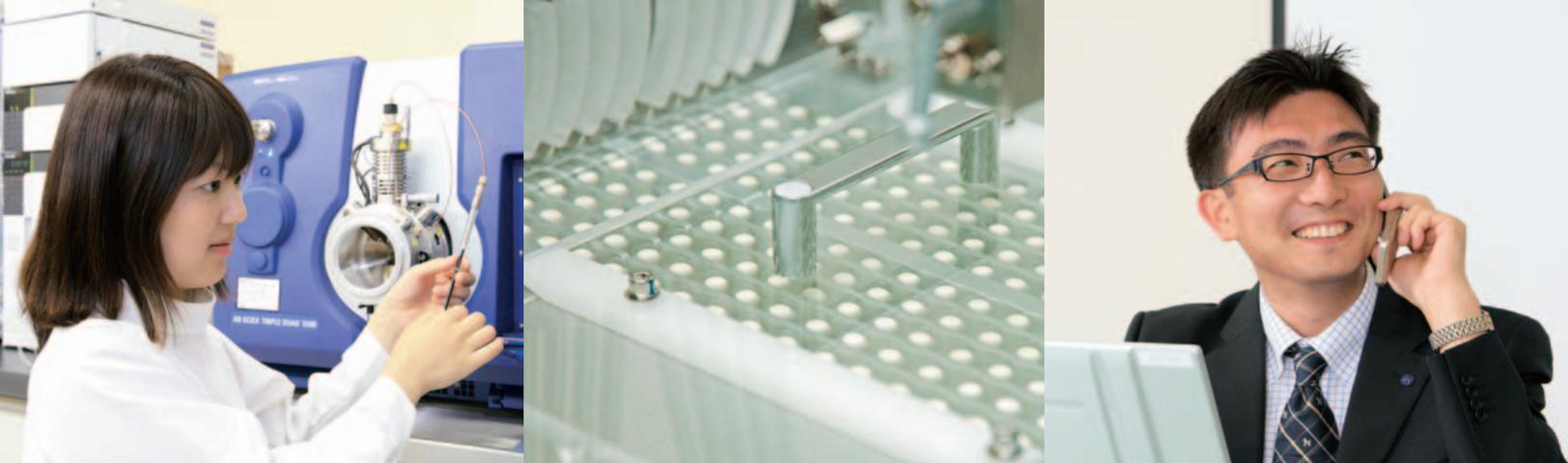




# Innovation and Growth

**ANNUAL REPORT 2010** Year ended March 31, 2010



## Corporate Slogan

# Helping people lead healthier, happier lives.

Through research and development in the fields of pharmaceuticals and nutraceutical products, Nippon Shinyaku aims to help people live longer, more fruitful and more energetic lives.



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### 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.

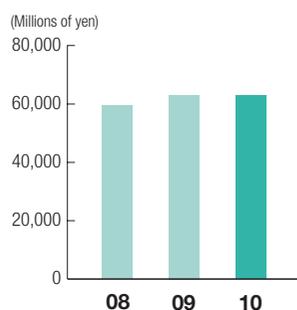
# Consolidated Financial Highlights

Nippon Shinyaku Co., Ltd. Years ended March 31	Millions of Yen			Thousands of U.S. Dollars
	2010	2009	2008	2010
Net sales	¥ 62,933	¥ 63,072	¥ 59,450	\$ 676,699
Operating income	6,462	7,547	6,461	69,484
Net income	4,096	4,500	4,031	44,043
Amounts per share (in yen and U.S. dollars):				
Basic net income	¥ 60.63	¥ 66.56	¥ 59.57	\$ 0.65
Net assets per share (Note 1)	1,187.42	1,127.49	1,135.40	12.77
Cash dividends	19.00	18.00	16.00	0.20
Total assets	¥ 103,576	¥ 98,286	¥ 103,116	\$1,113,720
Equity	80,206	76,193	76,804	862,430
Capital investment	1,859	2,332	1,650	19,989
R&D expenses	8,441	7,853	7,898	90,763
Return on equity (ROE) (%)	5.2	5.9	5.3	5.2

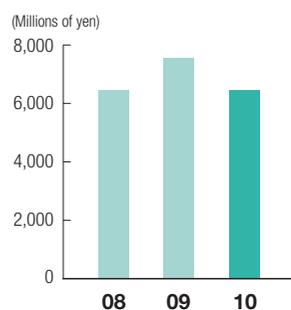
Notes: 1. Calculated on the basis of the average of the balances at the beginning and at the end of the term.

2. U.S. dollar amounts are converted from yen amounts at the rate of U.S.\$1 = ¥93, the approximate exchange rate on March 31, 2010.

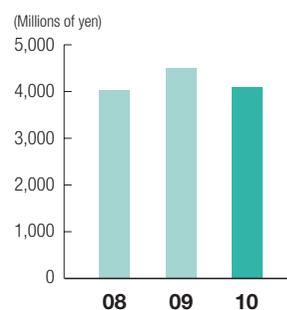
## Net Sales



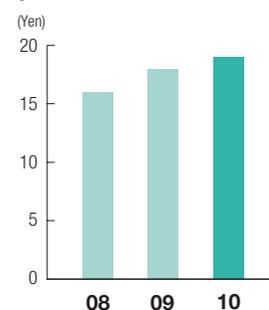
## Operating Income



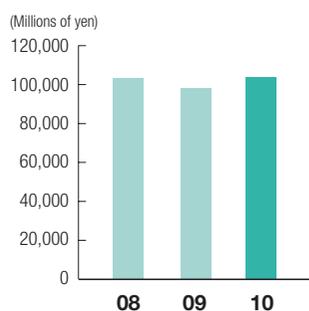
## Net Income



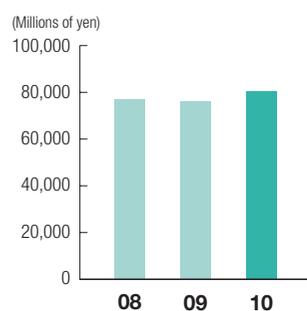
## Cash Dividends per Share



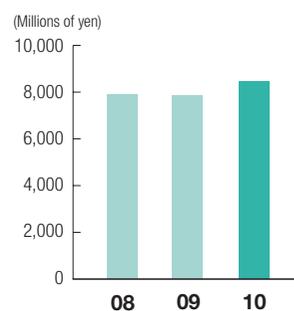
## Total Assets



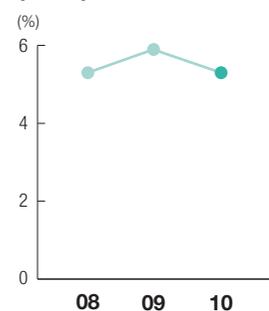
## Equity



## R&D Expenses



## Return on Equity (ROE)

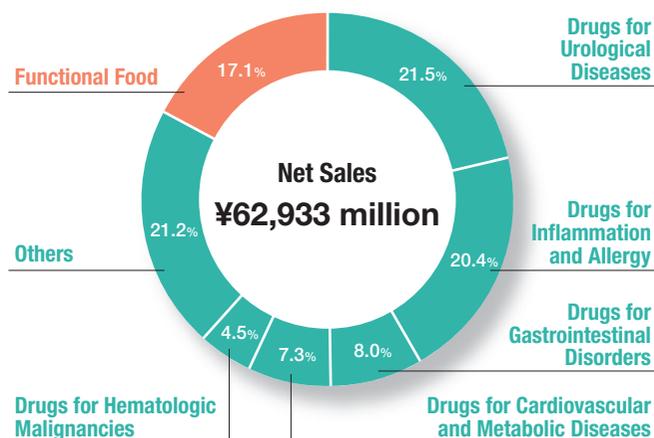


# At a Glance

## Pharmaceuticals

¥52,166 million (82.9%)

Our core products in this segment are drugs for urological diseases, inflammation and allergy and hematologic malignancies, as well as drugs for cardiovascular and metabolic diseases and gastrointestinal disorders. Eviprostat®, a remedy for benign prostatic hypertrophy, has been earning an especially high level of trust among urologists for many years.

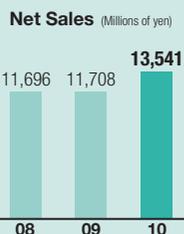


### • Drugs for Urological Diseases



- **Eviprostat®**  
(Herbal extracts)  
Remedy for benign prostatic hypertrophy
- **Bladderon®**  
(Flavoxate hydrochloride)  
Remedy for pollakisuria
- **Estracryt**  
(Estramustine sodium phosphate)  
Remedy for prostate cancer
- **Cialis®**  
Remedy for erectile dysfunction

In recent years, we have been recording further sales expansion of Eviprostat®, a remedy for benign prostatic hypertrophy, which has been increasing in step with the aging of society. We began selling the erectile dysfunction (ED) drug Cialis® in July 2009 and have been achieving steady growth in sales.

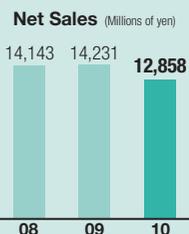


### • Drugs for Inflammation and Allergy



- **Hypen®**  
(Etodolac)  
Non-steroidal analgesic and anti-inflammatory agent
- **Erizas®**  
Remedy for allergic rhinitis
- **Livostin®**  
Remedy for allergy
- **Baynas®**  
Remedy for allergic rhinitis
- **Azunol® Gargle 4%**  
Gargling solution containing azulene

Erizas® was launched in December 2009 as the first once-daily dry powder-type steroid nasal spray remedy for allergic rhinitis. Besides requiring only once-daily use, its specialized sprayer capable of simultaneously spraying into both nasal cavities has been favorably acclaimed for its convenience.



### • Drugs for Hematologic Malignancies



- **Cylocide**  
(Cytarabine)  
Remedy for acute leukemia and solid cancer
- **Cylocide N**  
(Cytarabine)  
Remedy for relapsed and refractory acute leukemia and malignant lymphoma
- **Trisenox®**  
Remedy for relapsed and refractory acute promyelocytic leukemia
- **Amnolake®**  
Remedy for relapsed and refractory acute promyelocytic leukemia

We have been recording brisk sales of drugs for hematologic malignancies. Cylocide N is positioned as a core drug in the treatment of hematologic malignancies, primarily for treating leukemia, which has been rising rapidly among elderly people in recent years.

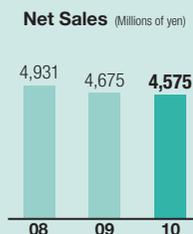


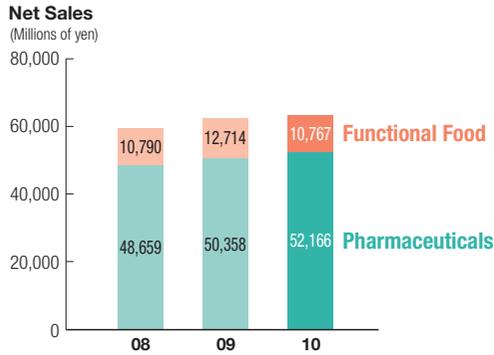
### • Drugs for Cardiovascular and Metabolic Diseases



- **Selectol**  
(Celiprolol hydrochloride)  
Remedy for hypertension and angina pectoris
- **Glycoran**  
(Metformin hydrochloride)  
Remedy for diabetes
- **Adcirca®**  
Pulmonary arterial hypertension treatment agent

Launched in December 2009, Adcirca® is a once-daily orally administered agent with phosphodiesterase-5 inhibitory activity for the treatment of pulmonary arterial hypertension. Following its launch, Adcirca® has been expanding its share.





# Functional Food

¥10,767 million (17.1%)

Our in-house functional food company leverages the sophisticated manufacturing technology and quality know-how accumulated by our pharmaceutical operations to contribute to human health through the supply of functional foods and ingredients. With safety and reliability as our top priorities, we supply highly original and helpful functional foods and ingredients.

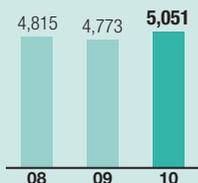
## • Drugs for Gastrointestinal Disorders



- **Gaslon N®**  
(Irsogladine maleate)  
Remedy for gastric ulcer and gastritis
- **Portolac®**  
(Lactitol hydrate)  
Remedy for hyperammonaemia

Although the protection factor potentiator market for gastric ulcer remedies has contracted slightly, sales of mucosal protective Gaslon N®, our remedy for gastric ulcer and gastritis, are achieving further growth because of new findings.

**Net Sales** (Millions of yen)



## • Others

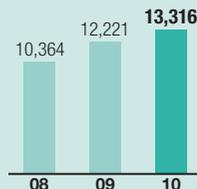
Including the Proceeds from Intellectual Property Rights



- **Lunabell®**  
Remedy for dysmenorrhea resulting from endometriosis
- **Cephadol®**  
(Difenidol hydrochloride)  
Remedy for vertigo
- **Prulifloxacin**  
Synthetic antibacterial agent

Lunabell®, a remedy for dysmenorrhea resulting from endometriosis launched in July 2008, is penetrating the market as a drug covered by insurance, achieving growth as the top choice for managing pain from endometriosis.

