

Year ended March 31, 2009



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.

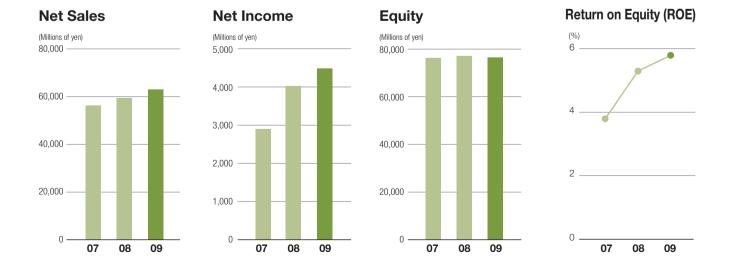
# Consolidated Financial Highlights

Nippon Shinyaku Co., Ltd. Years ended March 31

		Millions of Yen					
	2009	2008	2007	2009			
Net sales	¥ 63,072	¥ 59,450	¥ 56,321	\$ 643,592			
Operating income	7,547	6,461	4,851	77,010			
Net income	4,500	4,031	2,900	45,918			
Amounts per share (in yen and U.S. dollars):							
Basic net income	¥ 66.56	¥ 59.57	¥ 42.73	\$ 0.68			
Net assets per share (Note 1)	1,127.49	1,135.40	1,123.56	11.51			
Cash dividend	18	16	12	0.18			
Total assets	¥ 98,286	¥ 103,116	¥ 104,873	\$1,002,918			
Equity	76,193	76,804	76,070	777,480			
Capital investment	2,332	1,650	1,409	23,796			
R&D expenses	7,853	7,898	8,200	80,133			
Return on Equity (ROE) (%)	5.9	5.3	3.8	5.9			

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 = \frac{9}{9}8, the approximate exchange rate on March 31, 2009.





Shigenobu Maekawa President

# Message from the President

Society still has many diseases where little progress has been made in effective drug treatment despite the strong needs in the healthcare workplace. At Nippon Shinyaku, we view our mission as responding promptly and accurately to those needs and continuing to create medicine with special advantages that patients will consider good news. In our functional food business, we aim to manufacture high quality products that utilize the strong technological capabilities that we possess as a pharmaceutical company.

Pharmaceutical companies bear a great social responsibility as corporate citizens. As one that wishes for people's health, we seek to be a company that contributes to the prosperous and happy lives of people and one that has society's trust and is recognized as being a positive and significant company. As we move forward with our mission of "creating the health of the future," we would very much appreciate the continued support of our shareholders and other stakeholders.

> S. maekawa Shigenobu Maekawa

President



# Would you tell us about the business environment surrounding Nippon Shinyaku?

Japan's economy could not escape the impact of the global financial crisis that began in the United States and caused stagnation in global consumption and substantial declines in stock prices, not to mention a sharp appreciation of the Japanese yen. Along with the difficult conditions faced by the domestic economy, our business environment is severe as well.

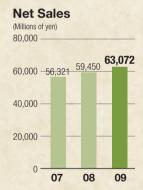
In pharmaceutical industry, multiple measures to reduce medical expenses occurred in tandem, including another round of reductions in drug prices covered by the NHI (national health insurance) plan in April 2008, the promotion of the use of generic drugs, and the introduction of Diagnosis Procedure Combination. The food product industry suffered one scandal after the other about contaminants in foods or misrepresentation of the regional origin of products that damaged the industry's reputation as a whole, while the price competition remains as severe as ever. Despite these circumstances, looking at the healthcare field from a long-term perspective, we still believe that it remains in an expansionary trend along with the progressive aging of society. Guided by our business philosophy of "contributing to people's health and prosperous lifestyles," we seek to be "a positive and significant company" in society that is recognized as being essential in the healthcare field.







# Would you give us an overall summary of performance in fiscal 2008?



Despite the difficult circumstances I have mentioned, our consolidated net sales rose 6.1% year on year, to ¥63,072 million while operating income increased by 16.8% to ¥7,547 million. Net income advanced 11.6% from a year earlier, to ¥4,500 million.

In our pharmaceutical business, we launched several new products during the fiscal year while carrying out steady marketing activities, primarily for our core products.

