital sales offices. 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.

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

#### Our commitment to compliance

We are constantly mindful of compliance and make efforts to ensure compliance is practiced appropriately so that each and every one of our employees is self aware as a member of the medical professional community that has peoples' lives in its hands.

Every month we hold compliance training at all of our sales offices 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 2013, we disclosed data on money we have provided to medical institutions in accordance with the Transparency guidelines for relationship between corporate activities and medical institutions established by the Japan Pharmaceutical Manufacturers Association. Furthermore, as measures against counterfeit pharmaceutical drug products, we work to educate medical professionals by exhibiting counterfeit erectile dysfunction (ED) drugs at events co-sponsored with the Japanese Society for Sexual Medicine.



#### Making efforts to maximize the potential of our new drug products quickly in order to achieve continual growth

Fiscal 2013 turned out to be a very challenging year for pharmaceutical companies, as efforts to promote the use of generics were further strengthened. Despite this environment, we continued to grow by focusing our marketing activities on our new drug products, such as Vidaza®, the myelodysplastic syndrome treatment, and providing comprehensive information to meet the needs of both patients and medical professionals.

In fiscal 2014, which will be the first year in our 5th Five-year Medium-term Management Plan, we launched Zalutia®, a much-anticipated new drug for the urology field used to treat urinary disorders caused by benign prostatic hypertrophy. Going forward, each of our departments will work together to carry out marketing activities and achieve further growth by expanding

our new drug product lines, with a focus on the three fields of urology, hematology, and pulmonary hypertension. To quickly maximize the potential of our new drug products, we will ensure the proper usage, strengthen our system for collecting information and enhance the quality of our MRs' marketing activities in order to be a company that is continually trusted by patients and the entire medical professional community.

Tetsuyasu Yuno Director, General Manager, Sales and Marketing Division

## **Production**

#### **Core Measures**

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

Because our single greatest mission is to provide stable supplies of high quality active pharmaceutical ingredients and drug products, we have sourced raw materials from two separate suppliers, ensured the stable operation of production equipment, and pursued a rigorous approach to GMP\*3 controls.

In fiscal 2012 we established a target and began building inventory of anti-cancer drugs because of their great impact on society and in fiscal 2013 we reached this target. Also, in fiscal 2013, we systematically upgraded the central monitoring equipment for controlling air conditioning and the water used in the manufacturing process at our Odawara Central Factory in accordance with its BCP. In fiscal 2013 we were also able to supply our newly launched drug products to market without delay. In fiscal 2014, we will step up our facilities maintenance and increase our utilization performance in order to provide further stable supplies of drug products to market.

\*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 continue to implement cost reduction efforts within each division in order to enhance our profit margin. In fiscal 2013, we expanded the scope of staggered work schedules to curb personnel costs associated with overtime and also centralized shipment locations to reduce logistics costs.

Meanwhile, in addition to current drug products being manufactured on consignment, we received orders for five drugs and eight items on consignment, with manufacturing slated to begin in fiscal 2014. We are now focused on

#### 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. In fiscal 2013, which marked the end of our 4th Five-year Medium-term Management Plan, we established a BCP for the Odawara Central Factory and systematically implemented risk aversion strategies for the entire supply chain, as part of our efforts to ensure a stable supply of drug products. Furthermore, in fiscal 2013 we steadily increased the number of candidates for consigned products in our Consignment Manufacturing Business thanks to highly positive assessments of our technological prowess and reliability as a novel drug manufacturer. Fiscal 2014 represents the start of our 5th Five-year Medium-term Management Plan. Under a new set of management targets, we will further enhance our stable product supply system by reinforcing facilities maintenance and increasing utilization performance. At the same time we will proactively work to make contributions to local communities, expand our Consignment Manufacturing Business including formulation designs and manufacture of investigational new drugs, and further reduce procurement, production and logistics costs.

developing our Consignment Manufacturing Business, from formulation of investigational new drugs to commercial production, by utilizing one of Japan's largest microparticle coating machines used to manufacture orally-disintegrating tablets\*4 which we installed at the Odawara Central Factory.

\*4 A tablet that can be disintegrated inside the mouth with saliva or a small amount of wate and can easily be swallowed

## Striving to advance quality assurance and safety management

Our Assurance Division is mainly in charge of product quality and safety management, which are both essential elements of any pharmaceuticals company.

The division performs audits at the appropriate stage to ensure the reliability of research data when preparing trials and application documents to obtain new drug manufacture and marketing approval. In addition, it also implements audits at sites that manufacture active pharmaceutical ingredients and formulations to verify their compliance status with GQP\*5 and GMP.

As for managing the safety of our pharmaceutical products, in addition to adhering to GVP,\*6 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 necessary we provide feedback to medical professionals and patients.

In fiscal 2013, we developed and enhanced an operational manual and 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. This enables us to manage the risk of pharmaceuticals better as well as properly respond when applying for new drug approval.

In fiscal 2014, we will comply with the package insert notification system instituted under the revised Pharmaceutical Affairs Act (issued in November 2013) and carry out further efforts in safety management.

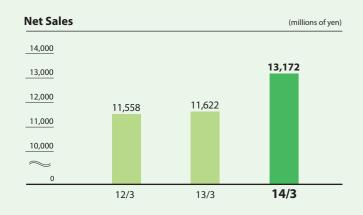
\*5 Good Quality Practice: Quality management standards for pharmaceutical products \*6 Good Vigilance Practice: Safety management standards for pharmaceutical products after marketing approval

Hitoshi Saito 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." As the functional food business division of a pharmaceutical company, we are able to help people lead healthier, happier lives by providing functional food materials for processed foods and healthcare foods that are not only safe and secure, but also high quality and highly original.



#### **Market Conditions**

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

Japan's processed food market continues to face challenging conditions amidst consumer's thrifty inclinations. The increase in major retailer's private brands has spurred competition with national brands. Additionally, there are concerns over the impacts Japan's consumption tax hike in April 2014 will have on spending. On top of this, processed food manufacturers have suffered a blow in terms of costs from the elevated cost of various ingredients and weakening yen. Although the series of economic stimulus measures known as "Abenomics" has resulted in a positive economic outlook, more time will likely be required before the positive effects on the economy and consumer spending trickle down to the processed food industry. At the same time, 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.

To break through this challenging environment, currently processed food manufacturers are moving forward with product development that opens up new demand channels by establishing a competitive edge in terms of quality, under the key words of functionality, health consciousness, safety, ease and simplicity of preparation, authentic taste, and menu proposals.

#### Sales Conditions

## Revenue increased on the back of a rise in sales of preservatives, nutritional ingredients and protein preparations

We focused on new product development and expanding sales channels by strengthening initiatives for flagship products. As a result, sales of preservatives increased thanks to "Mikaku Fine Z," although sales of health food ingredients declined due to the impact of price competition. Sales of nutrition ingredients steadily increased thanks to a hike in product prices and a larger volume of whey protein. Sales of protein preparations saw a significant increase thanks to strong growth in the volume of soy protein and product price hikes.

Based on the above, sales rose 13.3% year-on-year to ¥13,172 million.

#### Main Strategy

### Focus on product development and sales growth with clearly defined targets

The Functional Food Company manufactures and markets seasonings and spices, preservatives, health food ingredients, nutritional ingredients, protein preparations, sterilizers, and cleansers. These are used as auxiliary ingredients and food additives in processed foods, health foods, and nutritional foods for seniors and hospitals, and are used in keeping factories sanitary. 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 terms of R&D, we are focused on developing functional food ingredients with high added value for the fields of nutrition and nutraceuticals\* with an eye on the growing health inclination of consumers and Japan's aging society.

In terms of sales, we have regarded preservatives, health food ingredients, nutritional ingredients, and protein preparations as our flagship products and will expand sales of these products by narrowing the focus of targets. For preservatives, we will focus on growing sales of our proprietary preparations such as "Mikaku Fine Z" and the all-new "Glycine GX-2." 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. 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 active seniors. As for protein preparations, our focus is on expanding sales of soy proteins.

In terms of quality assurance, in order to satisfy consumers' increasing demands for safe and secure foods, we are reinforcing our product risk management, and performing

#### We will contribute to society by providing original functional food ingredients that help people live longer, more active lives, ensure food safety, and reduce food waste

The Functional Food Company will leverage the advanced manufacturing techniques from Nippon Shinyaku's pharmaceuticals business as well as R&D and rigorous quality control standards to deliver high quality functional foods to the processed food and healthcare food fields that are highly original. With safety, quality and functionality our number one priority, we will pursue new product development based on research into the functionality of food ingredients and strive to operate our business efficiently and systematically. In turn, this will enable us to establish a stable earnings base and continually expand our business in the future.

Through these business activities, and under our philosophy of "helping people lead healthier, happier lives," we stand committed to supporting longer more active lives, helping improve food safety, and contributing to a reduction in food waste

audits across the entire supply chain from Japan to sites overseas, strengthening our guality assurance system and providing accurate product information.

In terms of production, we will pursue stable production of high quality products at our subsidiary Tajima Shokuhin Kogyo Co., Ltd. with the support of Nippon Shinyaku.

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

#### **Prospects for Fiscal 2014**

## In addition to bringing new products to market and expanding sales of core products, we will also begin exporting products

Sales for fiscal 2014 are projected to be ¥13.4 billion, a 1.7% increase year-on-year. Although hard times are expected to persist in Japan's food industry, we will strive to expand sales of our high margin flagship products, which include health food ingredients and preservatives.