**Net Sales** (Millions of yen)



- Health food ingredients
- Preservatives
- Protein preparations
- Nutritional ingredients
- Seasonings and spices
- Sterilization cleaning agents



Despite ongoing harsh conditions in the processed food industry and the health food industry, sales of health food ingredients grew steadily. However, sales of protein preparations and nutritional ingredients declined sharply, as we reflected the strong yen and a steep decline in prices of imported milk protein ingredients in our sales prices.

**Net Sales** (Millions of yen)

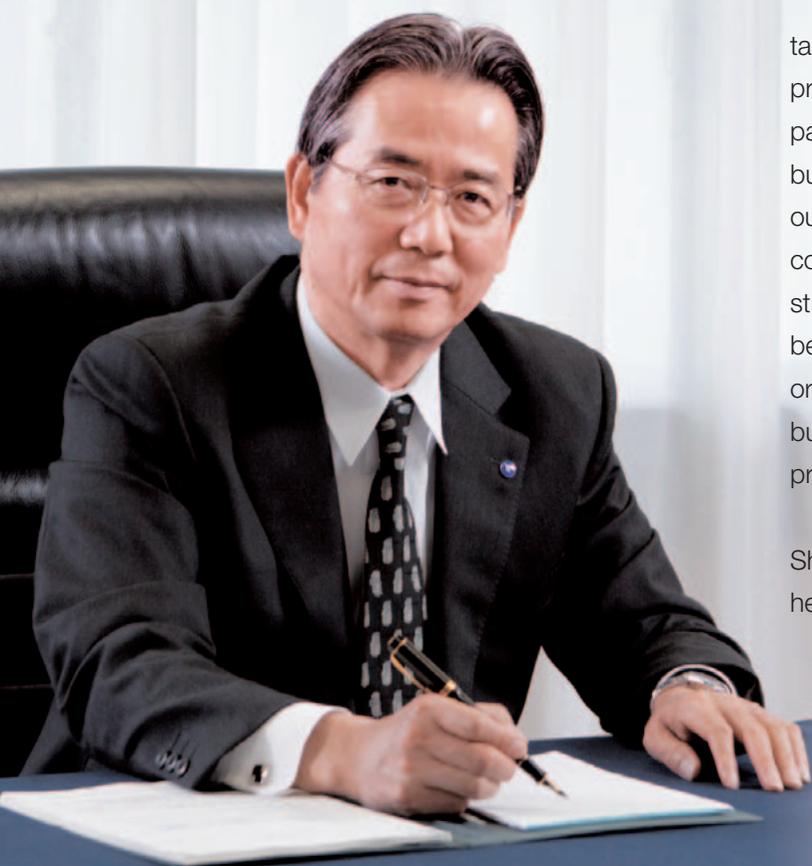


## Aiming to be a Company with a Meaningful Existence

I believe that Nippon Shinyaku's desired image should be a company that is trusted and respected by society and where each employee can grow and work with pride. In other words, we should aspire to become a company with a meaningful existence that is essential to society in the healthcare field.

To that end, in our pharmaceuticals business we are targeting our fields of strength and supplying high-quality products with distinctive benefits that are welcomed by patients suffering from diseases. In the functional food business, we aim to supply high-quality products utilizing our advanced technological capabilities as a pharmaceutical company. Additionally, we give top priority to patients and strive to supply them with ethical drugs that offer distinctive benefits over competing drugs in terms of efficacy, safety or quality of life (QOL). Meanwhile, in the functional food business, we endeavor to create and supply high-quality products that satisfy the needs of customers.

I am confident that these measures will allow Nippon Shinyaku to maintain its policy of helping people lead healthier, happier lives through its business activities.



*S. Maekawa*

**Shigenobu Maekawa**  
President



## Could you tell us about your business results in fiscal 2009 amid a severe market environment?

Despite visible signs of a pickup in the Japanese economy in fiscal 2009 (the fiscal year ended March 31, 2010), conditions remained harsh, as consumer spending was weak and capital investment continued to downtrend.

Similarly, difficult conditions persisted in Japan's pharmaceuticals industry due to the continued implementation of various measures to reign in healthcare costs. In the foods industry, protracted sluggishness in consumer spending, coupled with a pronounced preference for low prices, created a harsh operating environment.

Facing challenging conditions, Nippon Shinyaku posted consolidated net sales of ¥62,933 million, a slight decline from the previous fiscal year.

By segment, in the pharmaceuticals business, sales of allergy remedies declined due to diminished amounts of dispersed pollen, while revenues from the licensing of industrial property rights also decreased. On a brighter note, we recorded growth in sales of our core products Eviprostat<sup>®</sup>, a remedy for benign prostatic hypertrophy, and Gaslon N<sup>®</sup>, a remedy for gastric ulcer and gastritis. Additionally, sharp growth in Lunabell<sup>®</sup>, a treatment for dysmenorrhea resulting from endometriosis, together with favorable results from the erectile dysfunction (ED) drug Cialis<sup>®</sup> launched in July 2009, also contributed to performance. Consequently, sales of the pharmaceuticals business rose 3.6% from the previous fiscal year to ¥52,166 million.

During fiscal 2009, besides initiating sales of Cialis<sup>®</sup>, in November we launched Gaslon N<sup>®</sup> OD tablets (4mg), an orally disintegrating formulation of Gaslon N<sup>®</sup> tablet (4mg) for gastric ulcer and gastritis. Subsequently, in December, we launched Erizas<sup>®</sup> Capsule for Nasal Spray (400µg), a dry powder-type steroid nasal spray remedy for allergic rhinitis, as well as Adcirca<sup>®</sup> tablets (20mg) for the treatment of pulmonary arterial hypertension.

Turning to results in our functional food business, amid ongoing difficult conditions in the processed food industry and the health food industry, we posted favorable sales of health food ingredients. However, sales of protein preparations and nutritional ingredients declined sharply because we reflected the strong yen and a steep decline in prices of imported milk protein ingredients in our sales prices. Accordingly, sales in the functional food business totaled ¥10,767 million, a decline of 15.3% from the previous fiscal year.

At the profit level, operating income amounted to ¥6,462 million and net income totaled ¥4,096 million. The figures for each of these profit categories represent the first declines in four years. The principal factors underlying the downturn in profits were the aforementioned decline in sales of allergy remedies due to diminished amounts of pollen; a decline in revenues from the licensing of industrial property rights; an increase in R&D expenses accompanying the progression of clinical development; and worsening profitability in the functional food business.



## In fiscal 2009, you launched the “Innovation and Growth” medium-term management plan. Could you tell us about the vision encapsulated in your medium- and long-term management strategies?

Nippon Shinyaku is firmly aware that it must work to be trusted and respected by society as a business enterprise that is essential to society in the healthcare field. In other words, we should strive to become a company with a meaningful existence and take our utmost efforts toward making this goal a reality. Additionally, I would like to see Nippon Shinyaku become an organization where each and every employee can grow and work with pride.

I believe that our management plan draws the specific roadmap enabling us to realize our desired image. Accordingly, we have positioned the five-year period of our management plan, from fiscal 2009 to fiscal 2013, as the time for realizing “Nippon Shinyaku’s desired image.”

Fiscal 2010 will mark the second year of this fourth five-year management plan “Innovation and Growth,” which we launched in May 2009, when we also clarified our management strategies to make these easier to understand. Although our business results in fiscal 2009 were slightly below our initial plans, our targets remain unchanged for the plan’s final year in fiscal 2013. Adhering to our business philosophy of “contributing to people’s health and prosperous lifestyles,” our management policy incorporates three perspectives: supplying high-quality products with distinctive benefits (customer perspective); being trusted by society (society perspective); and growing as individuals (employee perspective). By thoroughly emphasizing each perspective in a wide range of areas, we aim to attain the targets of our medium-term management plan.

I am confident that we can surmount the many challenging issues that lie ahead by combining the strengths of all employees and working toward attaining ambitious targets with a spirit of challenge, speed and investigation, which are watchwords shared by all employees. While striving to achieve the objectives of our management plan, we aim to become a vibrant, strong and forward-looking company where motivated employees perform their jobs with a positive attitude.

### Company with a Meaningful Existence in Healthcare

#### Pharmaceuticals Business

We target our fields of strength and supply high-quality pharmaceutical products with distinctive benefits welcomed by patients suffering from diseases.

#### Functional Food Business

We aim to supply high-quality products utilizing our advanced technological capabilities as a pharmaceutical company.



Q  
3

### What is your forecast for business results in fiscal 2010 and the outlook for the future?

We are forecasting an increase in revenues in our pharmaceuticals business in fiscal 2010 despite an anticipated decrease in revenues from the licensing of industrial property rights and the adverse impact of further revisions of drug prices. We anticipate that this increase will be supported by maintaining sales of our existing core pharmaceuticals and by the full-year contribution to sales of products launched last year as well as contributions made by two new products scheduled for launch in the current fiscal year.

Turning to our functional food business, we forecast an increase in revenues due to a recovery in import prices of raw materials for milk protein products and an emphasis on high value-added priority products.

At the profit level, however, we expect profits to decline owing to such factors as lower revenues from industrial property.

In consideration of these factors, we are forecasting consolidated net sales of ¥64,700 million, operating income of ¥5,300 million and net income of ¥3,700 million.

Viewed from the medium-term, I believe that our profits will bottom out in the current fiscal year. We have continually enhanced our development pipeline over the years. This will enable us to consistently introduce new products in the future as well, which in turn will allow us to further improve our business results. In our functional food business, we plan to expand sales and raise profitability by focusing on our priority products while developing highly original new products, re-evaluating our business structure, expanding business in growth fields and promoting business alliances.

Q  
4

### Could you explain your thoughts on returns to shareholders, including your dividend policy?

In accordance with our basic policy of maximizing enterprise value, Nippon Shinyaku strives to strengthen its R&D structure to enhance its product development pipeline and consistently introduce new products into markets. At the same time, we fortify our business foundation by bolstering retained earnings to establish a corporate structure that can withstand intensifying competition.

To ensure an appropriate level of return to shareholders, our policy is to maintain a consolidated payout ratio of about 30%, depending on our business performance. In calculating the payout ratio, we may possibly exclude extraordinary gains and losses.

For fiscal 2009, we paid cash dividends per share of ¥19, which included an interim dividend of ¥9 per share and a year-end dividend of ¥10 per share.

For fiscal 2010, we plan to maintain our interim dividend at ¥9 per share and our year-end dividend of ¥10 per share, for a total annual cash dividend of ¥19 per share.

# Innovation

2009

## Basic Corporate Policy

Nippon Shinyaku's business philosophy is "contributing to people's health and prosperous lifestyles." We aim to be trusted and respected by society as a business enterprise essential to society in the healthcare field. In other words, we aspire to be a company with a meaningful existence. In keeping with our business philosophy, as our basic policy for becoming such a company, we are implementing a management policy consisting of three perspectives: supplying high-quality products with distinctive benefits (customers); being trusted by society (society); and growing as individuals (employees). Based on this management policy, in our pharmaceuticals business and functional food business, we are supplying products that meet the needs of patients and customers. By doing so, we aim to earn the trust of society as well as raise our competitiveness and profitability, thereby maximizing enterprise value.

## "Innovation and Growth" Medium-Term Management Plan

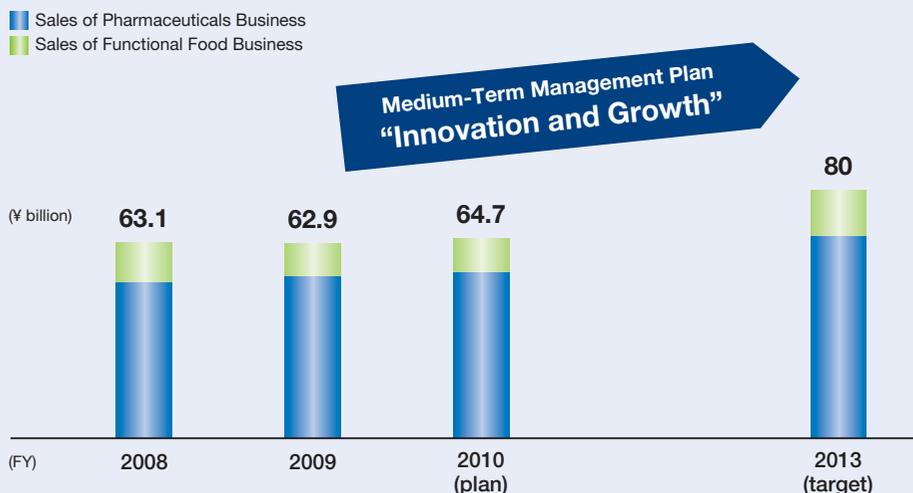
The environment surrounding the pharmaceuticals and foods industries is becoming increasingly severe, reflecting such factors as the continuation of measures to curtail medical costs and sluggish consumption resulting from global financial uncertainties. To realize our desired image within this challenging environment, we must push forward with unprecedented reform measures and achieve growth as a company. "Innovation and

Growth," our fourth five-year management plan launched in fiscal 2009, spells out the measures we will take for achieving our goals.