Under pressure from competitors, sales of such products as our non-steroidal analgesic and anti-inflammatory agent Hypen® and Bladderon®, a remedy for pollakisuria, suffered. Nevertheless, sales of such products as Eviprostat®, a remedy for benign prostatic hypertrophy for which the Comapny launched a new formulation with a double amount of the active ingredient in July 2008; Baynas®, a remedy for allergic rhinitis; Livostin® Eye Drops, a remedy for allergic conjunctivitis; and Azunol® Gargle 4%, a gargling solution containing Azulene, expanded. Sales of LUNABELL®, a treatment for dysmenorrhea resulting from endometriosis that was launched in July 2008, also contributed to sales growth. Furthermore, the licensing of NS-304, a pulmonary hypertension preparation, to Actelion Pharmaceuticals Ltd. of Switzerland (April 2008), and NST-141, an anti-itching remedy, to Taiho Pharmaceutical Co., Ltd. of Japan (October 2008), increased licensing fees and other industrial property revenues.

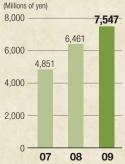
Consequently, sales of the pharmaceutical business totaled  $\pm 50,358$  million, rising 3.5% from the previous fiscal year.

In April 2009, we signed a license agreement with Eli Lilly Japan K.K. for Cialis® (generic name tadalafil) as an erectile dysfunction (ED) remedy. We also signed a license agreement with the same company for tadalafil's use in treating pulmonary arterial hypertension, which is currently under development (still waiting for approval as of July 2009) and in treating urinary disorder caused by benign prostatic hypertrophy (in Phase III clinical trials as of July 2009).

In our functional food business, we endeavored to achieve expansion based mainly on new businesses and a stable profit structure.

Although sales of health food ingredients struggled, sales of food preservatives grew firmly as did sales of protein preparations, our lineup of which has been strengthened. Sales of nutritional ingredients, which we began supplying to the market in February 2008, also contributed to sales growth. Overall, sales of the functional food business totaled ¥12,714 million, rising 17.8% from the previous fiscal year.

#### Operating Income





# Would you please explain your medium- to long-term management strategy?

Nippon Shinyaku's business philosophy is "contributing to people's health and prosperous lifestyles." We aim to be a company that is essential to society in the healthcare field and trusted and respected by it—in other words, a "significant company." Guided by that business philosophy, we have three management strategies that form our basic strategy for achieving that goal.

- Supplying high quality products with special advantages (Customers)
- Being trusted by society (Society)
- · Growing as individuals (Employees)

Based on these management strategies, in our pharmaceuticals business we consider the patients suffering from disease as our top priority and aim to create and supply ethical drugs that feature some special advantage over competitors in terms of efficacy, safety, or quality of life. Our targeted markets include the fields of urology and hematology, our areas of strength. To that end, our research and development (R&D) endeavors to enhance our product development pipeline based on our own proprietary drugs, licensing, and product lifecycle management. This enables us to launch a steady and continuous stream of new products on the market. Our primary goal in production is to earn the trust of society by stably providing high quality bulk substances and final products to the market. Along with that goal, we seek to achieve greater efficiency by pursuing low cost management and to strengthen our cost competitiveness. Our sales strategies entail achieving efficient and scientific product management through our information providing and marketing activities. In addition, we work to improve the productivity of each of our medical representatives (MRs) and achieve balanced growth based on existing and new products.

In our functional food business, we aim to manufacture high quality products that utilize the strong technological capabilities that we possess as a pharmaceutical company. We endeavor to develop products which meet customers' needs, run an effective and organized business by clarifying priority products and their sales expanding measures, and realize growth through business expansion and stable profit-earning structure.

By steadily pursuing those strategies, we plan to achieve a compound annual growth rate (CAGR) of 5% in net sales and 6% in operating income— both above industry averages. Our five-year performance targets (fiscal 2013) are net sales of ¥80.0 billion and operating income of ¥10.0 billion.



Eviprostat<sup>®</sup>



Gaslon N<sup>®</sup>

#### Medium- to Long-Term Management Plan (FY2009-FY2013)





# Would you tell us about your performance forecasts for the current fiscal year?

In the pharmaceutical business, we will clarify which products are really our core products and carry out scientific and efficient marketing activities as well as scientific information activities. Among our main products, we will target further sales growth for such products as Eviprostat®, a remedy for benign prostatic hypertrophy; Gaslon N®, a remedy for gastric ulcer and gastritis; and the Azulene-containing Azunol®Gargle 4%. We also expect LUNABELL®, a treatment for dysmenorrhea resulting from endometriosis that we launched in 2008, to further penetrate the market and increase its sales. In addition, from July 2009, we will begin exclusive sales of the ED remedy Cialis®, which we took over from Eli Lilly Japan K.K. The main medical treatment field for ED is urology, one of our specialty areas. Therefore, we are looking forward to Cialis® not only contributing to sales, but also providing a synergistic boost to our other product lines.