We will also bring at least one new product to market each year 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 set up a dedicated department for product exports for markets in Asia, where economic and population growth remains strong.

Hiroshi Adachi Director, COO, Functional Food Company



## **CSR** Management

### **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

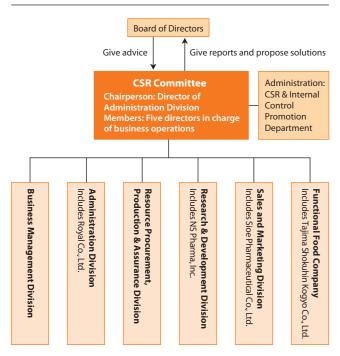
responsibility (CSR). To realize this approach, we have established codes of conduct for each group of stakeholders.



## 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

#### Framework for Corporate Social Responsibility (as of April 1, 2014)



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.

### **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.

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

The 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.

As such, the 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.
I	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.
Ш	We will maintain a safe and comfortable work environment by respecting each individual's rights and personality.
N	We will promote business activities that are environmentally friendly, and will aim to maintain and improve the global environment.
V	We will build a trusting relationship with our stakeholders through timely and adequate communication of company information.
VI	We will implement unfettered competition that is fair and transparent by maintaining a healthy and adequate relationship with the politicians, governments, and business partners.
VI	We fully recognize the values of our corporate assets including information asset, and will manage these appropriately.
VII	We will not comply with inappropriate or unlawful requests from antisocial forces or organizations who threaten the safety and order of civil society.
X	As a member of society, we will take a proactive approach in social contribution activities.
х	We will comply with international rules and local regulations, as well as respect local culture and customs in our global business activities.

#### Aspiring to achieve sustainable growth together with the society

To achieve our goal of becoming a "Company with a meaningful existence in healthcare," we must grow sustainably together with society and I believe this represents the true meaning of the Nippon Shinyaku Group's CSR. I also find it very important for us to carry out CSR initiatives that meet the demands of society outside our business activities.

From this perspective, we run the Nippon Shinyaku Children's Literary Awards, which nurtures the spirited growth and future dreams of children, and the Nippon Shinyaku & Seitaro Kuroda Smiles Art Project, which helps to soothe patients' minds by drawing a picture on hospital walls and pillars. In addition to environmental conservation initiatives, in recent years we are also promoting the "Maruenu Supplement" project, which provides support to working women.

Going forward, our executive officers and employees are fully committed to carrying out fair and honest corporate activities based on highly esteemed ethics, with the ultimate goal of achieving sustainable growth together with society.

## **Respect for Human Rights**

The Nippon Shinyaku Group respects human rights and the personalities of individuals. We believe that a company can grow only after the individuals' independence and creativity are fully leveraged.

Among human rights problems, harassment, in particular, is a serious issue that can hurt people's dignity. To eradicate harassment, Nippon Shinyaku expanded its Sexual Harassment Prevention Rules into the Harassment Prevention Rules in January 2014. We are also working to prevent harassment through compliance training and other means.

## **Ethical Considerations for R&D**

Nippon Shinyaku has established a framework to ensure that human rights and animal welfare are rightly considered in each stage of new drug development.

Basic research that predicts the safety and efficacy of medicines in humans follows internal rules established according to the ethical guidelines issued by the Japanese government to give ethical consideration to the providers of human specimens, such as cells, tissue, and blood. Our ethical committee for basic research relating to humans, comprising insiders and external parties, carefully and fairly reviews the research and publicly discloses information related to these reviews.

Clinical trials to verify the efficacy and safety of medicines in humans are carried out with a strong emphasis on the human rights of patients who participate in these trials, and protecting their personal information as well as securing their safety and welfare. We adhere to legislation such as the Pharmaceutical Affairs Law and standards such as GCP<sup>\*1</sup> and strive to conduct high quality clinical trials by reviewing the ethical and scientific validity of the clinical trial through our internal review committee

Research using animals to confirm the safety and efficacy of medicines follows internal rules that are compliant with regulations and guidelines on animal welfare. We make sure all animal testing gives proper consideration to the 3R principles\*2 through the operations of a committee for animal testing.

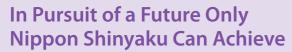
\*1 GCP: Good Clinical Practice

\*2 The 3R principles refer to "replacement" for considering alternatives to animal testing, "reduction" to minimize the use of animals, and "refinement" to reduce the agony or discomfort animals suffer

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



## Standing Alongside Patients and Medical Professionals



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 passionately committed to making unique medicines. Our job goes beyond supplying medicines and includes providing information on the medicines we market, educating patients, and finding ways to eradicate counterfeit drugs that can cause serious health consequences. 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.

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 ED. In addition, we are actively providing information and promoting awareness about



Our support site for alcohol dependence

counterfeit ED drugs. We manage other websites as well, including our "Nose Care" site (http://hana783.jp/), which focuses on allergic rhinitis.

#### 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 patient and medical professional 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.

We also contribute 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.

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

 $^{\ast}2$  Explanation sheets (in Japanese, English, and other languages) intended for patients

#### **Common Inquiries**



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

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

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

At the R&D stage of product development, we carry out clinical and non-clinical tests, and prepare application documents for manufacture and marketing approval. Our Assurance Division audits these documents at the appropriate stage to assure the accuracy of non-clinical test data and the reliability of clinical trials. After receiving manufacture and marketing approval, we assure the quality of the product being manufactured and sold, affirm its safety, and work to manage and maintain manufacture and marketing approval and marketing authorization.

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

R&D stage				
Nonclinical test	ts	Clinical trials		
Test data reliability assur on GLP*3 and reliability c		Clinical trial reliability assurance based on GCP		
Post-manufacture and marketing				
Manufacturing	Marketing		Maintenance and management of approval and authorization	
Post-manufacture and marketing quality assurance based on GMP and GQP	Post-manufacture and marketing safety management based on GVP		Maintenance and management of manufacture and marketing approval and marketing authorization	
and GQP GVP marketing authorization *3 GLP: Good Laboratory Practice				

GLP: Good Laboratory Practice

#### Close Collaboration between Three Management Chiefs

To become a marketing authorization holder a company must obtain official government approval to manufacture and market new drugs. This system requires that marketing authorization holders 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 brought to market.

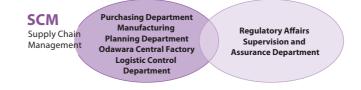
At Nippon Shinyaku, we follow these stipulations and appoint the three officials as a team of leaders that meets regularly to share information and ensure close, collaborative operations between all relevant departments.

Nippon Shinyaku's Quality Assurance Division works 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, to check the status of 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.

#### **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.

#### Framework for Supplying Products



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.

#### 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>\*4</sup> and a cell manufacturing system<sup>\*5</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 2013, with our continued focus on avoiding shortage risk, we have increased the inventory on hand of products with great importance in society.

\*4 Training and education that makes each employee proficient in multiple tasks

\*5 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

### **Responding to Patient Needs**

Nippon Shinyaku makes product modifications and quality improvements based on feedback received from patients and medical professionals. Examples of this include the development of products that are both easy to swallow and convenient to use.

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

### **Measures Against Counterfeit Drugs**

Counterfeit medicines can have serious health consequences and have grown into a major worldwide issue. With the spread of the Internet there has been a steady increase in the number of counterfeit products that have been imported to Japan by individuals.

Nippon Shinyaku recognizes that improved counterfeiting awareness represents a means to eliminate counterfeit drugs and an important aspect of its corporate social responsibility. In 2013, we worked with three companies involved in the manufacture and distribution of ED treatments on measures to combat the counterfeiting of ED medicines, and since 2009 we have raised greater awareness by hosting press seminars for the media and displaying counterfeit products at academic society meetings. Additionally, information related to ED pharmaceutical counterfeiting is available through our ED Care Support website (see page 23).

We also have an anti-Counterfeiting Committee to check and 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 information for governmental initiatives.

## 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 fostering a corporate culture where individual human rights are respected, developing systems to ensure the health and safety of employees, promoting a work-life balance, supporting women in the workplace, and creating environments where people can work without worry.

#### **Creating Employee-friendly Workplaces**

As part of its work-life balance promotion efforts, Nippon Shinyaku is carrying out the "Good Job Initiative," which is defined 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, while advancing productivity and equality through incorporating appropriate rotation of duties. This prevents work from being disproportionately assigned only to certain individuals.

In fiscal 2013, we established a new system for taking paid leave, encouraged the entire company to leave work together on time, shared messages from the president, and disseminated information on company initiatives biweekly. We plan on continuing these initiatives in fiscal 2014 as well.

## 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 employee, 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, Nippon Shinyaku started the "Maruenu Supplement" project to provide support for women in the workplace.

Up to fiscal 2013 we held presentations and in-house study sessions on the theme of diversity, supported female science students, held networking sessions with companies from different industries, and held training for newly appointed managers. We have also rolled out a wide range of measures to develop workplaces where female employees can thrive professionally more than ever. We will continue to carry out these initiatives in fiscal 2014 and beyond, as well as examine and carry out new measures too.

#### **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 high-quality drugs as a pharmaceuticals manufacturer, our other role is contributing to the development of communities as a member of society. We are working hard to educate patients, support organizations carrying out activities that benefit the public, sponsor and host sporting and cultural events, and carry out cultural preservation activities in our hometown of Kyoto. We have also instituted the Nippon Shinyaku Children's Literary Awards with the hope that we can nurture the spirited growth and future dreams of the children who will inherit our world.