## Details of the Medium-Term Management Plan

In the pharmaceuticals business, we are targeting urology, hematology and our other fields of expertise, giving top priority to patients suffering from diseases as we strive to create and supply pharmaceuticals with distinctive benefits over competing drugs

## Medium-Term Management Plan



# and Growth 2013

in terms of efficacy, safety or quality of life (QOL) of patients. To do so, in R&D we are enhancing our development pipeline based on the three pillars of in-house research, in-licensing and product life cycle management (PLCM), and are making an effort to steadily and continuously launch new drugs. Our overriding goal in production is to earn the trust of society by providing stable supplies of high-quality bulk substances and products. At the same time, we strive to sharpen cost competitiveness and enhance efficiency by promoting low cost management. On the sales front, we carry out efficient and scientific product management through our information provision and marketing activities. Concurrently, we make efforts to raise the productivity of each medical representative (MR) and achieve well-balanced growth between existing products and new products.

In our functional food business, we work to supply high-quality products that utilize our strong technological capabilities

as a pharmaceutical company. We also work to develop products matched to customer needs and carry out business efficiently and systematically by identifying priority products and taking measures to expand sales of these products. We will also build a stable profit-earning structure and attain growth through an expansion of our business activities.

Nippon Shinyaku's action guidelines are challenge, speed and investigation. Taking advantage of our accurate and speedy management decision-making based on in-depth investigation and analysis, we will appropriately allocate management resources in our priority fields. At the same time, in keeping with our aim to be a company with a meaningful existence, we will expand our human resource development policies, re-evaluate our personnel systems and actively support the motivation and growth of employees to ensure that each employee acts taking a forward-looking perspective with a sense of challenge and pride.

## Research and Development ▶ P10-12

- Enhance our pipeline and steadily launch new products

## Manufacturing ▶ P13

- Ensure stable supplies of high-quality bulk substances and products
- Emphasize low cost management

## Marketing ▶ P14

- Carry out efficient and scientific product management

## Functional Food Company ▶ P15

- Expand sales of priority products and build a structure for stable earnings

### Targets for Fiscal 2013

Net sales	<b>¥80</b>	billion (5%)
Pharmaceuticals Business	<b>¥65</b>	billion (5%)
Functional Food Business	<b>¥15</b>	billion (3%)
Operating income	<b>¥10</b>	billion (6%)
Net income	<b>¥6</b>	billion (6%)

\* Figures in parentheses are CAGR for fiscal 2009-2013.

# Research and Development



## • Enhance Our Pipeline and Steadily Launch New Products

Based on the three pillars of in-house research, in-licensing and product life cycle management (PLCM), Nippon Shinyaku will enhance its pipeline and steadily launch new products.

**Akira Matsuura, Ph. D.**

Director and General Manager, Research & Development Division

### Rapid and Steady Achievements through Concentration on Core Competencies

At Nippon Shinyaku, we focus on the fields in which we specialize, operating under the concept of supplying the market with ethical drugs that feature distinctive benefits in terms of efficacy, safety or quality of life (QOL).

To unify our R&D with sales strategies, we have determined our main R&D domains as diseases in the five diagnostic and treatment fields of urology, hematology, obstetrics & gynecology, otorhinolaryngology and orthopedics. Through our own drug production based on drug discovery research, licensing-in from other companies and PLCM, we aim to bring products to market that patients will consider to be beneficial as quickly as possible.

Our drug discovery research concentrates on our priority diagnostic and treatment fields centering on hematology and urology. By elucidating the causes of new diseases, we can focus on the speedy development of proprietary drugs that offer distinctive benefits. In addition, we proactively license in marketed products and development-stage products as a method of enhancing our product pipeline. Moreover, through our PLCM activities, we consider new indications and formulations for our existing products and development-stage

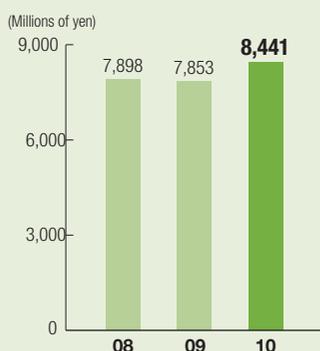
products, seeking to maximize product value.

Overall, our goal is to contribute to society by supplying a stable source of high-quality products to the market. To achieve this goal, we clarify our R&D targets, allocating our business resources appropriately to drug discovery, in-licensing and PLCM.

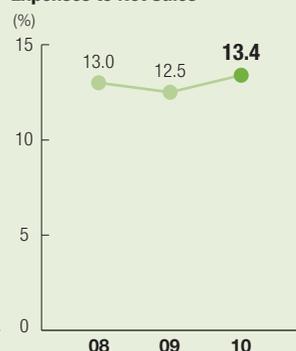
### R&D Organization

Our pharmaceutical R&D organization carries out its operations through four divisions, the R&D Administration Division, Business Development & Licensing Division, Discovery Research Laboratories and Clinical Development Division. The Discovery Research Laboratories, located in the same area as our head office (Kyoto), and our Drug Discovery Laboratories in Tsukuba, Ibaraki Prefecture, cooperate and search for new drug seeds. Our Discovery Research Laboratories focus on the use of low-molecular weight compounds as pharmaceuticals; pharmacological, toxicological, pharmacokinetic, formulation and pilot synthesis studies of drug seeds; and establishment of Nippon Shinyaku's proprietary drug formulation technologies. Our Drug Discovery Laboratories carry out advanced research focused on genomic drug discovery and nucleic acid drugs. The Clinical Development Division is in charge of clinical trials to assess efficacy and safety in humans.

Consolidated R&D Expenses



Consolidated Ratio of R&D Expenses to Net Sales



### Enhance Our R&D Pipeline and Steadily Launch New Products



Promote the nucleic acid drug business and the nucleic acid business

## Approach toward Genomic Drug Discovery and Nucleic Acid Drugs

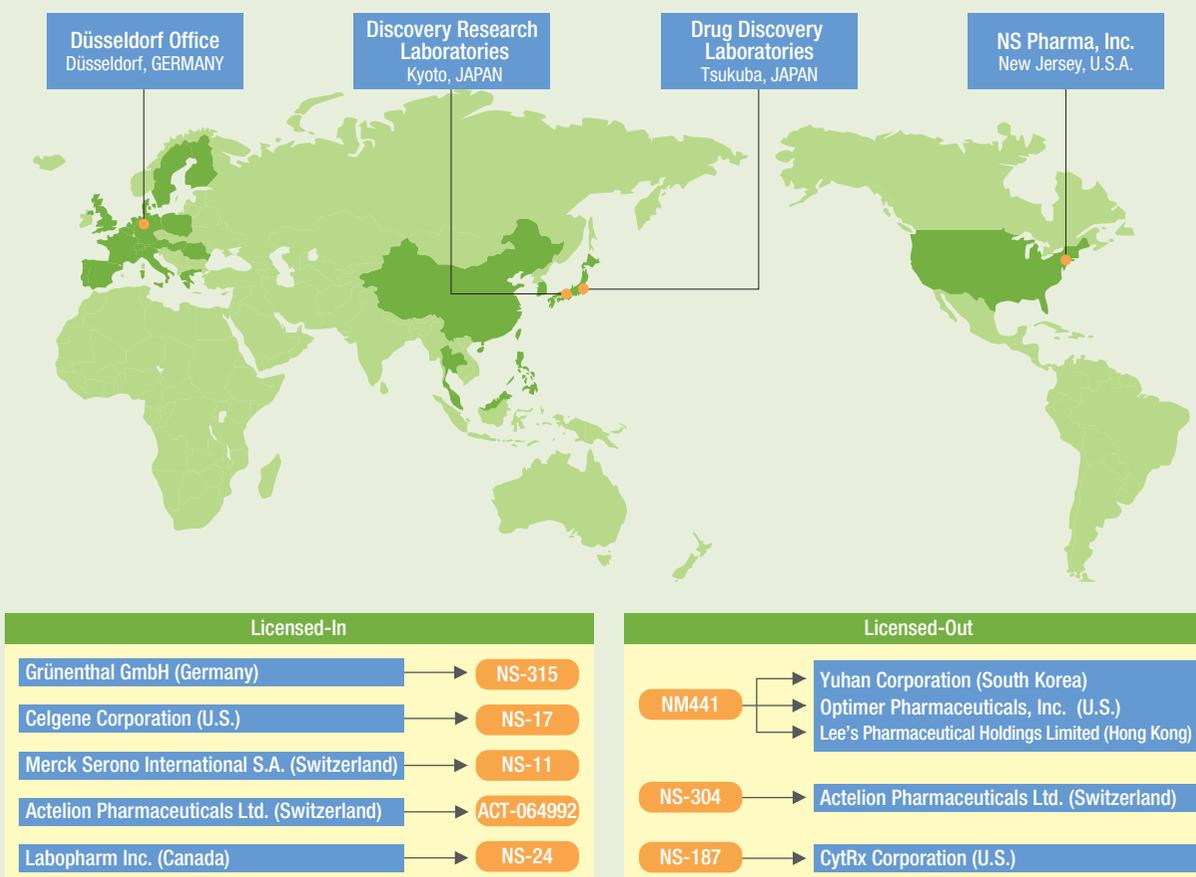
Drug creation by pharmaceutical companies is set to change dramatically in the 21st century. At present, Nippon Shinyaku proactively undertakes advanced research centered on genomic drug discovery and nucleic acid drugs at its Drug Discovery Laboratories. At the Discovery Research Laboratories, we focus on specific high-need diseases within our principal therapeutic domains and concentrate on developing new therapeutic agents that selectively act on biological molecules related to the disease.

### (1) New Drug Seeds Discovery

As a result of unraveling the sequence of the human genome, researchers discovered that much of the DNA sequence did not control the genes governing the production of proteins important to the functioning of the human body. In fact, 98.5% of the human genome was not relevant to these proteins. However, it was discovered that functional ribonucleic acid (RNA), which is closely involved with the onset of disease, was hidden within this “useless” DNA sequence. By understanding the role of functional RNA, we hope to discover ways to conquer diseases that up to now have been unresponsive to existing pharmaceuticals. In addition to our own research, Nippon Shinyaku is undertaking joint research in collaboration with universities and public research institutes to discover drug seeds in this field.

### (2) Nucleic Acid Drug R&D

Nucleic acid drugs act directly on genes that cause diseases. This enables the treatment of illnesses that could not be treated previously with traditional low-molecular drugs or antibody drugs. Consequently, there are high expectations being placed on nucleic acid drugs as next-generation bio-pharmaceuticals. For practical application, however, it is necessary to overcome two technological obstacles, namely, nucleic acid synthesis and drug delivery. Nippon Shinyaku has succeeded in the development of an efficient and highly versatile RNA synthesis method that also allows the synthesis of long-chain RNA whereby 50 to 100 nucleotide bases are joined. Additionally, Nippon Shinyaku was a frontrunner in research on drug delivery for delivering nucleic acid drugs to the target site. We also developed technologies that allow the safe administration of these pharmaceuticals to people. As one research outcome realized through these proprietary technologies, Nippon Shinyaku was the first in the world to demonstrate the cancer-controlling effect of small interfering RNA (siRNA) utilizing a compound in a cancer model using mice. Applying our proprietary technologies cultivated over the years, we aim to create unique nucleic acid drugs beneficial in the treatment of illnesses for which there are still no effective drugs.



## Product Development

### • NS-315 (Tramadol hydrochloride)

Licensed in from Grünenthal GmbH of Germany, this non-narcotic oral analgesic is currently being marketed in more than 100 countries around the world. We submitted an application for approval of NS-315 as an analgesic for the treatment of mild to moderate cancer pain in July 2008. Phase II clinical trials for chronic non-cancer pain started in July 2009.

### • NS-17 (Azacitidine)

As an agent for the treatment of myelodysplastic syndrome (MDS), we licensed in NS-17 from Celgene Corporation of the United States. In that country, it is the first-line drug for MDS. In December 2008, Celgene received approval for the drug in the EU. NS-17 is effective in all subtypes of MDS and delays conversion to leukemia (AML). The agent's mechanism of action involves inhibiting the methylation of the DNA of blood forming cells. In November 2008, NS-17 was designated an orphan drug. In December 2009, we filed an application for approval for the indication of MDS.

### • NS-11 (Acamprosate)

We licensed in NS-11 from Merck Serono International S.A. of Switzerland as an agent for the treatment of alcohol dependency. NS-11 is already being sold in the United States and Europe. Phase III clinical trials started in Japan in March 2009.