In the functional food business, we will strengthen our efforts to market priority products, expand our sales channels, and focus on developing new products. At the same time, we will work to convert our profit structure to a stable one that is not easily impacted by fluctuations in the prices of raw materials or exchange rates.

Based on those efforts in our pharmaceutical and functional food businesses, we expect consolidated net sales will be ¥64.7 billion. Among profits, operating income will amount to ¥7.7 billion, and net income will reach ¥4.7 billion in fiscal 2009.



# Q

# What is your perspective on dividend policy and other methods of returning profits to shareholders?



Beginning with a basic policy of maximizing enterprise value, Nippon Shinyaku focuses on maintaining and improving its strength. We build up our research and development capabilities and strengthen our product development pipeline while reinforcing our fundamentals by maintaining a sufficient level of retained earnings to enable us to withstand the intensifying competition in our markets.

To ensure an appropriate level of return to shareholders, our payout ratio target is about 30% on a consolidated basis, depending on our business performance. From a medium- to long-term perspective, we seek to increase our dividend per share through the improvement of our profit level. We also have a basic policy of making continuous and stable annual dividend payments of at least ¥10 per share. We may possibly exclude any extraordinary gains or losses.

Our basic policy is to make two dividend payments a year, at the end of the first half and at fiscal year end. In fiscal 2008, both these dividend payments were ¥9 per share, for a total annual dividend of ¥18 per share.

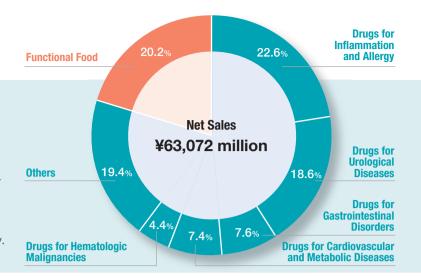
For fiscal 2009, we are planning to keep our interim dividend at ¥9 per share and increase our yearend dividend by ¥10 per share, for a total annual dividend of ¥19 per share.

#### At a Glance

#### **Pharmaceuticals**

#### ¥50,358 million (79.8%)

Our core products are drugs for urological diseases, inflammation and allergy, and hematologic malignancies. We also supply drugs for cardiovascular and metabolic diseases and for gastrointestinal disorders. Our drugs for urological diseases have an especially high reputation with urologists, particularly Eviprostat®, a remedy for benign prostatic hypertrophy.



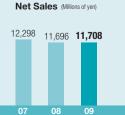
#### Drugs for Urological Diseases



#### **Main Products**

- Eviprostat®
   (herbal extracts)
   Remedy for Benign Prostatic Hypertrophy
- Bladderon®
  (flavoxate hydrochloride)
  Remedy for Pollakisuria
- Estracyt
  (estramustine sodium phosphate)
  Remedy for Prostate Cancer
- Urocalun® (quercus salicina extract) Remedy for Urinary Calculus

The number of patients with urological diseases is growing along with the aging of society. Over and above this trend, sales of the remedy for benign prostatic hypertrophy Eviprostat® have grown particularly strongly because we have made it easier to take by reducing the required number of tablets and doubling the amount of active ingredient in one tablet.



# Drugs for Inflammation and Allergy



#### **Main Products**

- Hypen®
   (etodolac)
   Non-Steroidal Analgesic and
   Anti-inflammatory Agent
- Livostin<sup>®</sup> Eye Drops (levocabastine hydrochloride)
   Remedy for Allergic Conjunctivitis
- Livostin® Nasal Spray (levocabastine hydrochloride)
   Remedy for Allergic Rhinitis
- Azunol<sup>®</sup> Gargle 4%
   A Gargling Solution Containing Azulene
- Baynas<sup>®</sup>
   Remedy for Allergic Rhinitis

With one in four persons in Japan said to suffer from hay fever, Baynas®, one of our remedies for allergic rhinitis, sells well because of several advantages. The drug demonstrates high effectiveness in clearing nasal congestion and does not make the user feel drowsv.