#### **Disease Education Activities**

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 as well as hosts seminars on menstrual pains primarily during Women's Health Week between March 1 and 8, and also educates patients through its involvement in the Dysmenorrhea Education Forum, which was established in February 2014.

Also, we regularly update information on menstrual cramps on our website called "Talking About Menstrual Cramps" (http://seiritsu.jp/) to provide information to women troubled by this medical condition.



Our "Talking About Menstrual Cramps" website

#### 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 created the Nippon Shinyaku Children's Literary Awards to commemorate our 90th anniversary in 2009. The Nippon Shinyaku Children's Literary Awards work with the support of the Japan Juvenile Writers Association to call for works of art as either stories or illustrations. 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 (http://kodomo-bungaku.jp/) are able to see electronic versions of the books and hear them read aloud as they browse the pages.

We invited winners and children from the local community to attend an awards ceremony in October, which also included workshop where the children made original illustrated plastic umbrellas using hints from the picture book titled *Amekun Debut* created in the fifth Awards.

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.



Picture book Amekun Debut



Group photograph from the Awards Ceremony

## **VOICE**

#### Encouraging More Children to Enjoy Reading through a Literary Award

The Storybook Category of the Nippon Shinyaku Children's Literary Awards receives nearly 2,000 submissions each time. I screen works using my experience as a children's fairy tale author to check if the story can be enjoyed by children and open their heart, and if the story is written rhythmically using easy words. I find it very helpful that members of the selection committee, which include a physician involved in pediatric medicine and a painting instructor, among others, are able to use their life experiences during the screening process. I look forward to the further expansion of these activities for

encouraging even more children to enjoy picture books, including the hosting of reading sessions at hospitals and other facilities.

#### Ms. Nobuko Oka

Author of children's picture books and fairy tales Selection Committee Chair for the Nippon Shinyaku Children's Literary Awards



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.

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

Beginning in 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 art.

The second project took place at Hoai Hospital in Osaka which provides comprehensive rehabilitation services. A group of around 50, comprising rehabilitation patients, their families and hospital staff, worked with Mr. Kuroda to create the wall art. Mr. Kuroda said he wanted people to feel at ease even for a moment looking at the adorable and attractive illustration. He drew a bird spreading its wings looking upward on the wall of the hospital and rehabilitation center.

The third project was held at the Kitakyushu Municipal No. 2 Night and Holiday Emergency Center (Kitakyushu City, Fukuoka Prefecture) in April 2014. A total of 35 children from the suburbs of the city worked with Mr. Kuroda to create unique wall art for the facility.

"I always feel a greater sense of motivation when working together with patients and children," said Mr. Kuroda about his experience. This time the wall art featured one of hope and inspiration, with birds taking flight and flowers the main subject.

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.



Group photo of participants from the Kitakyushu Municipal No. 2 Night and Holiday Emergency Center

#### 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, including 140 original species appearing in the Japanese Pharmacopoeia as natural remedies. The Institute preserves these, and carries out its horticultural research, as a way of contributing to the protection of our natural biodiversity. Additionally, the Institute maintains close contact with experts from universities and botanical gardens across Japan and also holds discussions on environmental issues as well as the protection and cultivation of species facing extinction through

seminars and other means.

The Institute offers tours by appointment and in fiscal 2013 some 1,100 people visited. The Institute also organized a tour of its facilities and held an indigo dyeing event during summer break for local elementary students.



Yamashina Botanical Research Institute

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

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



Calendar and the A washcloth featuring the Kyoto Tower in its design quarterly magazine Kyo

#### Supporting Education through Sports

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

In August 2013, we held the 1st JABA Kyoto Baseball Workshop sponsored by the Kyoto Baseball Federation at Kyoto's Wakasa Stadium. A total of four teams comprising around 50 players from Kyoto's Little Senior League received instructions. In November, 280 baseball players from 72 high schools in Kyoto took part in the Kyoto High School Baseball Federation Winter Training Workshop. Both events helped to enhance the skill level of elementary and high school baseball players in the prefecture. Also in January 2014, we held our 4th Youth Baseball Workshop for 27 teams and 285 youngsters. The workshop was organized by the Kyoto Baseball Association and co-sponsored by the Kyoto City Amateur Sports Association. Similarly, in the same month, we collaborated with the Odawara Sports Association to hold the 6th Odawara Youth Baseball

Clinic for 6 teams and approximately 70 players from local clubs in the city of Odawara. 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 4th 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 voluntary targets to reduce environmental impacts in accordance with the Nippon Shinyaku Basic Environmental Policy, which serves as a set of guidelines for our environmental conservation activities.

#### **Basic Environmental Policy**

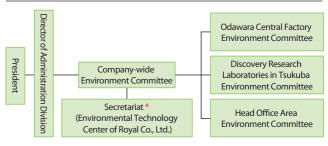
#### Nippon Shinyaku Basic Environmental Policy

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 setting 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.
- 3. 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. Additionally, the Committee verified the achievements of the 3rd Nippon Shinyaku Environmental Targets Plan (fiscal 2011 to fiscal 2013) and established the 4th Nippon Shinyaku Environmental Targets Plan (fiscal 2014 to fiscal 2016) after deliberating new targets for fiscal 2014 and beyond.



#### **Environmental Management Structure**

\* The Secretariat was moved from the Environmental Technology Section to the Environmental Technology Center of Royal Co., Ltd, a subsidiary company, in April 2014

#### Applying Environmental Management Certification

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

The Odawara Central Factory obtained ISO14001 certification, an international standard in environmental management systems, in August 2004. The head office area was certified by KES Environmental Management System Standard Step 2 (KES Step 2) in June 2012 following a revision to the Kyoto City Global Warming Countermeasures Ordinance in April 2011. This system employs the PDCA cycle for individual one-year periods, which bolsters ongoing environmental improvement activities.

#### Audits at Sites with Environmental Management Certification

For production facilities that have acquired ISO 14001 certification, namely the Odawara Central Factory, and the head office area which has obtained KES Step 2 certification, Nippon Shinyaku conducts internal audits and undergoes third-party audits by outside organizations every year.

The results of audits performed by outside organizations found no items to point out at the Odawara Central Factory, as efficient low-cost management considerate of the environment is being carried out. The head office area only had one item of observations, but no items considered to pose a serious environmental risk were found. We will continue to bolster ongoing environmental improvement activities and management efficiency through the operation of our environmental management system.

#### **Audits at Other Sites**

The department that oversees environmental management for the 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 environmental management systems, to confirm the status of environmental preservation activities and compliance with environmental laws and regulations.

In fiscal 2013, we audited our consolidated subsidiary Sioe Pharmaceutical Co., Ltd. This audit verified that the company is operating in full compliance with all laws and regulations.

#### The 3rd Nippon Shinyaku Environmental Targets Plan and Results, and the 4th Nippon Shinyaku Environmental Targets Plan

Nippon Shinyaku has drawn up a Basic Environmental Policy to serve as a set of guidelines for its environmental conservation activities. Voluntary environmental targets have been established to help guide the entire company toward reducing environmental impacts and making contributions to society. Since establishing the 1st Nippon Shinyaku Environmental Targets Plan in fiscal 2004, we have evaluated the results of these plans and revised targets every three years. As a result, we were able to achieve most of our environmental targets in the 3rd Nippon Shinyaku Environmental Targets Plan (fiscal 2011 to fiscal 2013), including CO<sub>2</sub> emissions reduction targets. Given this positive progress, we have drawn up the 4th Nippon Shinyaku Environmental Targets Plan (fiscal 2014 to fiscal 2016) in order to carry out further environmental conservation activities.

Objective	3rd Nippon Shinyaku Environmental Targets Plan	3rd Nippon Shinyaku Environmental Targets Plan Results	4th Nippon Shinyaku Environmental Targets Plan
CO2 Emissions Reductions (Global Warming Countermeasures)	<ul> <li>Hold FY 2013 CO<sub>2</sub> emissions at or below FY 1990 levels.</li> <li>(JPMA target: 23% reduction by FY 2020, as compared to FY 2005 levels)</li> </ul>	• FY 2013 CO2 emissions were reduced by 1.5% compared with FY 1990 to 10,412 tons,*1 achieving the target.	<ul> <li>Reduce total energy consumption (GJ) in FY 2016 to below 1990 levels.<sup>*2</sup></li> <li>Medium- to long-term target: the target for reducing CO<sub>2</sub> emissions shall be the same as that of JPMA.</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>Achieved zero emissions as the final landfill waste ratio was 0.4% thanks to proactive 3R efforts.</li> </ul>	<ul> <li>Actively pursue the 3Rs (Reduce, Reuse, Recycle) and work to increase our usage ratio of recycled materials.</li> <li>Reduce the final amount of landfilled waste in FY 2016 by more than 65% of FY 2005 levels.</li> <li>Keep the final landfill waste ratio below 1% in FY 2016.</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>	<ul> <li>Compared with FY 2011, the amount of chloroform, dichloromethane, and n-hexane handled in FY 2012*4 decreased by 29.0%, 58.4%, and 11.0%, respectively, while that of acetonitrile increased by 25.6%.</li> </ul>	<ul> <li>Promote the proper management of chemical substances, including those stipulated under the PRTR system, and continuously reduce their emission into the natural environment.</li> </ul>
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 area.</li> </ul>	<ul> <li>ISO14001 certification was maintained at the Chitose Synthesis Plant, Chitose Functional Food Plant<sup>+5</sup> and Odawara Central Factory, which are production sites with large environmental impacts, and efforts were made to bolster their EMS.</li> <li>The head office area had not installed an environmental management system, but it acquired certification of KES Environmental Management System (KES Step 2) in June 2012 and strived to make continual improvements.</li> </ul>	<ul> <li>Effectively improve the results of our environmental performance by maintaining certifications for environmental management systems (ISO14001 and KES Step 2).</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>Green purchasing of office supplies was promoted at our main business locations (89% of purchases were green in FY 2013).</li> </ul>	<ul> <li>Reduce product packaging materials as part of pharmaceutical and food product package simplification efforts.</li> <li>Promote green purchasing and procurement practices.</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>Collected aluminum cans at our Odawara Central Factory and donated wheel chairs to the Odawara-city Welfare for the Disabled Conference. Implemented 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>	<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 communities around our business offices.</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>	*6
<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>	*7