### • LY450190 (Tadalafil)

This is a remedy for urinary disorder caused by benign prostatic hypertrophy (BPH), for which Eli Lilly Japan K.K. is carrying out Phase III clinical trials in Japan.

### • NS-304 (Selexipag)

This is an orally administered prodrug developed by Nippon Shinyaku. The active metabolite remains in the blood for a long duration and demonstrates strong and selective PGI2 agonist activity. NS-304 has been designated as an orphan drug by the European Medicines Agency. In April 2008, we licensed out NS-304 to Actelion Pharmaceuticals Ltd. of Switzerland. Actelion will now be responsible for the development of the drug in all regions other than Japan. In December 2009, Phase III clinical trials commenced for the indication of pulmonary arterial hypertension (PAH). In Japan, this will be a collaborative development effort with

Actelion Pharmaceuticals Japan Ltd. In April 2010, Phase II clinical trials were commenced for the indication of chronic thromboembolic pulmonary hypertension (CTEPH). Preparations are underway for commencing Phase II clinical trials for PAH at the end of 2010.

### • ACT-064992 (Macitentan)

This is a pulmonary hypertension treatment agent licensed in from Actelion. Overseas, Actelion is carrying out Phase III clinical trials for the indication of PAH. In Japan, we plan to commence clinical trials jointly with Actelion Pharmaceuticals Japan. Macitentan is a highly potent tissue-targeting dual endothelin receptor antagonist developed by Actelion.

### • NS-187 (Bafetinib)

NS-187 is a potent inhibitor of Bcr-abl tyrosine kinase and Lyn tyrosine kinase being developed for chronic myelogenous leukemia. NS-187 is effective even in imatinib-resistant patients. We licensed out NS-187 to CytRx Corporation of the United States at the end of 2005. Plans call for the commencement of Phase II clinical trials in 2010 for B cell chronic lymphocytic leukemia, glioblastoma multiforme and advanced prostate cancer.

### • NST-141

We are developing this agent as an external-use drug with a new mechanism of action. NST-141 is not an antihistamine drug. There are hopes that it will be effective as a treatment for difficult-to-treat itching complaints unresponsive to existing drugs. We plan to develop the agent as an anti-itching remedy for atopic dermatitis. In October 2008, we signed a license agreement with Taiho Pharmaceutical Co., Ltd. to collaborate on development and marketing in Japan. The agent entered Phase I clinical trials in May 2009.

### • NS-24 (Tramadol hydrochloride)

NS-24 is a once-daily oral tramadol hydrochloride sustained release analgesia licensed in from Labopharm Inc. of Canada. This drug utilizes Labopharm's formulation technology platform (Contramid®) and attains effective blood concentration one hour after dosage and retains effective blood concentration for 24 hours. Preparations are underway for the commencement of Phase I clinical trials during fiscal 2010.

## Domestic

Code No.	Generic name	Therapeutic field	Indications	Development	Stage
NS-315	Tramadol hydrochloride	Inflammation/allergy	Cancer pain (non-narcotic analgesic)	Licensed in from Grünenthal GmbH	Phase I → Phase II → Phase III → Application
			Non-cancer related pain (non-narcotic analgesic)		Phase I → Phase II
NS-17	Azacitidine	Hematologic malignancies	Myelodysplastic syndrome	Licensed in from Celgene Corporation	Phase I → Phase II → Phase III → Application
NS-11	Acamprosate	Others	Alcohol dependence	Licensed in from Merck Serono International S.A.	Phase I → Phase II → Phase III
LY450190	Tadalafil	Urology	Urinary disorder caused by BPH	Licensed in from Eli Lilly Japan K.K.	Phase I → Phase II → Phase III
NS-304	Selexipag	Cardiovascular	Pulmonary hypertension	Co-development with Actelion	Phase I → Phase II
ACT-064992	Macitentan	Cardiovascular	Pulmonary arterial hypertension	Licensed in from Actelion	Phase I → Phase II (Preparation)
NST-141		Inflammation/allergy	Pruritus associated with atopic dermatitis, etc.	Co-development with Taiho Pharmaceutical Co., Ltd.	Phase I
NS-24	Tramadol hydrochloride	Inflammation/allergy	Cancer pain Non-cancer related pain	Licensed in from Labopharm Inc.	Phase I (Preparation)

## Overseas

Code No.	Generic name	Therapeutic field	Indications	Development	Stage
NM441	Prulifloxacin	Infectious diseases	Synthetic antibacterial	Yuhan Corporation	Phase I → Phase II → Phase III → Application → Launch Preparation
				Optimer Pharmaceuticals, Inc.	Phase I → Phase II → Phase III → Application (Preparation)
				Lee's Pharmaceutical Holdings Limited	Phase I → Phase III → Phase III (Preparation)
NS-304	Selexipag	Cardiovascular	Pulmonary hypertension	Actelion Pharmaceuticals Ltd.	Phase I → Phase II → Phase III
NS-187	Bafetinib	Hematologic malignancies	Chronic myelogenous leukemia B cell chronic lymphocytic leukemia Glioblastoma multiforme Advanced prostate cancer	CytRx Corporation	Phase I → Phase II (Preparation)

# Manufacturing

- **Ensure Stable Supplies of High-Quality Bulk Substances and Products**
- **Emphasize Low Cost Management**

By enhancing production efficiency and streamlining inventories, Nippon Shinyaku will promote low cost management while ensuring steady supplies of high-quality bulk substances and products.

## **Tsugio Tanaka, M.S. Pharmacy**

Director and General Manager, Resource Procurement,  
Production & Assurance Division



## **Providing Stable Supplies of High-Quality Bulk Substances and Products**

Providing stable supplies of high-quality pharmaceutical products is the overarching mission of the Resource Procurement, Production & Assurance Division.

Nippon Shinyaku operates a plant in Odawara for pharmaceutical formulations and a plant in Chitose for the production of bulk substances. To ensure stable supplies of bulk substances and products, Nippon Shinyaku clarifies any risks that could impede the uninterrupted flow of product supplies and implements a host of measures to avoid risk.

For example, in procuring raw materials for our principal products, we purchase from two companies whenever possible to avoid the risk of being unable to procure raw materials. For production machinery, we perform preventive maintenance and undertake systematic renewal of old facilities to prevent any sudden malfunctions. Also, as production management systems to prevent human error during manufacturing, we have introduced a Manufacturing Execution System (MES) at the Odawara Central Factory and a Distributed Control System (DCS) at the Chitose Synthesis Plant. In fiscal 2009, we adopted upgraded versions of both systems to further improve the reliability of these systems.

In our role as a pharmaceutical company, we recognize that we have a crucial social responsibility to undertake continuous production to prevent shortages of our core products in the event of an earthquake or other natural disasters or during a pandemic such as an outbreak of a new influenza virus. In fulfilling this responsibility, we have prepared a Business Continuity Plan (BCP) to respond to any type of contingency.

Of particular note, the Odawara Central Factory is situated in western Kanagawa Prefecture, where a major earthquake exceeding magnitude 6 on the seismic intensity scale is forecast. To minimize damage and resume plant operations within two months following such a powerful earthquake, under our fourth medium-term management plan we are systematically implementing preventive countermeasures covering facilities, IT,

logistics and the storage of raw materials.

In addition, we also deliberate and carry out mutual consultations about crisis management with companies to which we outsource production. As these measures demonstrate, we make our utmost efforts to ensure stable supplies of high-quality bulk substances and products.

## **Low Cost Management**

In the Resource Procurement, Production & Assurance Division, our foremost goal is to earn the trust of society by providing stable supplies of high-quality bulk substances and products. In addition, we aim to enhance efficiency and strengthen cost competitiveness by promoting low cost management. The Procurement Division strives to reduce procurement costs by introducing new suppliers while seeking more reasonable prices by investigating raw materials prices and obtaining competitive bids. The Manufacturing Division undertakes efficient production of reliable, high-quality pharmaceutical products by renewing its cutting-edge crushers and Comprima ultra-high-speed tablet presses. The division also raises production efficiency by introducing time-staggered production and work systems. Also, taking into consideration high cost ratios and the cost effectiveness of investments for small-lot production, some products are outsourced when external manufacturing is deemed more cost efficient. Conversely, we are also actively promoting consigned production to improve our fixed costs and operating rates. With an eye toward streamlining and maintaining appropriate levels of inventories of raw materials and products, we are verifying lead times from the procurement of raw materials to supplying products, changing production methods and establishing criteria for maintaining appropriate inventories to achieve a reduction in inventories. The Logistics Division is reducing costs by outsourcing the operation of its logistics bases and considering outsourcing order-receiving operations.



# Marketing

## • Carry Out Efficient and Scientific Product Management

Nippon Shinyaku carries out efficient and scientific product management, aiming for well-balanced growth between its new products and existing products.

### Toshihiko Sago

Managing Director and General Manager, Marketing Division

### Basic Strategy

Despite a harsh environment in the domestic pharmaceutical market, we expect to launch numerous new products during the span of our fourth medium-term management plan, as we gear up for an unprecedented period of growth. Our expansion over the next 10 to 20 years will depend largely on whether we can maximize sales of each new product. However, we cannot simply concentrate our resources solely on new products. For us to attain growth, it is essential that expansion of new products contributes directly to our overall sales growth. Therefore, during the execution period of our fourth medium-term management plan, one of our principal goals will be to realize well-balanced growth whereby we record increases in new products while maintaining sales of our existing high-margin products.

### Initiatives for Expanding Business

In fiscal 2010, we will work to quickly achieve our sales targets for four new products expected to become major pillars of income in the future. They include Lunabell<sup>®</sup>, a treatment for dysmenorrhea resulting from endometriosis launched in July 2008; Cialis<sup>®</sup>, an erectile dysfunction (ED) remedy introduced in July 2009; Adcirca<sup>®</sup> for the treatment of pulmonary arterial hypertension (PAH) introduced in December 2009; and Erizas<sup>®</sup>, a remedy for allergic rhinitis also launched in December 2009.

Also in fiscal 2010, we plan to launch two new products, namely, an agent for the treatment of cancer pain and an agent for the treatment of myelodysplastic syndrome (MDS).

To achieve growth through sales of our new products, we must also maintain sales of existing products. To prevent declines in sales of high-margin existing products, we will categorize existing products into those for which we will target further growth and those for which we will seek to maintain sales levels despite limited growth potential. The first category includes Eviprostat<sup>®</sup>, our remedy for benign prostatic hypertrophy, and Gaslon N<sup>®</sup>, our remedy for gastric ulcer and gastritis. We will plan our marketing activities with a detailed balance of these two categories in mind. In addition, our medical representatives (MRs) will utilize sales force effectiveness (SFE) to thoroughly target priority facilities and physicians for management. Through effective MR activities, we will strengthen our relationships with priority customers. Based on those efforts, we will nurture more loyal customers, aiming to achieve stable sales growth for existing products.

In fiscal 2010, we will increase our staff of MRs to carry out these activities and achieve well-balanced growth based on existing and new products to become a company with a meaningful existence in the eyes of society.

### Sales of Principal Products (Millions of yen)

Product Name	FY2008	FY2009
Eviprostat <sup>®</sup>	5,950	6,629
Hypen <sup>®</sup>	5,746	5,655
Gaslon N <sup>®</sup>	4,080	4,498
Selectol	3,415	3,251
Bladderon <sup>®</sup>	3,153	3,094
Cephadol <sup>®</sup>	2,842	2,858

Product Name	FY2008	FY2009
Estracyt	3,029	2,832
Cylocide	2,676	2,706
Azunol <sup>®</sup> Gargle	2,182	2,388
Baynas <sup>®</sup>	2,663	2,237
Cialis <sup>®</sup>	—	1,799
Prulifloxacin bulk	1,009	1,296

# Functional Food Company

## • Expand Sales of Priority Products and Build a Structure for Stable Earnings

Nippon Shinyaku is supplying highly original products that respond to market needs and working to steadily expand our business.

### Hiroshi Adachi

Director and COO, Functional Food Company



### Basic Strategy

In 2011, the Functional Food Company will celebrate the 50th anniversary of its establishment. Placing great value on the deep trust and confidence we have earned and the high reputation we have built by carrying out our business over many years, we aim to expand and grow our business as well as improve profitability. In the future, we will continue focusing on sales of our high value-added products including health food ingredients, preservatives, nutritional ingredients, soybean proteins, milk proteins and other protein preparations. We also plan to develop highly original new products, re-evaluate our business structure, expand business in growth fields and promote business alliances. By doing so, we aim to steadily expand our business.

### Initiatives for Expanding Business

As our first target, we will look at the processed food industries, including the meat processing, seafood paste products, and bread and confectionery industries. Despite the harsh environment created by the protracted slump in consumption and a pronounced trend toward a preference for low prices, the scale of this market is large and we aim to develop new products matched to market needs. At the same time, we aim to expand sales, centering on such protein ingredients as soybean proteins and milk proteins as well as on preservatives.