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#### Drugs for Hematologic Malignancies



#### **Main Products**

- 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<sup>®</sup>
  Remedy for Relapsed and Refractory
  Acute Promyelocytic Leukemia

In recent years we have seen a particularly large increase in cases of leukemia among elderly people. Against that backdrop, sales of our drugs for hematologic malignancies have steadily grown centered on our core product Cylocide N.



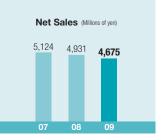
# Drugs for Cardiovascular and Metabolic Diseases

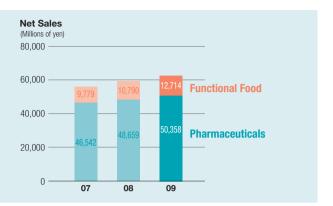


#### **Main Products**

- Selectol (celiprolol hydrochloride) Remedy for Hypertension and Angina Pectoris
- Glycoran (metformin hydrochloride) Remedy for Diabetes
- Odric®
  (ACE inhibitor)
  Remedy for Anti-hypertension

The westernization of Japanese eating habits has produced such an increase in patients with metabolic syndrome that it has become a social issue. Reflecting this trend, sales of Glycoran (metformin hydrochloride), our oral remedy for diabetes, have steadily risen.





# Drugs for Gastrointestinal Disorders



#### **Main Products**

- Gasion N® (irsogladine maleate) Remedy for Gastric Ulcer and Gastritis
- Portolac®
  (lactitol hydrate)
  Remedy for Hyperammonaemia

Although the protection factor potentiator market for gastric ulcers has contracted slightly, sales of mucosal protective Gaslon N®, our remedy for gastric ulcers and gastritis, have continued to grow following the addition in 2007 of a new easy-to-take orally disintegrating tablet.



#### Others Including the Proceeds from



#### **Main Products**

- Cephadol® (difenidol hydrochloride) Remedy for Vertigo
- LUNABELL®
   Remedy for Dysmenorrhea
   Resulting from Endometriosis
- Prulifloxacin Synthetic Antibacterial Agent

In response to the demand among patients suffering from dysmenorrhea resulting from endometriosis, we launched a remedy, LUNABELL®, which quickly began contributing to overall sales growth.



#### **Functional Food**

#### ¥12,714 million (20.2%)

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.









#### **Main Products**

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

With the food processing and health food industries facing difficult conditions, sales of health food ingredients struggled. However, sales of preservatives were firm. In addition, sales of an enhanced lineup of protein preparations and of the newly added nutritional ingredients contributed to sales.



Review of Operations

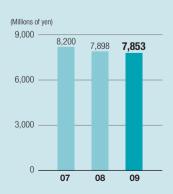
# Research and Development



**Junichi Yano, Ph. D.**Director: General Manager, Research & Development Division

As a medium-sized pharmaceutical company, Nippon Shinyaku focuses its product development on meeting unmet needs. Looking at rare and difficult diseases where there is still no definitive treatment, we aim to create pharmaceuticals that will contribute to better lives and a happier society.

#### **Consolidated R&D Expenses**



# Consolidated R&D Expenses Ratio to Net Sales



#### **Basic R&D Policy**

At Nippon Shinyaku, we focus on the fields which major pharmaceutical companies may not pursue, operating under the concept of supplying the market with ethical drugs that features some special advantage over competitors in terms of efficacy, safety, or quality of life.

To unify our R&D in the 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 product lifecycle management (PLCM), we aim to bring products to the market that patients will consider good news as quickly as possible.

Our drug discovery research concentrates on our priority diagnostic and treatment fields centering on urology and hematology. By elucidating the causes of new diseases, we can focus on the speedy development of a proprietary drug that offers special advantages. 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 market. To achieve this goal, we clarify our R&D targets, allocating our business resources appropriately to drug discovery, licensing-in, and PLCM.

#### **R&D Organization**

Our pharmaceuticals R&D organization carries out its operations through four divisions—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; 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

#### **R&D Concepts**







genomic drug discovery and nucleic acid drugs. Clinical Development Division is in charge of clinical trials to assess efficacy and safety in humans.