\*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 13,136 tons. Calculations are made using the CO<sub>2</sub> real emission coefficients from the Ministry of Economy, Trade and Industry

\*2 Total energy consumption, which is not dependent on CO2 emission coefficient and directly reflects energy-saving efforts, was chosen as the indicator for the three-year period

\*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

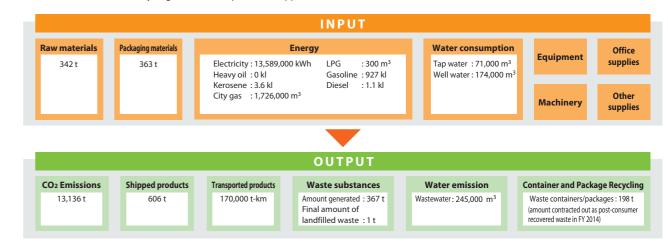
\*4 Due to compilation methods, data displayed extends up to fiscal 2012

5 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 \*6 Carried out as part of the operations of Environmental Technology Center

7 It was determined that solid progress has already been made with the establishment of the Energy Efficiency and Conservation Promotion Committee as a company-wide organization and the introduction of KES Step 2 in the head office area

#### 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



#### **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

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

#### E

Environmental Conservation Co	sts		(thousands of yen)
Costs	Investments	Expenses	Primary Initiatives
Costs within our business areas	11,322	150,678	
Pollution prevention costs	11,322	28,024	Maintenance management of wastewater processing facilities
Global environmental conservation costs	0	67,192	Energy conservation activities
Resource recycling costs	0	55,462	Proper waste disposal efforts
Upstream and downstream costs	0	7,940	Contract costs for post-consumer container/packaging recovery efforts'8
Management activity costs	850	83,694	EMS maintenance and operation, green space conservation, environment-related personnel expenses
R&D costs	0	0	-
Social activity costs	0	2,743	Donations and funding for groups involved with our Elementary School lectures and environmental preservation initiatives
Environmental remediation costs	0	0	-
Total	12,172	245,055	

#### **Environmental Conservation Benefits**

Benefit verification	Units	FY 2012 Results	FY 2013 Results	Amount of Increase/Reduction	Rate of Increase/Reduction
CO <sub>2</sub> emissions	Tons	13,900	13,136	(764)	(5.5%)
Electricity usage	Thousand kWh	14,800	13,589	(1,211)	(8.2%)
Oil, kerosene usage	kl	205	4	(201)	(98.0%)
City gas, LPG usage	Thousand m <sup>3</sup>	1,948	1,726	(222)	(11.4%)
Gasoline, diesel usage	kl	927	928	1	0.1%
Water consumption (main business locations)	Thousand m <sup>3</sup>	260	245	(15)	(5.8%)
Waste substances generated (main business locations)	Tons	471	367	(104)	(22.1%)
Final amount of landfilled waste (main business locations)	Tons	2	1	(1)	(50.0%)

\*8 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 2013 amounted to 5,188,000 yen

Shinyaku's effect on the environment.

Nippon Shinyaku uses the material balance information in its efforts to decrease the amounts of resource and energy inputs as well as environmentally detrimental outputs from its business activities.

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.

#### (excluding our sales offices)

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

Targets	Hold fiscal 2013 CO <sub>2</sub> emissions at or below fiscal 1990 levels.
Results	Decreased by 1.5% to 10,412 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 CO2. 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 2013, in addition to across-the-board electricity conservation and energy saving activities, the Research Laboratories switched its gas refrigerator to a high efficiency electric refrigerator.

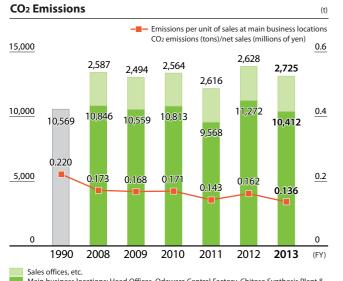
On top of the above tangible and intangible efforts, the transfer of the Chitose Synthesis Plant and Chitose Functional Food Plant to a manufacturer of active pharmaceutical ingredients and intermediates resulted in a reduction in total energy usage\*2 for fiscal 2013 by 30,300 GJ, which marked a 13.1% reduction\*3 compared to fiscal 2012.

CO2 emissions for fiscal 2013 decreased by 7.6%, or 860 tons, compared to fiscal 2012 (11,272 tons). This also marked a decrease of 1.5%, or 157 tons, to 10,412 tons compared with the benchmark year of fiscal 1990 (10,569 tons). A gradual increase in the CO<sub>2</sub> emission coefficient caused by a decline in the operating rate of nuclear power plants meant that the reduction in total energy usage was not effectively reflected in CO2 emissions.

\*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 13,136 tons. Calculations are made using the CO2 real emissions coefficients from the Ministry of Economy, Trade and Industry

\*2 Total energy usage of main business locations excluding sales offices, etc.

3 Reduction from transfer of factories [2012 results]: 17,600 GJ (7.6%); reduction from other sources: 12,700 GJ (5.5%)



Main business locations: Head Offices, Odawara Central Factory, Chitose Synthesis Plant & Functional Food Plant (until FY2012), Discovery Research Laboratories in Tsukuba

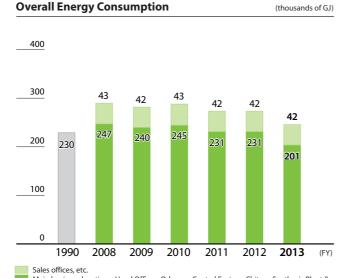
#### **Introducing Environmental Friendly Vehicles in Our Sales Fleet**

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 2013, 98.0% of the 706 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.

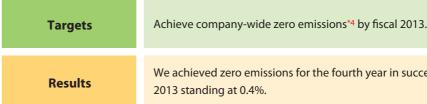


Sales force hybrid vehicle



Main business locations: Head Offices, Odawara Central Factory, Chitose Synthesis Plant & Functional Food Plant (until FY2012), Discovery Research Laboratories in Tsukuba

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



#### **Results of Initiatives**

The amount of waste generated in fiscal 2013 was 367 tons, which marked a decrease of 104 tons from fiscal 2012 following the transfer of the Chitose Synthesis Plant and Chitose Functional Food Plant. Meanwhile, we achieved zero emissions for the fourth year in succession with the final landfill waste ratio standing at 0.4%.

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, in fiscal 2013 we completed the disposal of 20 items, including early registered high-pressure capacitors, at our head office area.

\*4 "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

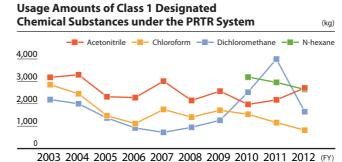
## **Proper Management of Chemical Substances**

Targets	Continue to reduce emissions to the na chemical substances, including chemic
Results	Compared with fiscal 2011, the amount c fiscal 2012 decreased by 29.0%, 58.4%, ar

#### **Results of Initiatives**

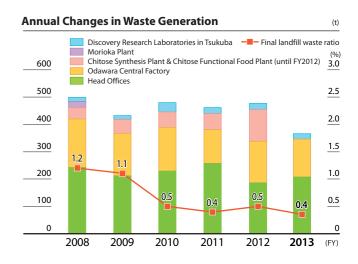
We submit reports to the legal authorities on business sites that handle more than 1 ton of Class 1 designated chemical substances per year based on the PRTR system under the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof.

The amount of chloroform, dichloromethane, and n-hexane handled in fiscal 2012 decreased by 29.0%, 58.4%, and 11.0%, respectively, compared with fiscal 2011, whereas the amount of



Note: Due to compilation methods, data displayed extends up to fiscal 2012

We achieved zero emissions for the fourth year in succession with the final landfill waste ratio in fiscal



natural environment by promoting appropriate management of ical substances designated under the PRTR system.

of chloroform, dichloromethane, and n-hexane handled in and 11.0%, respectively, while that of acetonitrile increased by 25.6%.

acetonitrile handled increased by 25.6%.

In the head office area, we worked 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.

#### Measures for Chemical Hazards and Biohazards

One of our most important tasks is to properly and lawfully handle new chemical substances, genetically modified organisms, and pathogens used in the research and development of pharmaceuticals to prevent environmental pollution as well as occupational accidents and harmful health effects.

Nippon Shinyaku's experiments involving chemical substances hazardous to the environment and people's health are carried out at facilities that can control chemical hazards. We have also organized an Environmental Committee and Chemical Substance Management Committee to enhance in-house training and IT systems based on related laws and company regulations on occupational safety and health. Research materials that are genetically modified or considered pathogenic are handled carefully at facilities that can control biohazards after a pre-screening carried out by our Biosafety Committee and other organizations. In the event that an accident occurs during these experiments or research, we have a system in place to quickly notify the regulatory authorities and relevant persons in-house.