The next market of interest is the field of nutraceuticals. While the field is currently stagnating because of excessive publicity from TV health programs, we expect that growing interest in self-medication and healthcare will produce future growth in this market. Promoting R&D in this field on a scientific basis, we will supply new health food ingredients to the market aimed at such areas as anti-aging.

Another promising field is nutrition. Although the market for clinical nutrition, sports nutrition and other nutritional foods is still small, we expect to see sharp growth in the market along with the increased number of elderly people and elderly people requiring nursing care. Nutritional foods clearly respond to the needs of an aging society. The use of nutritional ingredients in liquid foods can improve the health of elderly people, helping them to more quickly recover their strength. Nutritional foods also can prevent elderly people from becoming bedridden.

Our in-house functional food company utilizes the advanced manufacturing technology and quality know-how accumulated by our pharmaceutical operations. Giving top priority to safety and reliability, the Functional Food Company will supply highly original functional food ingredients that are useful to society, thereby contributing to people's health. In our aim to be a company trusted by society, we will steadily carry out and expand our businesses and raise enterprise value.

## Expand Sales of Priority Products

### Protein Preparations

- Secure profits and expand new sales routes
- Raise technological capabilities and realize low prices, high stability and high quality

### Preservatives

- Expand new sales routes and launch new products
- Consider setting up overseas operations

### Nutritional Ingredients

- Expand new sales routes, develop new materials and strengthen technological capabilities
- Enhance product lineup

### Health Food Ingredients

- Develop new products that have a high degree of recognition and expand sales routes
- Strengthen technological capabilities and secure high profits

# Corporate Governance

## Basic Policies and Management System

Nippon Shinyaku pursues ongoing strengthening of corporate governance, striving to achieve greater management transparency and to increase enterprise value.

In undertaking corporate governance, the Company has adopted the statutory auditor system, which is based on a system built around the general meeting of shareholders, a board of directors and a board of auditors. The Board of Directors comprises seven directors and aims to conduct efficient management of the Company by allocating responsibility for operations to individual directors who carry out business execution. The Board of Auditors has four corporate auditors. Based on Japan's Companies Act, the Company's internal control system is managed using a system determined in accordance with basic policies decided by the Board of Directors. This system aims to increase the effectiveness and efficiency of business operations as well as ensure the accuracy of financial information. In addition to being audited by an accounting auditor, the Company also has established an independent Internal Audit Department that audits the effectiveness of the key systems of the Company's management—internal control, compliance and risk management.

## Compliance

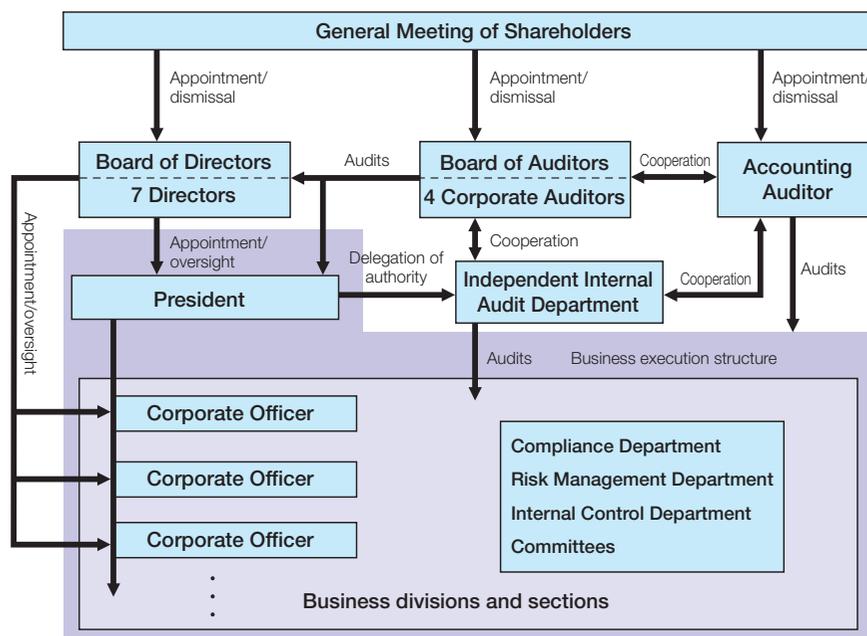
Nippon Shinyaku promotes compliance on an organizational basis. In addition to formulating the Group Charter of Business Conduct, compliance is overseen by a compliance officer

who is appointed from among the directors of the Company. Moreover, the Compliance Department has been set up within the Company and carries out educational, training and awareness activities. In fiscal 2009, the compliance organization implemented activities to increase knowledge of laws, ordinances and regulations related to Nippon Shinyaku's businesses, develop a heightened awareness of compliance and improve corporate culture. Furthermore, to enable the Company to discover and deal with illegal behavior on an internal basis, compliance hotlines have been established to allow employees from Group companies to make inquiries and report incidents.

## Risk Management

Companies face a diverse range of risks in their business. To enable sustained development, they have to take measures to reduce their exposure to these risks. To guide its risk management activities, the Nippon Shinyaku Group has established a set of Basic Risk Management Rules that clarify the sections responsible for each risk and outline prevention and response measures. Moreover, the Group utilizes its annually conducted risk assessments to determine major risk themes. Led by the Risk Management Department, the Group determines and implements enhanced measures to address those major risk themes. In fiscal 2009, the Group developed activities directed toward preparing an operations manual on response to the highly virulent new influenza outbreak as well as optimizing information security.

## Corporate Governance Structure



# Board of Directors and Corporate Auditors



**Tsugio Tanaka**  
Director

**Kazuo Fukushima**  
Director

**Hiroshi Adachi**  
Director

**Yoshiro Yura**  
Director

**Akira Matsuura**  
Director

**Shigenobu Maekawa**  
President

**Toshihiko Sago**  
Managing Director

## President

**Shigenobu Maekawa**

## Managing Director

**Toshihiko Sago**

(General Manager, Marketing Division)

## Directors

**Hiroshi Adachi**

(COO, Functional Food Company)

**Kazuo Fukushima**

(General Manager, Corporate Planning Division)

**Yoshiro Yura**

(General Manager, CSR & Business Management Division)

**Tsugio Tanaka**

(General Manager, Resource Procurement, Production & Assurance Division)

**Akira Matsuura, Ph. D.**

(General Manager, Research & Development Division)

## Corporate Auditors

**Yoichi Toriyama**

**Yojiro Ukai**

**Yasuo Tanabe**

**Hajime Nishikawa**

## Corporate Officers

**Kazushige Itabashi**

(General Manager, Business Development & Licensing Division)

**Taro Sakurai**

(General Manager, Finance & Accounting Dept.)

**Toru Sakata**

(General Manager, Marketing Planning Division)

**Kiyotaka Konno, Ph. D.**

(General Manager, Clinical Development)

**Yoshinori Sato**

(General Manager, Marketing Promotion Division)

**Yoshitaka Fukuda**

(General Manager, Personnel Division)

**Hirokata Harada**

(General Manager, Planning Division)

**Shigeki Sonoda**

(General Manager, Odawara Central Factory)

**Hironori Ninomiya**

(General Manager, Production & Assurance Division)

**Hitoshi Saito**

(General Manager, Research & Development Planning Division)

**Tetsuya Sugiyama**

(General Manager, Tokyo Business Office)

**Kenro Kobayashi**

(General Manager, Nagoya Business Office)

# Corporate Social Responsibility

## Basic CSR Policies and Promotional System

Nippon Shinyaku's business philosophy is "contributing to people's health and prosperous lifestyles." Our corporate social responsibility (CSR) activities aim to demonstrate the Company as an essential entity to society through our environmentally conscious management of pharmaceuticals and functional food businesses within the healthcare sector and their sustained development. In other words, we aim to fulfill our social responsibilities through our business activities. Based on that awareness, our employees seek in their daily work activities to conduct themselves—each in their own way—so that the Company will meet the expectations and trust of society and be recognized as a company with a meaningful existence.

## Supplying High-Quality Products with Distinctive Benefits

Today, the rapid aging of Japanese society has been accompanied by rising interest in a healthy life span and growing expectations placed on the healthcare field. We believe these developments will provide Nippon Shinyaku with excellent opportunities for dramatic growth. We aim to develop ethical drugs that feature distinctive benefits over competing drugs in terms of efficacy, safety or quality of life (QOL) of patients. At the same time, we are boldly taking on the challenge of developing pharmaceuticals in fields where effective treatment methods have yet to be established, such as domains where there are few patients or large sales cannot be expected. In the functional food business, we will supply high-quality products that utilize our high level of technological strengths as a pharmaceutical company.

## Being Trusted by Society

Earning the trust of society is contingent on addressing the broad-ranging expectations and demands of society. We ensure that our overall business activities are undertaken appropriately through the implementation of corporate governance and internal control systems. We also carry out a host of activities not just in development, manufacturing and sales in our core pharmaceuticals and functional food businesses but throughout our entire business operations as well.

Based on the Environmental Basic Policies formulated by the Board of Directors, Nippon Shinyaku established the Environment Committee, which set up company-wide autonomous environmental targets in eight categories. These include cutting CO<sub>2</sub> emissions and reducing the volume of waste material generated. The Environment Committee works systematically to attain these targets through measures such as introducing energy-saving equipment and lowering final waste

disposal rates.

In a different sphere, Nippon Shinyaku seeks to inspire dreams and watch over the sound spiritual development of children. As one measure, in fiscal 2009 Nippon Shinyaku began hosting the Nippon Shinyaku Children's Literary Awards contest. As part of this contest, we solicit works in the Story Category and the Pictorial Category and then produce a picture book containing the best works. These books are widely distributed to children across Japan through medical institutions, libraries and other public institutions.

Nippon Shinyaku also proactively implements a variety of social contribution activities in response to requests from various groups. For example, we support the Yellow Ribbon drive run by The World Endometriosis Society and the Orange Balloon Project promoted by the Japanese Society for Palliative Medicine. We also send lecturers (on-demand classes) to educate elementary school children about the environment at the request of the Kyoto Chamber of Commerce and Industry.



Nippon Shinyaku Children's Literary Awards contest



## Growing as Individuals

Working to become a healthcare business enterprise essential to society gives each employee motivation and pride in his or her job. Also, employees grow through the pursuit of their work. Recognizing our employees as one group of stakeholders, we have introduced various systems to increase their work satisfaction. We believe that together these create an upward spiral that increases the value of our human resources. In turn, this added value leads to a further increase in our enterprise value.

# Financial Section

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## Six-Year Summary (Consolidated)

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

	Millions of Yen					
	2010	2009	2008	2007	2006	2005
Net sales	<b>¥ 62,933</b>	¥63,072	¥ 59,450	¥ 56,321	¥ 53,947	¥54,252
Income before income taxes and minority interests	<b>6,933</b>	7,686	6,879	5,290	3,285	9,630
Net income	<b>4,096</b>	4,500	4,031	2,900	1,612	5,639
Amounts per share (in yen):						
Basic net income	<b>¥ 60.63</b>	¥ 66.56	¥ 59.57	¥ 42.73	¥ 22.84	¥ 81.22
Cash dividends applicable to the year	<b>19.00</b>	18.00	16.00	12.00	10.00	15.00
Total assets	<b>¥103,576</b>	¥98,286	¥103,116	¥104,873	¥104,899	¥98,910
Equity	<b>80,206</b>	76,193	76,804	76,070	75,412	70,010
Capital investment	<b>1,859</b>	2,332	1,650	1,409	1,184	1,745
R&D expenses	<b>8,441</b>	7,853	7,898	8,200	10,071	8,479

# Management's Discussion and Analysis

## I. Financial Strategy

In keeping with its policy of maximizing enterprise value, the Company strengthens its research and development capabilities and reinforces its development pipeline, while further fortifying its business foundation and ensuring ample retained earnings for establishing a corporate structure that can withstand intensifying competition. Regarding the return of profits to shareholders, our policy is to maintain a consolidated payout ratio of about 30%, depending on our business performance. In calculating the payout ratio, in some instances we exclude extraordinary gains and losses. For the fiscal year under review, we paid cash dividends per share of ¥19, which includes an interim dividend of ¥9 per share and a year-end dividend of ¥10 per share.

## II. Liquidity and Capital Resources

Total assets increased ¥5,290 million from the previous fiscal year-end to ¥103,576 million. Although notes and accounts receivables declined, cash and cash equivalents, time deposits and marketable and investment securities increased.

Total liabilities increased ¥1,264 million from the previous fiscal year-end to ¥23,206 million. Notes and accounts payable increased, but long-term debt and income taxes payable decreased.

Total equity amounted to ¥80,370 million.

The equity ratio was 77.4%.

Net cash provided by operating activities amounted to ¥9,225 million. This consisted mainly of such cash inflows as income before income taxes and minority interests, depreciation and amortization, and a decrease in notes and accounts receivables, while a principal outflow was income taxes paid.

Net cash used in investing activities totaled ¥3,648 million. The principal cash outflows were payments for acquisition of license rights and capital expenditures, while the primary inflow was proceeds from redemption of marketable securities.