#### **New Technologies**

In the 21st century, pharmaceutical companies' drug discovery is about to change. Nippon Shinyaku is now actively conducting advanced research mainly related to genomic drug discovery and nucleic acid drugs at our Drug Discovery Laboratories in Tsukuba, Ibaraki Prefecture. Especially by elucidating the relationship between new function of RNA and diseases, we aim to develop medicines based on new therapeutics principle.

#### New pharmaceutical 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 RNA, which is closely involved with occurrence 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 pharmaceutics seeds in this field. In related activities, we are participating in the ongoing research of the Functional RNA Project run by Japan's Ministry of Economy, Trade and Industry (METI) and the New Energy and Industrial Technology Development Organization (NEDO).

#### Nucleic acid pharmaceuticals R&D

The world has great expectations for nucleic acid pharmaceuticals as the next generation pharmaceuticals after antibody drugs. Focusing our efforts particularly on RNA delivery system, we have developed RNA drug therapy that can be safely administered to humans. Furthermore, we have successfully developed a new RNA synthesis method, although RNA synthesis had previously been considered too difficult. Using these proprietary technologies as a base, we were the first in the world to demonstrate the cancer controlling effect of small interfering RNA (siRNA) using test compounds in a cancer model. We are now working on creating RNA drugs useful in treating patients with diseases previously considered difficult to treat.

#### **Our Globally Expanding R&D Network**

In addition to using its own internal R&D resources, Nippon Shinyaku utilizes external resources and actively collaborates with domestic and international research institutions. Concentrating primarily on our







# **Research and Development**

priority disease areas, we work with medical research institutions, utilizing gene analysis methods such as microarrays, to elucidate the mechanisms of action of pharmaceuticals and discover target genes.

Through joint operation with 20 pharmaceutical companies, we have constructed a specialized beamline in the Harima synchrotron radiation facility, SPring-8, and are applying protein structure analysis to development of molecular targeted drug therapy for hematological malignancies and other diseases. We also participate in the Functional RNA Project run by NEDO and are developing next-generation nucleic acid drugs through partnerships in industry and academia.

To help people around the world suffering from diseases for which we have created new drugs, we proactively license out our products to companies overseas. We license-out our synthetic antibacterial drug (NM441) to Angelini ACRAF S.p.A. of Italy; Yuhan Corporation of the Republic of Korea; Optimer Pharmaceuticals, Inc. of the United States; and Lee's Pharmaceutical Holdings Limited (Lee's Pharma) of Hong Kong. Similarly, we have licensed-out NS-187, our remedy for chronic myelogenous leukemia to CytRx Corporation of the United States, and our cardiovascular pulmonary hypertension preparation NS-304 to Actelion Pharmaceuticals Ltd. of Switzerland. On the flip side, we also actively license-in marketed products and development-stage products of special interest to us, such as the non-narcotic analgesic NS-315 from Grünenthal GmbH of Germany, the alcohol dependency treatment agent NS-11 from Merck Serono of Switzerland, and the myelodysplastic syndrome (MDS) treatment agent NS-17 from Celgene Corporation of the United States, for development in Japan.

Our Düsseldorf Office is active in many areas as the European base of Nippon Shinyaku's globalization drive. The office establishes support networks for the European clinical trials of the newly discovered pharmaceutical candidates. It also introduces those pharmaceutical candidates to companies in the different countries of Europe, searching for



Düsseldorf Office

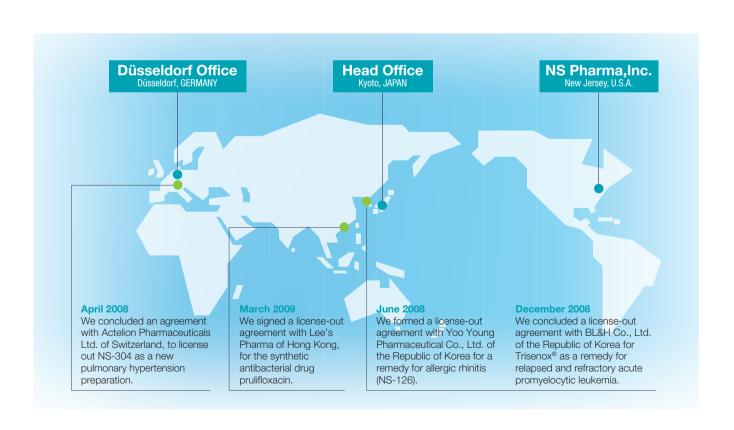
the optimum licensing-out partner. In addition, the office carries on information gathering activities to enable Nippon Shinyaku to license-in promising pharmaceuticals developed by these European companies for supply to the Japanese market.