## **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.

Two external directors have been elected since fiscal 2013 to further strengthen the supervisory function related to the execution of duties by directors and to further boost transparency and objectivity in management. The Board of Directors is comprised of nine directors, including these two external 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 operating properly. 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 the Director of the Administration Division acting as a compliance officer and a dedicated department to oversee compliance initiatives. The supervising director for each department in place is responsible for departmental compliance initiatives, which are carried out by the managers in each department.

#### **Compliance Initiatives**

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

In fiscal 2013, the President and compliance officer issued messages to employees in April and October 2013 to stress the need for compliance, and we implemented the training and education activities outlined below. Also, training sessions for all Nippon Shinyaku Group employees were held in order to ensure thorough compliance with the Nippon Shinyaku Group Code of Practice enacted on April 1 covering rules on the promotion of prescription drugs.

#### **Compliance Training in Fiscal 2013**

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 mangers.
Direct training (October to December)	Employees are sent to business offices and Group companies nationwide to provide training. In fiscal 2013, the training was focused on the correct understanding of power harassment to foster thriving workplace.
Training on the Charter of Business Conduct for new employees	Request to enhance understanding of and compliance with the Charter of Business Conduct.

#### **Education Initiatives**

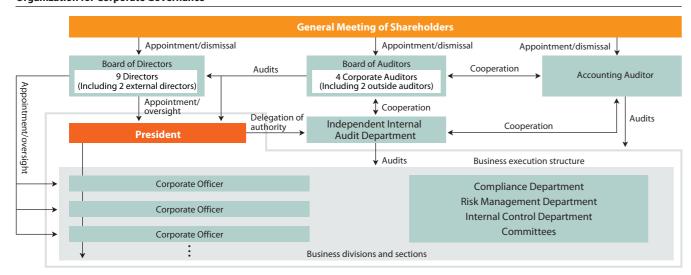
 Conducted e-learning education for compliance for employees in the 2nd year of employment.

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.

#### **Employee Hotline for Compliance Reporting**

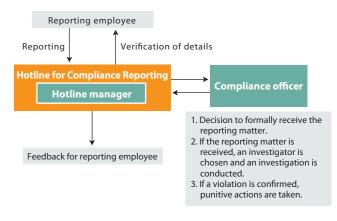
We operate an employee hotline for compliance reporting, so that any employee of Nippon Shinyaku or Group companies can report on or discuss regulatory violations or other compliance issues, as a means of

#### Organization for Corporate Governance



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" and "harassment" as priority areas of risks in fiscal 2013 based on a risk awareness survey conducted in fiscal 2012, and worked to strengthen the management system.

First, in terms of "information management," we formulated rules on the handling of electronic data for each division and reinforced our approach to properly managing electronic data by thoroughly complying with these rules. Additionally, as part of compliance training and e-learning, we addressed ways to deal with computer viruses and cyber terrorism and ways to prevent leakages of confidential information. We also carried out efforts to make these measures known to all.

In terms of "harassment," as part of compliance training, new employee training and e-learning, we covered the topic of harassment and took steps to heighten employees' awareness toward preventing harassment in the workplace. Furthermore, we expanded our Sexual Harassment Prevention Rules into the Nippon Shinyaku Group Harassment Prevention Rules, which were enacted on January 1, 2014, in order to develop a framework for dealing with all forms of harassment.

As a result of discussions with directors in charge of each division based on the achievements of activities to date and the results of the risk awareness survey conducted on managers, "information management" and "harassment" will once again be positioned as priority areas of risks in fiscal 2014 and efforts will be strengthened further.

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

## **Corporate Governance**

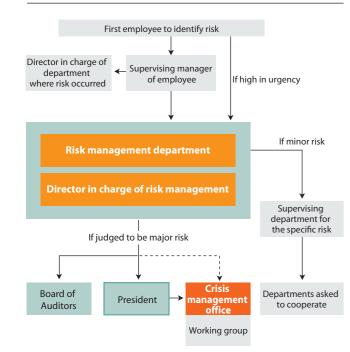
#### Framework for Risk Management

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's 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.

#### Path of Risk Notification (as of April 1, 2014)



#### 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 disclose information to the public in a timely, appropriate and fair manner as well as responsibly protect and manage personal information and customer information obtained through our business activities. We are also advancing technological measures tailored to progress in IT and changes in society in order to protect the Nippon Shinyaku Group's information assets from physical and technological risks. At the same time, as a countermeasure against human risks, we have revised various company rules and educate our employees on the importance of information security and following the rules.

In recent years, there has been an increasing frequency of cyber-attacks on government institutions and companies in Japan and abroad. Cyber terrorism, which can paralyze a company by disabling its core systems and important infrastructure, and the threat of cyber intelligence, which involves spying with ICT, have both become serious issues facing companies today. Since measures must also be taken at the individual level to address these issues, we are educating our employees on security measures, including management of electronic data, through compliance training.

In fiscal 2013, we re-assessed Nippon Shinyaku's situation in terms of its preparedness for computer viruses and cyber terrorism, and carried out discussions or measures to protect vulnerabilities that were found. Going forward, we will continue to reinforce our information security system while placing emphasis on the prevention of leakages of confidential information.

#### **Respect for Intellectual Property Rights**

In recognizing the importance of intellectual properties, the Nippon Shinyaku Group's Patent Strategy Committee formulates global patent application strategies as well as examines and determines measures to address various issues associated with intellectual properties created during various stages, from early R&D to post-marketing.

To ensure the freedom of our business activities, we properly secure intellectual property rights, including patents and trademarks, related to our proprietary drugs and functional foods. Our basic stance is to also respect the intellectual property rights of third parties, which we ensure by carefully managing intellectual property risk through the examination of rights and other means.



Front row, from left: Yura, Tanaka, Maekawa, Adachi, Matsuura Back row, from left: Sugiura, Yuno, Saito, Sakata

#### President

Shigenobu Maekawa

#### **Managing Director**

Tsugio Tanaka (General Manager, Business Management)

#### Directors

Hiroshi Adachi (General Manager, Functional Food Div.)

Yoshiro Yura (General Manager, Administration Div.)

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

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

Hitoshi Saito (General Manager, Resource Procurement Production & Assurance Div.)

Yukio Sugiura (External Director)

Hitoshi Sakata (External Director)



From left: Tanabe, Toriyama, Kameyama, Suzuma

**Corporate Auditors** 

Yoichi Toriyama

(Standing Corporate Auditor)

Kenji Kameyama

(Standing Corporate Auditor)

Yoshishige Suzuma

Yasuo Tanabe

(Outside Auditor

(Outside Auditor)

### Comments from External Directors

With globalization advancing, Nippon Shinyaku has expanded its presence internationally through its commitment to originality and ingenuity. Nevertheless, I believe that simply doing things the way they have always been done will not enable us to unlock further growth and development in the future. We will need to identify what to change and what to maintain, carry out measures and implement a positive reform program. An organization is nothing without its people, so we will need

to value our people more and our people will need to give their best efforts under a shared vision for the growth of the organization

I hope to leverage my professional expertise and acumen developed as a pharmacologist to deliver proper and objective advice that benefits Nippon Shinyaku and its shareholders.



Yukio Sugiura

#### **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 Centra Factory)

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

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

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.)

Takanori Edamitsu (General Manager, BusinessManagement)

Yuji Kamiyoshi (General Manager, Nishinihon Div.)

As of June 27, 2014

They say that robust internal controls are a prerequisite for the sound growth of any company. An efficient organization tends to focus on its own set of norms and rules, and so I believe the role of an external director is to encourage such an organization to incorporate third-party input and follow a more universal set of norms and rules. I am constantly aware of this role when pursuing my duties. Additionally, the environment surrounding pharmaceutical companies is growing even more difficult, I

hear, because of the expanded use of generics and changes in the NHI drug price scheme, which promotes novel drug development. It is my great joy to be part of a growing business within these times of change.

Going forward, I hope to capitalize on my expertise and experience as an attorney to help support the growth and sound management of Nippon Shinyaku for the benefit of its shareholders



Hitoshi Sakata

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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**

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#### **Subsidiaries**

#### NS Pharma, Inc.



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





Beijing Representative Office

London Office

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NS Pharma, Inc.

# **Financial Section**

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## **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, 2014, we issued an annual cash dividend of ¥23 per share, comprising an interim dividend of ¥11 per share and year-end dividend of ¥12 per share.

For the year ending March 31, 2015, we are projecting an annual dividend of ¥25 per share, comprising an interim dividend of ¥12 per share and year-end dividend of ¥13 per share.

#### 2. Financial Condition

An increase in inventory assets compared to the previous fiscal year end caused current assets to rise ¥3,751 million. Fixed assets increased by ¥706 million due to an increase in investment securities, despite a decrease in tangible fixed assets compared to the previous fiscal year end. As a result, total assets increased by ¥4,458 million compared to the previous fiscal year end to ¥118,188 million.

Current liabilities decreased by ¥420 million compared to the previous fiscal year end because of a decrease in accrued liabilities, despite an increase in notes and accounts payables–trade. Long-term liabilities increased by ¥1,221 million compared to the previous fiscal year end, attributed to an increase in liabilities for retirement benefits. As a result, total liabilities increased by ¥801 million compared to the previous fiscal year end to ¥25,002 million.