Net cash used in financing activities totaled ¥1,318 million. This consisted primarily of cash dividends paid.

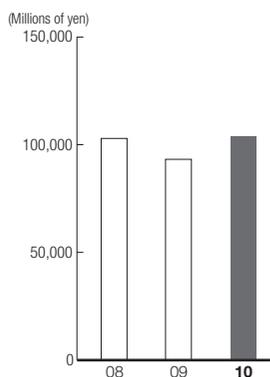
As a result, cash and cash equivalents at the end of the fiscal year increased ¥4,002 million from the previous fiscal year-end to ¥19,448 million.

The Company will continue to focus on maintaining a sound balance sheet as well as ensure appropriate levels of liquidity and the availability of necessary funds for carrying out its business activities.

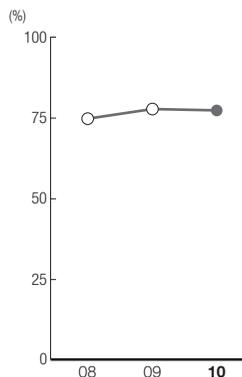
### Consolidated Cash Flows (Millions of yen)

	2008	2009	2010
Net cash provided by operating activities	7,347	6,370	<b>9,225</b>
Net cash used in investing activities	(1,070)	(3,566)	<b>(3,648)</b>
Net cash used in financing activities	(2,150)	(2,300)	<b>(1,318)</b>
Cash and cash equivalents, end of year	15,154	15,446	<b>19,448</b>

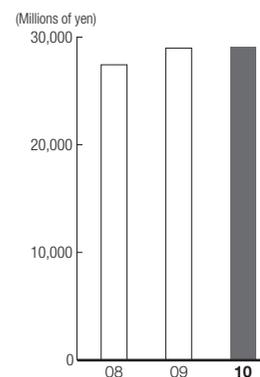
### Consolidated Total Assets



### Consolidated Equity Ratio



### Consolidated Cost of Sales



### III. Results of Operations (Consolidated)

The environment surrounding the pharmaceutical industry became increasingly severe during the fiscal year under review. Measures to curtail medical expenses were further strengthened, including a reduction in prices of pharmaceuticals under the national health insurance scheme, the promotion of the greater use of generic drugs and the introduction of the lump-sum Diagnosis Procedure Combination payment system. On the other hand, R&D expenses for the development of new pharmaceuticals increased.

Operating within a harsh economic environment amid sluggish consumption, the functional food industry is expected to face increasingly stringent customer demands for quality and food safety.

Under these conditions, the Nippon Shinyaku Group continued to undertake solid business activities during the fiscal year under review. Consolidated net sales amounted to ¥62,933 million, down 0.2% from the previous fiscal year, and operating income was ¥6,462 million, a decline of 14.4%. Net income totaled ¥4,096 million, a decrease of 9.0% from the previous fiscal year.

Earnings by segment were as follows.

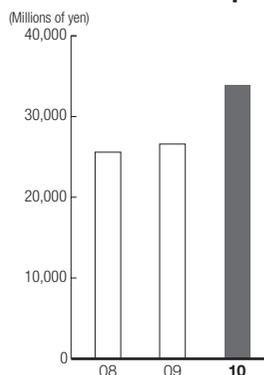
### Pharmaceuticals Business

In the pharmaceuticals business, we posted a decline in sales of Livostin<sup>®</sup>, a remedy for allergic rhinitis and allergic conjunctivitis, as well as lower sales of Baynas<sup>®</sup>, a remedy for allergic rhinitis, due to diminished amounts of pollen dispersal. Although revenue from the licensing of industrial property rights also declined, we recorded growth in sales of mainstay products such as Eviprost<sup>®</sup>, a remedy for benign prostatic hypertrophy, and Gaslon N<sup>®</sup>, a remedy for gastric ulcer and gastritis. Also making a contribution to sales was the erectile dysfunction (ED) drug Cialis<sup>®</sup>, for which we obtained the sales rights from Eli Lilly Japan K.K. in July 2009. As a result, sales in the pharmaceuticals business amounted to ¥52,166 million, an increase of 3.6% from the previous fiscal year.

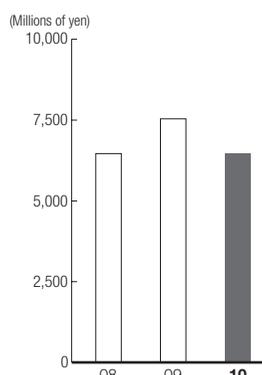
### Functional Food Business

In the functional food business, amid ongoing difficult conditions in the processed food industry and the health food industry, we posted favorable sales of health food ingredients. However, sales of protein preparations and nutritional ingredients declined sharply, as we reflected the strong yen and a steep decline in prices of imported milk protein ingredients in our sales prices. Accordingly, sales of the functional food business totaled ¥10,767 million, a decline of 15.3% from the previous fiscal year.

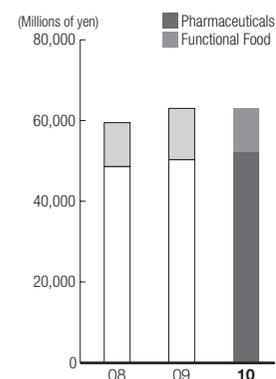
#### Consolidated Selling, General and Administrative Expenses



#### Consolidated Operating Income



#### Consolidated Sales by Industry Segment



# Consolidated Balance Sheets

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
March 31, 2010 and 2009

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2010	2009	2010
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents (Note 10)	¥ 19,448	¥ 15,446	\$ 209,118
Time deposits (Note 10)	80	40	860
Marketable securities (Notes 3 and 10)	596	1,000	6,409
Notes and accounts receivables (Note 10):			
Trade notes	231	300	2,484
Trade accounts	24,586	27,332	264,365
Other	126	317	1,355
<b>Total notes and accounts receivables</b>	<b>24,943</b>	<b>27,949</b>	<b>268,204</b>
Inventories (Note 4)	10,866	10,832	116,839
Deferred tax assets (Note 9)	1,632	1,617	17,548
Other current assets	1,909	710	20,527
Allowance for doubtful accounts		(16)	
<b>Total current assets</b>	<b>59,474</b>	<b>57,578</b>	<b>639,505</b>
<b>PROPERTY, PLANT AND EQUIPMENT:</b>			
Land	8,160	8,162	87,742
Buildings and structures	25,924	25,641	278,753
Machinery and equipment	12,385	12,208	133,172
Tools, furniture and fixtures	9,106	9,197	97,914
Construction in progress	230	114	2,473
<b>Total</b>	<b>55,805</b>	<b>55,322</b>	<b>600,054</b>
Accumulated depreciation	(35,970)	(34,916)	(386,774)
<b>Net property, plant and equipment</b>	<b>19,835</b>	<b>20,406</b>	<b>213,280</b>
<b>INVESTMENTS AND OTHER ASSETS:</b>			
Investment securities (Notes 3 and 10)	12,765	11,532	137,258
Long-term prepaid expenses	8,616	6,166	92,645
Deferred tax assets (Note 9)	56	165	602
Other assets	2,830	2,439	30,430
<b>Total investments and other assets</b>	<b>24,267</b>	<b>20,302</b>	<b>260,935</b>
<b>TOTAL</b>	<b>¥103,576</b>	<b>¥98,286</b>	<b>\$1,113,720</b>

See notes to consolidated financial statements.

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2010	2009	2010
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Notes and accounts payables (Note 10):			
Trade notes	¥ 968	¥ 1,168	\$ 10,409
Trade accounts	3,723	3,264	40,032
Other	3,520	663	37,849
<b>Total notes and accounts payables</b>	<b>8,211</b>	<b>5,095</b>	<b>88,290</b>
Income taxes payable (Note 10)	1,283	1,551	13,796
Accrued expenses	3,331	5,984	35,817
Deposits from customers	290	281	3,118
Other current liabilities	1,083	611	11,646
<b>Total current liabilities</b>	<b>14,198</b>	<b>13,522</b>	<b>152,667</b>
<b>LONG-TERM LIABILITIES:</b>			
Liability for retirement benefits (Note 5)	8,230	8,009	88,494
Deferred tax liabilities (Note 9)	406		4,366
Other long-term liabilities	372	411	4,000
<b>Total long-term liabilities</b>	<b>9,008</b>	<b>8,420</b>	<b>96,860</b>
<b>EQUITY (Notes 6 and 12):</b>			
Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares	5,174	5,174	55,634
Capital surplus	4,444	4,444	47,785
Retained earnings	68,434	65,554	735,850
Unrealized gain on available-for-sale securities	4,195	3,032	45,108
Deferred gain on derivatives under hedge accounting	3	1	32
Foreign currency translation adjustments	(25)	(26)	(269)
Treasury stock - at cost, 2,705,042 shares in 2010 and 2,674,288 shares in 2009	(2,019)	(1,986)	(21,710)
<b>Total</b>	<b>80,206</b>	<b>76,193</b>	<b>862,430</b>
<b>Minority interests</b>	<b>164</b>	<b>151</b>	<b>1,763</b>
<b>Total equity</b>	<b>80,370</b>	<b>76,344</b>	<b>864,193</b>
<b>TOTAL</b>	<b>¥103,576</b>	<b>¥98,286</b>	<b>\$1,113,720</b>



# Consolidated Statements of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Years Ended March 31, 2010 and 2009

	Thousands		Millions of Yen								
	Outstanding Number of Shares of Common Stock	Common Stock	Capital Surplus	Retained Earnings	Unrealized Gain on Available-for-sale Securities	Deferred Gain on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Treasury Stock	Total	Minority Interests	Total Equity
BALANCE, APRIL 1, 2008	67,645	¥5,174	¥4,441	¥62,271	¥ 6,822		¥(4)	¥(1,900)	¥76,804	¥147	¥76,951
Net income				4,500					4,500		4,500
Cash dividends, ¥18.00 per share				(1,217)					(1,217)		(1,217)
Purchase of treasury stock	(76)							(92)	(92)		(92)
Disposal of treasury stock	8		3					6	9		9
Net change during the year					(3,790)	¥1	(22)		(3,811)	4	(3,807)
BALANCE, MARCH 31, 2009	67,577	5,174	4,444	65,554	3,032	1	(26)	(1,986)	76,193	151	76,344
Net income				<b>4,096</b>					<b>4,096</b>		<b>4,096</b>
Cash dividends, ¥19.00 per share				<b>(1,216)</b>					<b>(1,216)</b>		<b>(1,216)</b>
Purchase of treasury stock	<b>(31)</b>							<b>(33)</b>	<b>(33)</b>		<b>(33)</b>
Disposal of treasury stock											
Net change during the year					<b>1,163</b>	<b>2</b>	<b>1</b>		<b>1,166</b>	<b>13</b>	<b>1,179</b>
<b>BALANCE, MARCH 31, 2010</b>	<b>67,546</b>	<b>¥5,174</b>	<b>¥4,444</b>	<b>¥68,434</b>	<b>¥4,195</b>	<b>¥3</b>	<b>¥(25)</b>	<b>¥(2,019)</b>	<b>¥80,206</b>	<b>¥164</b>	<b>¥80,370</b>

	Thousands of U.S. Dollars (Note 1)										
	Common Stock	Capital Surplus	Retained Earnings	Unrealized Gain on Available-for-sale Securities	Deferred Gain on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Treasury Stock	Total	Minority Interests	Total Equity	
BALANCE, MARCH 31, 2009	\$55,634	\$47,785	\$704,882	\$ 32,602	\$11	\$(280)	\$(21,355)	\$819,279	\$1,624	\$820,903	
Net income			<b>44,043</b>					<b>44,043</b>		<b>44,043</b>	
Cash dividends, \$0.20 per share			<b>(13,075)</b>					<b>(13,075)</b>		<b>(13,075)</b>	
Purchase of treasury stock							<b>(355)</b>	<b>(355)</b>		<b>(355)</b>	
Disposal of treasury stock											
Net change during the year				<b>12,506</b>	<b>21</b>	<b>11</b>		<b>12,538</b>	<b>139</b>	<b>12,677</b>	
<b>BALANCE, MARCH 31, 2010</b>	<b>\$55,634</b>	<b>\$47,785</b>	<b>\$735,850</b>	<b>\$45,108</b>	<b>\$32</b>	<b>\$(269)</b>	<b>\$(21,710)</b>	<b>\$862,430</b>	<b>\$1,763</b>	<b>\$864,193</b>	

See notes to consolidated financial statements.