We established NS Pharma, Inc. to gather R&D intelligence from pharmaceutical companies, venture companies, and research institutions in the United States and to support the rapid development of pharmaceutical candidates discovered by Nippon Shinyaku. The subsidiary is currently based in Paramus, New Jersey. Against the backdrop of an increasingly-difficult environment for discovering



Overseas Subsidiary NS Pharma, Inc.

and developing new drugs, NS Pharma is carrying out surveys of new pharmaceutical candidates in the United States and working in collaboration with our North American partners.



#### **Product Development**

#### • NS-126 (dexamethasone cipecilate)

We filed an application for approval of this once-a-day dosage steroid inhaler for the treatment of allergic rhinitis in December 2006. In June 2008, we licensed out NS-126 to Yoo Young of the Republic of Korea. Phase IIa clinical trial for bronchial asthma has been completed.

#### • 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 made 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 trial for chronic non-cancer pain is in preparation.

#### • LY450190 (tadalafil)

In April 2009, we signed a license agreement with Eli Lilly Japan K.K. for its erectile dysfunction (ED) drug, Cialis® (generic name tadalafil). We also signed license agreements for indications of tadalafil that are still under development. Eli Lilly Japan made an application for approval of tadalafil in Japan for pulmonary arterial hypertension in August 2008. Eli Lilly Japan is currently conducting Phase III clinical trials in Japan for urinary disorder caused by benign prostatic hypertrophy.

#### NS-11 (acamprosate)

We licensed in NS-11 from Merck Serono 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 trial started in Japan in March 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. Currently it is in Phase II clinical trial in Japan. In November 2008, NS-17 was designated an orphan drug.

#### • NS-304

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 an orphan drug by the European Medicines Agency (EMEA), with Phase II clinical trials underway in Europe. In Japan, we have completed Phase I clinical trials and are preparing to enter Phase II. 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, where it will collaborate with us.

#### • NS-187

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. Phase II study is in preparation.

#### 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. of Japan, to collaborate on development and marketing. The agent entered Phase I clinical trials in May 2009.

#### **Domestic**

Code No.	Generic name Therapeutic field		Indications	Development	Stage		
NS-126	dexamethasone	allergic rhinitis licensed-in from inflammation/allergy Hisamitsu Phamaceutical		Phase I	Phase II	Phase III Application	
110-120	cipecilate	irilia rirriation/allergy	bronchial asthma	(SSP)	Phase I	Phase II	
NS-315	tramadol	inflammation/allergy	cancer pain (non-narcotic analgesic)	licensed-in from	Phase I	Phase II	Phase III Application
	hydrochloride	irilia firriation/aliergy	Non-cancer related pain (non-narcotic analgesic)	Grünenthal GmbH	Phase I	Phase II (F	Preparation)
LY450190	cardiovascular O tadalafil —		pulmonary arterial hypertension	licensed-in from	Phase I	Phase II	Phase III Application
21400100	tadalalii	urology	urinary disorder caused by BPH	Eli Lilly Japan	Phase I	Phase II	Phase III
NS-11	acamprosate	others	alcohol dependence	licensed-in from Merck Serono	Phase I	Phase II	Phase III
NS-17	azacitidine	hematologic malignancies	myelodysplastic syndrome	licensed-in from Celgene Corporation	Phase I	Phase II	
NS-304		cardiovascular	pulmonary hypertension	co-development with Actelion Japan	Phase I	Phase II (F	Preparation)
NST-141		inflammation/allergy	pruritus associated with atopic dermatitis, etc.	co-development with Taiho Pharmaceutical	Phase I		

#### Overseas

Code No.	Generic name	Therapeutic field	Indications	Development	Stage				
				Yuhan Corporation	Phase I	Phase II	Phase III	Application	Launch preparation
NM441	prulifloxacin	infectious diseases	synthetic antibacterial	Optimer Pharmaceuticals	Phase I	Phase II	Phase III		
				Lee's Pharma	Phase I	Phase II	Phase III (F	Preparation)	
NS-304		cardiovascular	pulmonary hypertension	Actelion	Phase I	Phase II			
NS-187		hematologic malignancies	chronic myelogenous leukemia	CytRx Corporation	Phase I	Phase II (F	Preparation)		

# Manufacturing



Tsugio Tanaka, M.S. Pharmacy
Director: General Manager, Resource Procurement,
Production & Assurance Division

Safety and high quality are the top priorities of the pharmaceutical manufacturing operations. To comply with global standards, our operations carry out thorough quality control and environmental protection management.