Equity increased by ¥4,183 million compared to the previous fiscal year end to ¥88,549 million. Accumulated other comprehensive income decreased by ¥531 million to ¥4,432 million. As a result, net assets increased by ¥3,657 million to ¥93,186 million.

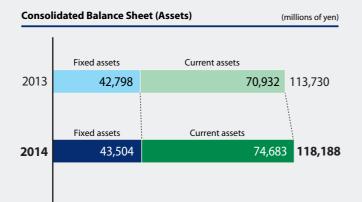
The equity ratio was 78.7%.

Net cash provided by operating activities amounted to ¥6,015 million. The main cash inflows were income before income taxes of ¥8,598 million, depreciation costs of ¥2,704 million, and an increase in trade payables of ¥1,071 million, while the main outflows were the amount of income tax paid ¥2,854 million and an increase in inventory assets of ¥2,466 million.

Net cash used in investing activities amounted to ¥3,357 million. The main cash outflows were expenditures of ¥1,243 million for the acquisition of license rights and ¥1,121 million for tangible fixed assets.

Net cash used in financing activities amounted to ¥1,606 million, primarily comprising cash payment of dividends.

As a result, cash and cash equivalents as of March 31, 2014 increased by ¥1,185 million compared to the previous fiscal year end to ¥21,229 million.



#### 3. Summary of Consolidated Business Results

#### (1) Pharmaceuticals

In the pharmaceuticals segment, sales of Vidaza<sup>®</sup>, a remedy for myelodysplastic syndrome, Lunabell<sup>®</sup>, a dysmenorrhea remedy, Adcirca<sup>®</sup>, a treatment agent for pulmonary arterial hypertension, and Tramal<sup>®</sup>, a cancer pain and chronic pain treatment, all increased. As a result, net sales in the pharmaceuticals segment increased 8.6% year-on-year to ¥63,345 million.

#### (2) Functional Food

In the functional food segment, sales of health food ingredients decreased somewhat, but sales of preservatives, protein preparations and nutritional ingredients all increased. As a result, net sales in the functional food segment increased 13.3% year-on-year to ¥13,172 million.

## **Business Risks**

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

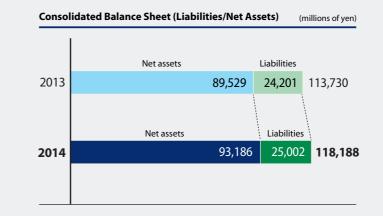
#### **1. Regulatory Control Risks**

The core pharmaceuticals and functional food businesses of the Nippon Shinyaku Group are strictly regulated under the 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 Nippon Shinyaku 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 Statement of Cash Flows**

(millions of yen)



## Consolidated Balance Sheet

ippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Iarch 31, 2014	Million	Millions of Yen						
SSETS	2014	2013	(Note 1) 2014					
CURRENT ASSETS:								
Cash and cash equivalents (Note 10)	¥ 21,229	¥ 20,044	\$ 206,106					
Time deposits (Note 10)	267	242	2,592					
Notes and accounts receivables (Note 10):								
Trade notes	328	274	3,184					
Trade accounts	33,808	33,992	328,233					
Other	280	234	2,718					
Total notes and accounts receivables	34,417	34,501	334,145					
Inventories (Note 4)	15,733	13,266	152,747					
Deferred tax assets (Note 9)	1,678	1,637	16,291					
Other current assets	1,357	1,239	13,174					
Total current assets	74,683	70,932	725,077					
PROPERTY, PLANT, AND EQUIPMENT:								
Land	7,433	7,888	72,165					
Buildings and structures	23,742	26,215	230,504					
Machinery, equipment, and vehicles	10,615	12,505	103,058					
Tools, furniture, and fixtures	8,784	9,138	85,281					
Construction in progress	104	62	1,009					
Total	50,680	55,811	492,038					
Accumulated depreciation	(35,009)	(38,672)	(339,893)					
Net property, plant, and equipment	15,670	17,138	152,135					
INVESTMENTS AND OTHER ASSETS:								
Investment securities (Notes 3 and 10)	16,063	13,873	155,951					
Long-term prepaid expenses	7,981	8,829	77,485					
Deferred tax assets (Note 9)	60	62	582					
Other assets	3,729	2,895	36,203					
Total investments and other assets	27,834	25,659	270,233					
TOTAL	¥ 118,188	¥ 113,730	\$ 1,147,456					

See notes to consolidated financial statements.

	Million	Thousands of U.S. Doll (Note 1)			
IABILITIES AND EQUITY	2014	2013	2014		
CURRENT LIABILITIES:					
Notes and accounts payables (Note 10):					
Trade notes	¥ 1,772	¥ 1,682	\$ 17,203		
Trade accounts	4,326	3,345	42,000		
Other	2,784	3,061	27,029		
Total notes and accounts payables	8,883	8,089	86,242		
Income taxes payable (Note 10)	1,537	1,665	14,922		
Accrued expenses	3,739	3,587	36,300		
Deposits from customers	279	315	2,708		
Other current liabilities	816	2,019	7,922		
Total current liabilities	15,257	15,677	148,126		
LONG-TERM LIABILITIES:					
Liability for retirement benefits (Note 5)	8,857	7,418	85,990		
Deferred tax liability (Note 9)	510	715	4,951		
Other long-term liabilities	376	389	3,650		
Total long-term liabilities	9,744	8,523	94,601		
EQUITY (Notes 6 and 13):					
Common stock, authorized, 200,000,000 shares;					
issued 70,251,484 shares	5,174	5,174	50,233		
Capital surplus	4,445	4,445	43,155		
Retained earnings	81,105	76,839	787,427		
Treasury stock - at cost, 2,820,656 shares in 2014 and					
2,774,507 shares in 2013	(2,175)	(2,092)	(21,116		
Accumulated other comprehensive income:					
Unrealized gain on available-for-sale securities	5,841	4,989	56,708		
Deferred gain on derivatives under hedge accounting	1	4	9		
Foreign currency translation adjustments	(4)	(30)	(38		
Defined retirement benefit plans	(1,406)		(13,650		
Total	92,982	89,330	902,737		
Minority interests	204	198	1,980		
Total equity	93,186	89,529	904,718		
TOTAL	¥ 118,188	¥ 113,730	\$ 1,147,456		

	Million	Thousands of U.S. Dollar (Note 1)				
20		2014				
¥	76,517	¥	69,941	\$	742,883	
	39,033		34,776		378,961	
	29,445		28,263		285,873	
	68,479		63,040		664,844	
	8,038		6,901		78,038	
	323		287		3,135	
	(4)		(8)		(38)	
	239		105		2,320	
	559		385		5,427	
	8,598		7,286		83,475	
	2,722		2,715		26,427	
	115		(90)		1,116	
	2,837		2,625		27,543	
	5,760		4,660		55,922	
	9		13		87	
¥	5,750	¥	4,647	Ś	55,825	
		2014 ¥ 76,517 39,033 29,445 68,479 8,038 323 (4) 239 559 8,598 2,722 115 2,837 5,760 9	¥       76,517       ¥         39,033	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Millions of Yen           2014         2013           ¥         76,517         ¥         69,941         \$           39,033         34,776         29,445         28,263           29,445         28,263	

		Y	U.S. Dollars			
AMOUNTS PER COMMON SHARE (Notes 2.p and 12):						
Basic net income	¥	85.25	¥	68.87	\$	0.83
Cash dividends applicable to the year		23.00		21.00		0.22

See notes to consolidated financial statements.

## Consolidated Statement of Comprehensive Income Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Year Ended March 31, 2014

#### NET INCOME BEFORE MINORITY INTERESTS

#### OTHER COMPREHENSIVE INCOME (Note 11):

- Unrealized gain on available-for-sale securities
- Deferred (loss) gain on derivatives under hedge accounting

Foreign currency translation adjustments

## Total other comprehensive income

#### **COMPREHENSIVE INCOME**

### TOTAL COMPREHENSIVE INCOME ATTRIBUTABLE TO:

Owners 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, 2014

	Thousands						Milli	ions of '	ŕen					
		_				Accumulated Other Comprehensive Income								
	Outstanding Number of Shares of Common Stock	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available- for-sale Securities	Defe Gair Deriva under Accou	n on atives Hedge	Cur Tran	reign rency slation stments	Defined Retirement Benefit Plans	Total	Minority Interests	Total Equity
BALANCE, APRIL 1, 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 share	2			(1,349)	1							(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
Net income				5,750								5,750		5,750
Cash dividends, ¥22.00 per share	2			(1,484)	1							(1,484)		(1,484)
Purchase of treasury stock	(46)				(82)							(82)		(82)
Net change during the year						852		(3)		25	¥ (1,406)	(531)	5	(526)
BALANCE, MARCH 31, 2014	67,430	¥ 5,174	¥ 4,445	¥ 81,105	¥(2,175)	¥ 5,841	¥	1	¥	(4)	¥ (1,406)	¥ 92,982	¥ 204	¥ 93,186

	Accumulated Other Comprehensive Income												
	Common Stock	Capital Surplus	Retained Earnings	Treasury Stock	Unrealized Gain on Available- for-sale Securities	G Der unde	eferred iain on rivatives er Hedge counting	Cu Tra	oreign Irrency nslation Istments	Defined Retirement Benefit Plans	Total	inority terests	Total Equity
BALANCE, MARCH 31, 2013	\$ 50,233	\$ 43,155	\$ 746,009	\$ (20,310)	\$ 48,436	\$	38	\$	(291)		\$ 867,281	\$ 1,922	\$ 869,213
Net income			55,825								55,825		55,825
Cash dividends, \$0.21 per share			(14,407)								(14,407)		(14,407)
Purchase of treasury stock				(796)							(796)		(796)
Net change during the year					8,271		(29)		242	\$ (13,650)	(5,155)	48	5,106
BALANCE, MARCH 31, 2014	\$ 50,233	\$ 43,155	\$787,427	\$ (21,116)	\$ 56,708	\$	9	\$	(38)	\$ (13,650)	\$ 902,737	\$ 1,980	\$ 904,718
See notes to consolidated finance	ial stateme	nts.											