# Consolidated Statements of Cash Flows

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries  
Years Ended March 31, 2010 and 2009

	Millions of Yen		Thousands of U.S. Dollars (Note 1)
	2010	2009	2010
<b>OPERATING ACTIVITIES:</b>			
Income before income taxes and minority interests	¥ 6,993	¥ 7,686	\$ 75,194
Adjustments for:			
Income taxes - paid	(3,241)	(2,918)	(34,849)
Depreciation and amortization	3,078	2,875	33,097
Changes in assets and liabilities:			
Decrease (increase) in notes and accounts receivables	3,006	(684)	32,322
Increase in inventories	(34)	(235)	(366)
(Increase) decrease in other current assets	(1,150)	104	(12,365)
Increase (decrease) in notes and accounts payables	259	(628)	2,785
Increase in other current liabilities	492	94	5,290
Increase (decrease) in liability for retirement benefits	221	(527)	2,376
Other - net	(399)	603	(4,291)
<b>Total adjustments</b>	<b>2,232</b>	<b>(1,316)</b>	<b>23,999</b>
<b>Net cash provided by operating activities</b>	<b>9,225</b>	<b>6,370</b>	<b>99,193</b>
<b>INVESTING ACTIVITIES:</b>			
Proceeds from redemption of marketable securities	1,084	600	11,656
Capital expenditures	(1,091)	(2,025)	(11,731)
Purchases of investment securities	(105)	(38)	(1,129)
Proceeds from redemption and sales of investment securities	211	48	2,269
Purchases of software	(455)	(128)	(4,892)
Acquisition of license rights	(3,245)	(2,207)	(34,893)
Other - net	(47)	184	(506)
<b>Net cash used in investing activities</b>	<b>(3,648)</b>	<b>(3,566)</b>	<b>(39,226)</b>
<b>FINANCING ACTIVITIES:</b>			
Repayments of long-term debt		(1,170)	
Cash dividends paid	(1,215)	(1,218)	(13,064)
Increase of treasury stock	(33)	(82)	(355)
Other - net	(70)	170	(753)
<b>Net cash used in financing activities</b>	<b>(1,318)</b>	<b>(2,300)</b>	<b>(14,172)</b>
<b>FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS</b>	<b>(257)</b>	<b>(212)</b>	<b>(2,763)</b>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>4,002</b>	<b>292</b>	<b>43,032</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	<b>15,446</b>	<b>15,154</b>	<b>166,086</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>¥19,448</b>	<b>¥15,446</b>	<b>\$209,118</b>

See notes to consolidated financial statements.

# Notes to Consolidated Financial Statements

## 1. BASIS OF PRESENTING THE 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 conformity with accounting principles generally accepted in Japan ("Japanese GAAP"), 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 which is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2009 financial statements to conform to the classifications used in 2010.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Nippon Shinyaku Co., Ltd. (the "Company") is incorporated and operates. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥93 to \$1, the approximate rate of exchange at March 31, 2010. 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, 2010 include the accounts of the Company and its significant two (three in 2009) domestic and one overseas subsidiaries (together, the "Companies"). Consolidation of the remaining subsidiary would not have a material effect on the accompanying consolidated financial statements.

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

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

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

In 2010, Laplus Pharma Co., Ltd., (consolidated subsidiary) was liquidated and excluded from the scope of consolidation for the year ended March 31, 2010.

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

**c. Marketable and Investment Securities** — Marketable and investment securities are classified and accounted for, depending on management's intent, as follows: i) held-to-maturity debt securities, which management has the positive intent and ability to hold to maturity, are reported at amortized cost; and ii) available-for-sale securities, which are not classified as held-to-maturity securities and are reported at fair value, with unrealized gains and losses, net of applicable taxes, 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. Non-marketable 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 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 15 to 50 years for buildings and structures, from eight to ten years for machinery and equipment, 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 would be recognized if the carrying amount of an asset or asset group exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss would be measured as the amount by which the carrying amount of the asset exceeds its recoverable amount, which is the higher of the discounted cash flows from the continued use and eventual disposition of the asset or the net selling price at disposition.

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

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

- h. Allowance for Doubtful Accounts** — The allowance for doubtful accounts is stated at an amount considered to be appropriate based on the Companies' past credit loss experience and an evaluation of potential losses in receivables outstanding.
- i. Leases** — In March 2007, the Accounting Standards Board of Japan (the "ASBJ") issued ASBJ Statement No. 13, "Accounting Standard for Lease Transactions", which revised the previous accounting standard for lease transactions issued in June 1993. The revised accounting standard for lease transactions is effective for fiscal years beginning on or after April 1, 2008 with early adoption permitted for fiscal years beginning on or after April 1, 2007.

Under the previous accounting standard, finance leases that were deemed to transfer ownership of the leased property to the lessee were to be 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 should be capitalized to recognize lease assets and lease obligations in the balance sheet. In addition, the accounting standard permits leases which existed at the transition date and do not transfer ownership of the leased property to the lessee to be accounted for as operating lease transactions.

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

- j. Bonuses to Directors and Corporate Auditors** — Bonuses to directors and corporate auditors are accrued at the year end to which such bonuses are attributable.
- k. Income Taxes** — The provision for income taxes is computed based on the pretax income included in the consolidated statements of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted tax laws to the temporary differences.

- l. Foreign Currency Transactions** — All short-term 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 statements of income to the extent that they are not hedged by forward exchange contracts.

**m. Foreign Currency Financial Statements** — The balance sheet accounts and revenue and expense accounts of the consolidated overseas 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" as a separate component of equity.

**n. 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 income statement and b) for derivatives used for hedging purposes, if 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.

**o. Per Share Information** — Basic net income per share 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 years including dividends to be paid after the end of the year.

**p. New Accounting Pronouncements**

**Asset Retirement Obligations** — In March 2008, the ASBJ published a new 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 increase or a decrease in the carrying amount of the liability and the capitalized amount of the related asset retirement cost. This standard is effective for fiscal years beginning on or after April 1, 2010 with early adoption permitted for fiscal years beginning on or before March 31, 2010.

**Accounting Changes and Error Corrections** — In December 2009, 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 with revision to current accounting standards, the new policy is applied retrospectively unless the revised accounting standards include specific transitional provisions.

When the revised accounting standards include specific transitional provisions, an entity shall comply with the specific transitional provisions.

(2) Changes in Presentation

When the presentation of financial statements is changed, prior period financial statements are reclassified in accordance with the new presentation.

(3) Changes in Accounting Estimates

A change in an accounting estimate is accounted for in the period of the change if the change affects that period only, and is accounted for prospectively if the change affects both the period of the change and future periods.

(4) Corrections of Prior Period Errors

When an error in prior period financial statements is discovered, those statements are restated.

This accounting standard and the guidance are applicable to accounting changes and corrections of prior period errors which are made from the beginning of the fiscal year that begins on or after April 1, 2011.

**Segment Information Disclosures** — In March 2008, the ASBJ revised ASBJ Statement No. 17 "Accounting Standard for Segment Information Disclosures" and issued ASBJ Guidance No. 20 "Guidance on Accounting Standard for Segment Information Disclosures". Under the standard and guidance, an entity is required to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. Operating segments are components of an entity about which separate financial information is available and such information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. Generally, segment information is required to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments. This accounting standard and the guidance are applicable to segment information disclosures for the fiscal years beginning on or after April 1, 2010.

### 3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2010 and 2009 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
<b>Current:</b>			
Government and corporate bonds	¥ 500	¥ 900	\$ 5,376
Trust fund investments	96	100	1,033
<b>Total</b>	<b>¥ 596</b>	<b>¥ 1,000</b>	<b>\$ 6,409</b>
<b>Non-current:</b>			
Equity securities	¥12,563	¥10,837	\$135,086
Government and corporate bonds	100	499	1,075
Trust fund investments	102	196	1,097
<b>Total</b>	<b>¥12,765</b>	<b>¥11,532</b>	<b>\$137,258</b>

The costs and aggregate fair values of marketable and investment securities at March 31, 2010 and 2009 were as follows:

March 31, 2010	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Securities classified as:</b>				
<b>Available-for-sale:</b>				
Equity securities	¥5,592	¥6,637		¥12,229
Government and corporate bonds	100			100
Trust fund investments	200		¥ 2	198
Held-to-maturity	500	3		503

March 31, 2009	Millions of Yen			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	¥5,560	¥4,911		¥10,471
Government and corporate bonds	100			100
Trust fund investments	300		¥ 5	295
Held-to-maturity	1,300		24	1,276

March 31, 2010	Thousands of U.S. Dollars			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	\$60,129	\$71,366		\$131,495
Government and corporate bonds	1,075			1,075
Trust fund investments	2,151		\$ 22	2,129
Held-to-maturity	5,376	32		5,408

Available-for-sale securities whose fair value is not readily determinable as of March 31, 2009 were as follows. The similar information for 2010 is disclosed in Note 10.

March 31, 2009	Carrying Amount	
	Millions of Yen	
Available-for-sale -		
Equity securities	¥366	

Proceeds from sales of available-for-sale securities for the years ended March 31, 2010 and 2009 were ¥211 million (\$2,269 thousand) and ¥48 million, respectively. Gross realized gains on these sales, computed on the moving average cost basis, were ¥208 million (\$2,237 thousand) and ¥27 million for the years ended March 31, 2010 and 2009, respectively. Gross realized losses on these sales, computed on the moving average cost basis, were immaterial for the year ended March 31, 2009.

#### 4. INVENTORIES

Inventories at March 31, 2010 and 2009 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
Finished products and merchandise	¥ 6,263	¥ 6,051	\$ 67,344
Work in process	1,037	1,171	11,151
Raw materials	3,566	3,610	38,344
Total	¥10,866	¥10,832	\$116,839

#### 5. RETIREMENT BENEFITS

The liability for employees' retirement benefits at March 31, 2010 and 2009 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
Projected benefit obligation	¥ 26,922	¥ 26,100	\$ 289,484
Fair value of plan assets	(12,466)	(10,630)	(134,043)
Unrecognized actuarial loss	(5,844)	(7,034)	(62,839)
Unrecognized prior service cost	(382)	(427)	(4,108)
Net liability	¥ 8,230	¥ 8,009	\$ 88,494

The components of net periodic benefit costs for the years ended March 31, 2010 and 2009 are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
Service cost	¥ 875	¥ 880	\$ 9,408
Interest cost	518	510	5,570
Expected return on plan assets	(423)	(447)	(4,548)
Recognized actuarial loss	663	522	7,129
Amortization of prior service cost	45	45	484
Premiums for defined contribution pension plan and other	78	74	838
Net periodic benefit costs	¥1,756	¥1,584	\$18,881

Assumptions used for the years ended March 31, 2010 and 2009 are set forth as follows:

	2010	2009
Discount rate	2.0%	2.0%
Expected rate of return on plan assets	4.0%	4.0%
Recognition period of actuarial gain/loss	15 years	15 years
Amortization period of prior service cost	15 years	15 years

#### 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 such as: (1) having a Board of Directors, (2) having independent auditors, (3) having a Board of Corporate Auditors, 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 (non-cash assets) to shareholders subject to a certain limitation and additional requirements.

Semiannual interim dividends may also be paid once a year upon resolution by the Board of Directors if the articles of incorporation of the company so stipulate.

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

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

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

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

The Companies Act also provides for companies to purchase treasury stock and dispose of such treasury stock by resolution of the Board of Directors. The amount of treasury stock purchased can not 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 ¥8,441 million (\$90,763 thousand) and ¥7,853 million for the years ended March 31, 2010 and 2009, respectively.

## 8. LEASES

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

Total rental expenses for the years ended March 31, 2010 and 2009 were ¥1,119 million (\$12,032 thousand) and ¥1,070 million, respectively.

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

ASBJ Statement No. 13, "Accounting Standard for Lease Transactions" requires that all finance lease transactions should be capitalized to recognize lease assets and lease

obligations in the balance sheet. However, ASBJ Statement No. 13 permits leases, without ownership transfer of the leased property to the lessee and whose lease inception was before March 31, 2008, to be accounted for as operating lease transactions if certain "as if capitalized" information is disclosed in the notes to the financial statements. The Company applied the ASBJ Statement No. 13 effective April 1, 2008 and accounted for such leases as operating lease transactions. Pro forma information of leased property whose lease inception was before March 31, 2008 and that does not transfer ownership of the leased property to the lessee on an "as if capitalized" basis such as acquisition cost, accumulated depreciation, accumulated impairment loss, obligations under finance leases, depreciation expense, interest expense and other information of finance leases was as follows:

Machinery and equipment, and tools, furniture and fixtures:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
Acquisition cost	¥11	¥15	\$119
Accumulated depreciation	7	8	75
Net leased property	¥ 4	¥ 7	\$ 44

Obligations under finance leases:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
Due within one year	¥2	¥3	\$22
Due after one year	2	4	22
Total	¥4	¥7	\$44

Depreciation expense and other information under finance leases:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
Depreciation expense	¥3	¥3	\$32
Lease payments	¥3	¥3	\$32

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

## 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 rate of approximately 41% for the years ended March 31, 2010 and 2009. The overseas subsidiary is subject to the income tax of the country in which it operates.