	Million	s of Yen		Thousa	nds of U.S. Dollars (Note 1)
	2014		2013		2014
¥	5,760	¥	4,660	\$	55,922
	852		1,660		8,271
	(3)		3		(29)
	25		10		242
	874		1,675		8,485
¥	6,634	¥	6,335	\$	64,407
¥	6,625	¥	6,322	\$	64,320
	9		13		87

Thousands of U.S. Dollars (Note 1)

Consolidated Statement of Cash Flows							
lippon Shinyaku Co., Ltd. and Consolidated Subsidiaries ear Ended March 31, 2014		Millions	of Yen		Thousar	nds of U.S. Dollar (Note 1)	
-	20	014	:	2013		2014	
OPERATING ACTIVITIES:							
Income before income taxes and minority interests	¥	8,598	¥	7,286	\$	83,475	
Adjustments for:							
Income taxes - paid		(2,854)		(2,341)		(27,708)	
Depreciation and amortization		2,704		2,759		26,252	
Changes in assets and liabilities:							
(Decrease) increase in trade notes and trade accounts							
receivables		129		(2,278)		1,252	
Increase in inventories		(2,466)		(1,341)		(23,941)	
Increase in other current assets		(117)		(527)		(1,135)	
Increase in trade notes and trade accounts payables		1,071		8		10,398	
Decrease in other current liabilities		(43)		(97)		(417)	
(Decrease) increase in liability for retirement benefits		(759)		60		(7,368)	
Other - net		(245)		239		(2,378)	
Total adjustments		(2,582)		(3,518)		(25,067)	
Net cash provided by operating activities		6,015		3,767		58,398	
INVESTING ACTIVITIES:					-		
Capital expenditures		(1,121)		(1,020)		(10,883)	
Purchases of investment securities		(904)		(104)		(8,776)	
Proceeds from redemption and sales of investment securities				3			
Purchases of software		(142)		(359)		(1,378)	
Acquisition of license rights		(1,243)		(677)		(12,067)	
Other - net		54		133		524	
Net cash used in investing activities		(3,357)		(2,026)		(32,592)	
FINANCING ACTIVITIES:							
Cash dividends paid		(1,484)		(1,350)		(14,407)	
Increase of treasury stock		(82)		(18)		(796)	
Other - net		(39)		(44)		(378)	
Net cash used in financing activities		(1,606)		(1,413)		(15,592)	
FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON							
CASH AND CASH EQUIVALENTS		133		51		1,291	
NET INCREASE IN CASH AND CASH EQUIVALENTS		1,185		379		11,504	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR		20,044		19,665		194,601	

¥

21,229

¥

20,044

\$ 206,106

See notes to consolidated financial statements.

CASH AND CASH EQUIVALENTS, END OF YEAR

#### 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 2013 consolidated financial statements to conform to the classifications used in 2014.

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 ¥103 to \$1, the approximate rate of exchange at March 31, 2014. 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, 2014 and 2013, 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 and influence concepts, those companies in which the Company, directly or indirectly, is able to exercise control over operations are fully consolidated, and those companies over which the Companies have the ability to exercise significant influence are accounted for by the equity method.

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

the accompanying consolidated financial statements would not be material.

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

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

Cash equivalents are short-term investments that are readily convertible into cash and 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

The Company has contributory funded defined benefit pension plans, unfunded retirement benefit plans and defined contribution pension plan for employees. Certain consolidated subsidiaries have funded retirement benefit plans.

Effective April 1, 2000, the Company adopted a new accounting standard for retirement benefits and accounted for the liability for retirement benefits based on the projected benefit obligations and plan assets at the balance sheet date. The projected benefit obligations are attributed to periods on a straight-line basis. Actuarial gains and losses are amortized on a straight-line basis over 15 years within the average remaining service period. Past service costs are amortized on a straight-line basis over 15 years within the average remaining service period.

In May 2012, the Accounting Standards Board of Japan (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 were followed by partial amendments from time to time through 2009.

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

(b) The revised accounting standard does not change

how to recognize actuarial gains and losses and past service costs in profit or loss. Those amounts are recognized in profit or loss over a certain period no longer than the expected average remaining service period 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 are 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 (see Note 2.r).

(c) 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 applied the revised accounting standard and guidance for retirement benefits for (a) and (b) above, effective March 31, 2014. As a result, liability for retirement benefits of ¥8,857 million (\$85,990 thousand) was recorded as of March 31, 2014, and accumulated other comprehensive income for the year ended March 31, 2014, decreased by ¥1,406 million (\$13,650 thousand).

#### h. Asset Retirement Obligations

In March 2008, the ASBJ issued 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.

#### 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 income tax rates to the temporary differences.

#### m. Foreign Currency Transactions

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

#### n. Foreign Currency Financial Statements

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

#### 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 statements of income are dividends applicable to the respective fiscal 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 were 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 service period 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 applied the revised accounting standard for (a) and (b) above effective March 31, 2014, and expects to apply (c) above from April 1, 2014, and is in the process of measuring the effects of applying the revised accounting standard for (c) above in future applicable periods.

#### **3. INVESTMENT SECURITIES**

Investment securities as of March 31, 2014 and 2013, consisted of the following:

		Millior	ns of	Yen	Thousands of U.S. Dollars
		2014		2013	2014
Noncurrent: Equity securities	¥	16,063	¥	13,873	\$ 155,951
Total	¥	16,063	¥	13,873	\$ 155,951

The costs and aggregate fair values of investment securities at March 31, 2014 and 2013, were as follows:

				Millions	of Yen		
March 31, 2014		Cost		Unrealized Gains	Unrealized Losses		Fair Value
Securities classified as:							
Available-for-sale:							
Equity securities	¥	6,958	¥	8,772		¥	15,73
				Millions	of Yen		
March 31, 2013		Cost	I	Jnrealized Gains	Unrealized Losses		Fair Value
Securities classified as: Available-for-sale:							
Equity securities	¥	6,053	¥	7,486		¥	13,54
			Т	housands of	U.S. Dollars		
March 31, 2014		Cost	1	Jnrealized Gains	Unrealized Losses		Fair Value
Securities classified as: Available-for-sale:							
Equity securities	Ś	67,553	Ś	85,165		Ś	152,71

#### **4. INVENTORIES**

Inventories at March 31, 2014 and 2013, consisted of the following:

		Millio	ns of	Yen	ousands of .S. Dollars
		2014		2013	2014
Finished products and merchandise	¥	9,983	¥	8,019	\$ 96,922
Work in process		1,643		1,842	15,951
Raw materials		4,106		3,404	39,864
Total	¥	15,733	¥	13,266	\$ 152,747

#### **5. RETIREMENT BENEFITS**

#### Year Ended March 31, 2014

1. Defined Benefit Pension Plan

(1) The changes in defined benefit obligation for the year ended March 31, 2014, were as follows:

	Millions of Yen	Thousands of U.S. Dollars
Balance at beginning of year	¥ 26,554	\$ 257,805
Current service cost	872	8,466
Interest cost	526	5,106
Actuarial gains	(850)	(8,252)
Benefits paid	(1,333)	(12,941)
Balance at end of year	¥ 25,769	\$ 250,184

## (2) The changes in plan assets for the year ended March 31, 2014, were as follows:

	Mill	lions of Yen	iousands of J.S. Dollars
Balance at beginning of year	¥	15,140	\$ 146,990
Expected return on plan assets		602	5,844
Actuarial gains		537	5,213
Contributions from the employer		1,621	15,737
Benefits paid		(990)	(9,611)
Balance at end of year	¥	16,911	\$ 164,184

#### (3) Reconciliation between the liability recorded in the consolidated balance sheets and the balances of defined benefit obligation and plan assets

	Mil	lions of Yen		nousands of U.S. Dollars
Funded defined benefit obligation	¥	19,824	\$	192,466
Plan assets		(16,911)		(164,184)
		2,912		28,271
Unfunded defined benefit obligation		5,944		57,708
Net liability (asset) arising from				
defined benefit obligation	¥	8,857	\$	85,990
			TI	nousands of
	Mil	lions of Yen		U.S. Dollars
Liability for retirement benefits	¥	8,857	\$	85,990
Net liability arising from defined				
benefit obligation	¥	8,857	\$	85,990

(4)The components of net periodic benefit costs for the year ended March 31, 2014, were as follows:

	Milli	ons of Yen	 ousands of S. Dollars
Service cost	¥	872	\$ 8,466
Interest cost		526	5,106
Expected return on plan assets		(602)	(5,844)
Amortization of prior service cost		45	436
Recognized actuarial losses		363	3,524
Others		22	213
Net periodic benefit costs	¥	1,226	\$ 11,902

(5) Accumulated other comprehensive income on defined retirement benefit plans as of March 31, 2014, is as follows:

	Milli	ons of Yen	 ousands of S. Dollars
Unrecognized prior service cost Unrecognized actuarial losses	¥	201 1,996	\$ 1,951 19,378
Total	¥	2,198	\$ 21,339

#### (6) Plan assets

a. Components of plan assets

Plan assets consisted of the following:

Domestic bonds	23.1%	
Home shares	16.3	
Foreign bonds	13.8	
Foreign shares	13.6	
General accounts	29.9	
Others	3.3	
Total	100.0%	

b. Method of determining the expected rate of return on plan assets

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

(7) Assumptions used for the year ended March 31, 2014, were set forth as follows:

Discount rate	2.0%
Expected rate of return on plan assets	4.0

2. Defined Contribution Pension Plan

Premiums for defined contribution pension plan were ¥46 million (\$446 thousand) for the year ended March 31, 2014.

#### Year Ended March 31, 2013

The liability for retirement benefits at March 31, 2013, consisted of the following:

	Mill	lions of Yen
Projected benefit obligation	¥	26,554
Fair value of plan assets		(15,140)
Unrecognized prior service cost		(246)
Unrecognized actuarial loss		(3,748)
Net liability	¥	7,418

The components of net periodic benefit costs for the year ended March 31, 2013, were as follows:

	Millions of Yer		
Service cost	¥	862	
Interest cost		518	
Expected return on plan assets		(516)	
Amortization of prior service cost		45	
Recognized actuarial loss		691	
Premiums for defined contribution			
pension plan and other		62	
Nat novia dis han aft sasts	v	1 662	
Net periodic benefit costs	¥	1,663	

Assumptions used for the year ended March 31, 2013, were set forth as follows:

2.0%
4.0%
15 years
15 years

#### 6. EQUITY

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

#### (a) Dividends

Under the Companies Act, companies can pay dividends at any time during the fiscal year in addition to the year-end dividend upon resolution at the shareholders meeting. For companies that meet certain criteria, including (1) having a Board of Directors, (2) having independent auditors, (3) having an Audit and Supervisory Board, and (4) the term of service of the directors 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 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.

#### 7. RESEARCH AND DEVELOPMENT COSTS

Research and development costs charged to income were ¥9,530 million (\$92,524 thousand) and ¥9,049 million for the years ended March 31, 2014 and 2013, respectively.

#### 8. LEASES

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

Total rental expenses for the years ended March 31, 2014 and 2013, were ¥1,240 million (\$12,038 thousand) and ¥1,227 million, respectively.

Future minimum payments under noncancelable operating leases were as follows:

		Operatin	g Leases	
		20	014	
	Million	ns of Yen		ands of Dollars
Due within one year	¥	3	\$	29
Due after one year		11		106
Total	¥	14	\$	135

#### 9. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes, which, in the aggregate, resulted in normal effective statutory tax rates of approximately 38% for the years ended March 31, 2014 and 2013. 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, 2014 and 2013, are as follows:

	Millions of Yen					Thousands of U.S. Dollars		
	<b>2014</b> 2013			2013	2014			
Deferred tax assets:								
Retirement benefits	¥	3,191	¥	2,674	\$	30,980		
Accrued expenses		1,084		1,100		10,524		
Property, plant, and equipment		59		71		572		
Other		1,380		1,225		13,398		
Less valuation allowance		(367)		(367)		(3,563)		
Deferred tax assets		5,349		4,704		51,932		
Deferred tax liabilities:								
Unrealized gain on available-								
for-sale securities		2,930		2,496		28,446		
Deferred gains on sales of								
property		1,155		1,186		11,213		
Other		35		37		339		
Deferred tax liabilities		4,120		3,720		40,000		
Net deferred tax assets	¥	1,228	¥	984	\$	11,922		

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, 2014 and 2013, are as follows:

	2014	2013
Normal effective statutory tax rate	38.0%	38.0%
Expenses not deductible for income tax purposes	2.4	2.5
Income not taxable for income tax purposes	(1.0)	(1.1)
Increase in valuation allowance		(0.1)
Tax credits for research and development costs	(7.1)	(5.3)
Effect of tax rate reduction	1.0	
Flat rate municipal tax	0.7	0.8
Other - net	(1.0)	1.2
Actual effective tax rate	33.0%	36.0%

New tax reform laws enacted in 2014 in Japan changed the normal effective statutory tax rate for the fiscal year beginning on or after April 1, 2014, from approximately 38% to 36%. The effect of this change was to decrease deferred tax assets in the consolidated balance sheet as of March 31, 2014, by ¥90 million (\$873 thousand) and to increase income taxes - deferred in the consolidated statement of income for the year then ended by ¥90 million (\$873 thousand).

#### 10. FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

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

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

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

Receivables, such as trade notes and trade accounts, are exposed to customer credit risk. Marketable securities, mainly 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

			Mi		
March 31, 2014		Carrying Fair \ Amount		Fair Value	Unrealized Gain/ Loss
Cash and cash equivalents	¥	21,229	¥	21,229	
Time deposits		267		267	
Notes and accounts receivables		34,137		34,137	
Investment securities		15,730		15,730	
Total	¥	71,363	¥	71,363	
Notes and accounts payables	¥	8,883	¥	8,883	
Income taxes payable		1,537		1,537	
Total	¥	10,421	¥	10,421	
			Mi	llions 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		1,665		1,665	
Total	¥	9,755	¥	9,755	
		Tho	ousar	nds of U.S. D	ollars
March 31, 2014		Carrying Amount		Fair Value	Unrealized Gain/ Loss
Cash and cash equivalents	\$	206,106	\$	206,106	
Time deposits		2,592		2,592	
Notes and accounts receivables		331,427		331,427	
Investment securities		152,718		152,718	
Total	\$	692,844	\$	692,844	
Notes and accounts payables	Ś	86,242	Ś	86,242	
Income taxes payable	Ş	86,242 14,922	Ş	86,242 14,922	
Total	Ś	101,174	Ś	101,174	
	4		+	,	

#### 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 payable, other payable, and income taxes payable

The carrying values of notes and accounts payable, other

payable, 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, 2014 and 2013.

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

-	Carrying Amount					
		Millior	is of Ye	n		usands of 5. Dollars
		2014	2	2013	2	2014
Investments in equity instruments that do not have a quoted market price in an active market	¥	332	¥	332	\$	3,223

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

	Due in One Year or Less			
March 31, 2014	Millions of Yen	Thousands of U.S. Dollars		
Cash and cash equivalents Time deposits Notes and accounts receivables	¥ 21,229 267 34,137	\$ 206,106 2,592 331,427		
Total	¥ 55,634	\$ 540,135		

## 11. COMPREHENSIVE INCOME

The components of other comprehensive income for the years ended March 31, 2014 and 2013, were as follows:

		Million	is of Yei	n		ousands of .S. Dollars
Unrealized gain on	2	2014	2	2013		2014
available-for-sale securities: Gains arising during the year Amount before income tax	¥	1,285	¥	2,599	\$	12,475
effect		1,285		2,599		12,475
Income tax effect		(433)		(939)		(4,203)
Total	¥	852	¥	1,660	\$	8,271
Deferred gain (loss) on derivatives under hedge accounting: (Loss) gain arising during the year	¥	(4)	¥	5	\$	(38)
Income tax effect		1		(2)		9
Total	¥	(3)	¥	3	\$	(29)
Foreign currency translation adjustments: Adjustments arising during						
the year	¥	25	¥	10	\$	242
Total	¥	25	¥	10	\$	242
Total other comprehensive income	¥	874	¥	1,675	Ś	8,485

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

As of March 31, 2014

#### **Corporate Data**

November 20, 1911

October 1, 1919

**Paid-in Capital** 

¥5,174 million

President

Employees

1,899

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.jp

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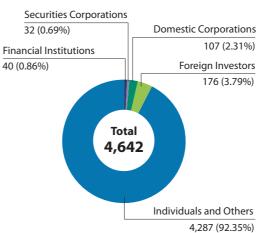
Deloitte Touche Tohmatsu Shijokarasuma FT Square 20, Naginataboko-cho, Karasuma-hio Shijo-dori Shimogyo-ku, Kyoto 600-8 Japan

#### Share Register

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

#### **Investor Information**

#### **Distribution of Shareholders**



Distribution of Shares Issued (Thousands of shares)

Total

70,251

Individuals and Others

Domestic Corporations

12,699

(18.08%)

Foreian

17.973 (25.58%)

7,036 (10.02%)

Investors

## 2,000 1,800 1,600 1,400 1,200

2,200

1,000



10,000 8,000 6,000 4,000 2,000

Financial

Securities Corporations

Institutions

32,115

425

(0.61%)

(45.71%)

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20, Naginataboko-cho

Deloitte Touche Tohmatsu LLC

Shimogya-ku, Kyata 600-8008

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, 2014, 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, 2014, 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, 2014

Member of Deloitte Touche Tohmatsu Limited

	Issued and Outstanding Number of Shares
noin,	70,251,484
	Number of Shareholders
	4,642
p/english/	
	Major Shareholders
ountants	Meiji Yasuda Life Insurance Company
	The Master Trust Bank of Japan, Ltd. (Trust account)
	Japan Trustee Services Bank, Ltd. (Trust account)
gashiiru,	The Bank of Tokyo-Mitsubishi UFJ, Ltd.
8008,	The Bank of Kyoto, Ltd.
	Nippon Life Insurance Company
	PERSHING-DIV. OF DLJ SECS. CORP.
	Tokio Marine & Nichido Fire Insurance Co., Ltd.
orporation	Nippon Shinyaku Employees' Stockholding
κu,	State Street Bank and Trust Company