The tax effects of significant temporary differences which resulted in deferred tax assets and liabilities at March 31, 2010 and 2009 are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2010	2009	2010
<b>Deferred Tax Assets:</b>			
Retirement benefits	<b>¥3,373</b>	¥3,283	<b>\$36,269</b>
Accrued expenses	<b>1,169</b>	1,206	<b>12,569</b>
Property, plant and equipment	<b>82</b>	87	<b>881</b>
Other	<b>1,336</b>	1,060	<b>14,366</b>
Less valuation allowance	<b>(810)</b>	(585)	<b>(8,710)</b>
<b>Deferred tax assets</b>	<b>5,150</b>	5,051	<b>55,375</b>
<b>Deferred Tax Liabilities:</b>			
Unrealized gain on available-for-sale securities	<b>2,439</b>	1,874	<b>26,226</b>
Deferred gains on sales of property	<b>1,385</b>	1,327	<b>14,892</b>
Other	<b>44</b>	68	<b>473</b>
<b>Deferred tax liabilities</b>	<b>3,868</b>	3,269	<b>41,591</b>
<b>Net deferred tax assets</b>	<b>¥1,282</b>	¥1,782	<b>\$13,784</b>

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, 2010 and 2009 is as follows:

	2010	2009
Normal effective statutory tax rate	<b>41.0%</b>	41.0%
Expenses not deductible for income tax purposes	<b>5.1</b>	4.4
Income not taxable for income tax purposes	<b>(0.6)</b>	(0.7)
Increase in valuation allowance	<b>3.2</b>	1.7
Tax credits for research and development costs	<b>(8.7)</b>	(5.4)
Other - net	<b>1.2</b>	0.4
<b>Actual effective tax rate</b>	<b>41.2%</b>	41.4%

## 10. FINANCIAL INSTRUMENTS AND RELATED DISCLOSURES

On March 10, 2008, the ASBJ revised ASBJ Statement No. 10 "Accounting Standard for Financial Instruments" and issued ASBJ Guidance No. 19 "Guidance on Accounting Standard for Financial Instruments and Related Disclosures". This accounting standard and the guidance are applicable to financial instruments and related disclosures at the end of the fiscal years ending on or after March 31, 2010 with early adoption permitted from the beginning of the fiscal years ending before March 31, 2010. The Companies applied the revised accounting standard and the new guidance effective March 31, 2010.

### (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 judgment by the purchase department. Such derivative transactions are entered into to hedge foreign currency exposures incorporated 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 & 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 its funding to high credit rating bonds in accordance with its 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 which 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 its 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 & 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

March 31, 2010	Millions of Yen		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	¥19,448	¥19,448	
Time deposits	80	80	
Notes and accounts receivables	24,817	24,817	
Marketable and investment securities	13,027	13,030	¥3
Total	¥57,372	¥57,375	¥3
Notes and accounts payables	¥8,211	¥8,211	
Income taxes payable	1,283	1,283	
Total	¥9,494	¥9,494	

March 31, 2010	Thousands of U.S. Dollars		
	Carrying Amount	Fair Value	Unrealized Gain/Loss
Cash and cash equivalents	\$209,118	\$209,118	
Time deposits	860	860	
Notes and accounts receivables	266,849	266,849	
Marketable and investment securities	140,075	140,107	\$32
Total	\$616,902	\$616,934	\$32
Notes and accounts payables	\$ 88,290	\$ 88,290	
Income taxes payable	13,796	13,796	
Total	\$102,086	\$102,086	

#### 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.

#### Marketable and investment securities

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

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

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

#### Derivatives

Information about the fair value of derivatives is omitted from disclosure because fair values and unrealized gains were immaterial for the year ended March 31, 2010.

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

March 31, 2010	Carrying Amount	
	Millions of Yen	Thousands of U.S. Dollars
Investments in equity instruments that do not have a quoted market price in an active market	¥334	\$3,592

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

March 31, 2010	Millions of Yen			
	Due in One Year or Less	Due after One Year through Five Years	Due after Five Years through Ten Years	Due after Ten Years
Cash and cash equivalents	¥19,448			
Time deposits	80			
Notes and accounts receivables	24,817			
Marketable and investment securities:				
Held-to-maturity:				
Government bonds	100			
Corporate bonds	300	¥100		
Available-for-sale with contractual maturities:				
Corporate bonds	100			
Other	100			
Total	¥44,945	¥100		

March 31, 2010	Thousands of U.S. Dollars			
	Due in One Year or Less	Due after One Year through Five Years	Due after Five Years through Ten Years	Due after Ten Years
Cash and cash equivalents	\$209,118			
Time deposits	860			
Notes and accounts receivables	266,849			
Marketable and investment securities:				
Held-to-maturity:				
Government bonds	1,075			
Corporate bonds	3,226	\$1,075		
Available-for-sale with contractual maturities:				
Corporate bonds	1,075			
Other	1,075			
Total	\$483,278	\$1,075		

## 11. NET INCOME PER SHARE

Net income per share ("EPS") for the years ended March 31, 2010 and 2009 was as follows:

	Millions of Yen	Thousands of Shares	Yen	U.S. Dollars
	Net Income	Weighted Average Shares	EPS	
For the year ended March 31, 2010 -				
Basic EPS				
Net income available to common shareholders	¥4,096	67,558	¥60.63	\$0.65
For the year ended March 31, 2009 -				
Basic EPS				
Net income available to common shareholders	¥4,500	67,605	¥66.56	

Diluted net income per share is not disclosed because there are no dilutive securities outstanding.

## 12. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 29, 2010, the Company's shareholders approved the following:  
Payment of a year-end cash dividend of ¥10 (\$0.11) per share to holders of record at March 31, 2010 for a total of ¥675 million (\$7,258 thousand).

## 13. SEGMENT INFORMATION

Information about industry segments of the Companies for the years ended March 31, 2010 and 2009 is as follows:

### Industry Segments

#### a. Sales and Operating Income

	Millions of Yen				Thousands of U.S. Dollars			
	2010				2010			
	Pharmaceuticals	Functional Food	Eliminations/Corporate	Consolidated	Pharmaceuticals	Functional Food	Eliminations/Corporate	Consolidated
Sales to customers	¥52,166	¥10,767		¥62,933	\$560,925	\$115,774		\$676,699
Intersegment sales			¥Nil				\$Nil	
Total sales	52,166	10,767		62,933	560,925	115,774		676,699
Operating expenses	45,472	10,999		56,471	488,946	118,269		607,215
Operating income (loss)	¥ 6,694	¥ (232)	¥Nil	¥ 6,462	\$ 71,979	\$ (2,495)	\$Nil	\$ 69,484

#### b. Assets, Depreciation and Capital Expenditures

	Millions of Yen				Thousands of U.S. Dollars			
	2010				2010			
	Pharmaceuticals	Functional Food	Eliminations/Corporate	Consolidated	Pharmaceuticals	Functional Food	Eliminations/Corporate	Consolidated
Assets	¥62,853	¥7,306	¥33,417	¥103,576	\$675,839	\$78,559	\$359,322	\$1,113,720
Depreciation	2,885	159	34	3,078	31,022	1,710	365	33,097
Capital expenditures	1,728	131		1,859	18,580	1,409		19,989

#### a. Sales and Operating Income

	Millions of Yen			
	2009			
	Pharmaceuticals	Functional Food	Eliminations/Corporate	Consolidated
Sales to customers	¥50,358	¥12,714		¥63,072
Intersegment sales			¥Nil	
Total sales	50,358	12,714		63,072
Operating expenses	43,559	11,966		55,525
Operating income	¥ 6,799	¥ 748	¥Nil	¥ 7,547

#### b. Assets, Depreciation and Capital Expenditures

	Millions of Yen			
	2009			
	Pharmaceuticals	Functional Food	Eliminations/Corporate	Consolidated
Assets	¥60,444	¥8,879	¥28,963	¥98,286
Depreciation	2,684	155	36	2,875
Capital expenditures	1,877	455		2,332

# Independent Auditors' Report

## Deloitte.

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### INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying consolidated balance sheets of Nippon Shinyaku Co., Ltd. (the "Company") and consolidated subsidiaries as of March 31, 2010 and 2009, and the related consolidated statements of income, changes in equity, and cash flows for the years then ended, all expressed in Japanese yen. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits 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 financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Nippon Shinyaku Co., Ltd. and consolidated subsidiaries as of March 31, 2010 and 2009, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in Japan.

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

*Deloitte Touche Tohmatsu LLC*  
June 29, 2010

Member of  
Deloitte Touche Tohmatsu

# Service Network

As of July 2010

## Head Office

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Kisshoin, Minami-ku,  
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## Other Domestic Business Offices

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Takamatsu, Okayama, Hiroshima,  
Fukuoka, Kumamoto, Kagoshima

## Research Laboratories

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## Domestic Subsidiaries

### Sioe Pharmaceutical Co., Ltd.

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### Tajima Shokuhin Kogyo Co., Ltd.

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Phone: +81-796-42-1095  
Facsimile: +81-796-42-3763

## Overseas Subsidiary

### NS Pharma, Inc.

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Phone: +1-201-986-3860  
Facsimile: +1-201-986-3865

## Overseas Office

### Düsseldorf Office

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Germany  
Phone: +49-211-350648  
Facsimile: +49-211-161429



# Corporate Data

As of March 2010

## Date of Incorporation

November 1911

## Founded

October 1919

## Paid-in Capital

¥5,174 million

## Issued and Outstanding Number of Shares

70,251,484

## Number of Shareholders

5,739

## Independent and Certified Public Accountants

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

## Transfer Agent

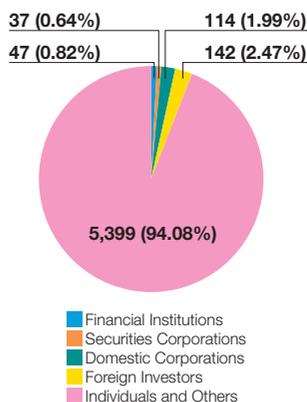
Mitsubishi UFJ Trust and Banking Corporation  
6-3, Fushimimachi 3-chome, Chuo-ku,  
Osaka 541-0044, Japan

## Major Shareholders

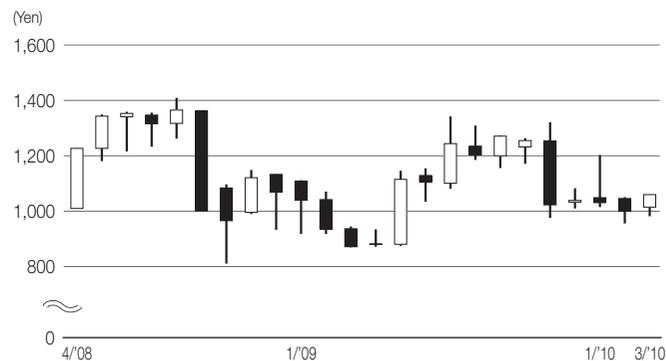
Meiji Yasuda Life Insurance Company  
Japan Trustee Services Bank, Ltd  
The Bank of Tokyo-Mitsubishi UFJ, Ltd.  
The Bank of Kyoto, Ltd.  
Nippon Life Insurance Company  
The Master Trust Bank of Japan, Ltd  
Tokio Marine & Nichido Fire Insurance Co.,Ltd.  
Mitsubishi Corporation  
Nippon Shinyaku Employees' Stockholding  
Mellon Bank N.A. as Agent for its Client Mellon Omnibus US Pension

# Investor Information

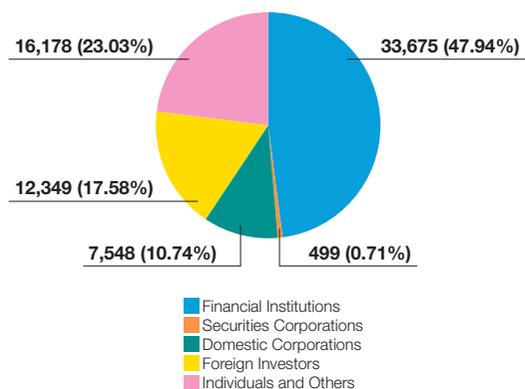
## Distribution of Shareholders



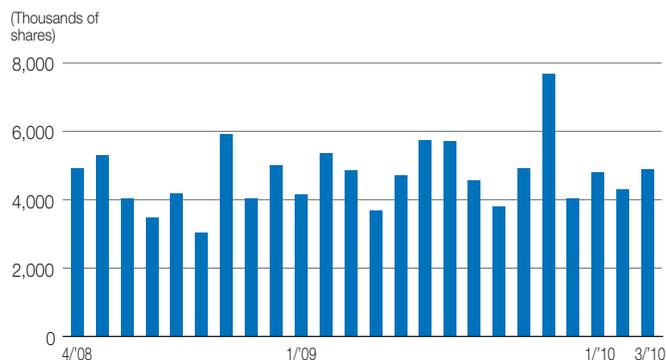
## Stock Price



## Distribution of Shares Issued (Thousands of shares)



## Trading Volumes



 **NIPPON SHINYAKU CO., LTD.**

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