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07

09

# Quality Control System Creates High-quality Products

As a manufacturer of pharmaceuticals that circulate within human bodies, the top priorities of the manufacturing lines are safety and high quality. Based on our Pharmaceuticals Quality Policy, we enforce manufacturing management and quality control standards determined on a scientific basis. We employ cutting-edge manufacturing environment, facilities, and management systems and devote our full energies to maintaining a system that meets current good manufacturing practice (cGMP) standards. We have installed validation-based control technologies and cutting-edge automation throughout our manufacturing systems, encompassing raw materials processing, manufacturing facilities, manufacturing environments, measurement instruments, and computer systems. Based on this integrated system, we endeavor to efficiently manufacture more reliable, high quality pharmaceuticals.

#### **Pharmaceuticals Quality Policy**

To contribute to human health and prosperous lives, we will comply with all pertinent laws and work to ensure that our products are high quality and reliable. We will provide our customers with stable supplies of products they will be satisfied with.

#### **Environmental Awareness**

Our Chitose Synthesis Plant, Chitose Functional Food Plant, and Odawara Central Factory have acquired ISO 14001 certification, the international environmental management system standard. We also continue to improve our systems, endeavoring to maintain environmental protection.

Following certification in 2002, the Chitose Synthesis and Functional Food plants underwent the second renewal inspections in October 2008 by an independent agency. Since the plants scored many environmentally positive points and few negative points in the inspections, it was evaluated that the spiral-up system was established and both plants were continuously recertified.

The Odawara Central Factory gained its ISO 14001 certification in 2004 and underwent a fourth annual periodic inspection in July 2008. In the inspection, the factory was given high marks not only for its environmental activities, but also new efforts, such as reducing the amount of packaging by using smaller PTP sheets and achieving a reduction in waste. As a result, the factory was continuously recertified.

09

07

08



#### **Odawara Central Factory**

As the mainstay formulation manufacturing plant of Nippon Shinyaku, the factory produces pharmaceuticals in many formulations, including tablets, granules, capsules, and injectable formulations. To contribute to people's health and prosperous lives, the factory employs high-performance manufacturing facilities and highly dependable systems that meet cGMP standards to provide a stable supply of high quality products.



#### Tajima Shokuhin Kogyo Co., Ltd.

A subsidiary of Nippon Shinyaku, Tajima Shokuhin Kogyo is the core production division of our in-house functional food company. As such, the plant manufactures protein preparations, preservatives, health food ingredients, wheat-based products, and other food-related ingredients. The subsidiary also manufactures herbal extracts for use in pharmaceutical manufacturing. Leveraging the high technology capabilities accumulated in our pharmaceutical operations, the subsidiary provides safe and reliable products.



#### **Chitose Synthesis and Functional Food plants**

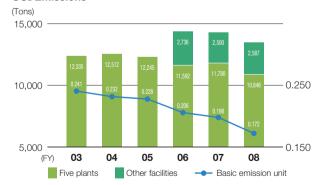
As a production base for bulk substances used as the active ingredients in pharmaceuticals, the synthesis plant manufactures core products of remedies for gastric ulcers/gastritis and for antirheumatic drugs as well as bulk substances for planned new drugs. In addition, the synthesis plant maintains international GMP standards, exporting bulk substances to other countries. The functional food plant is involved in production of extracts of fruits, vegetables and spices. The two plants utilize their excellent technology capabilities in developing operations.



#### Sioe Pharmaceutical Co., Ltd.

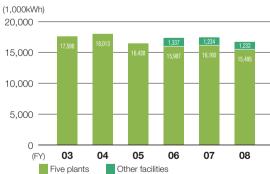
Also a subsidiary of Nippon Shinyaku, Sioe Pharmaceutical manufactures and sells ethical drugs and food product ingredients, especially pharmacopoeia-admitted drugs, such as antibacterial disinfectants and medical-use alcohol formulations. As part of its quality control, the subsidiary has established an integrated product information management system encompassing all its processes, from the delivery of raw materials to product shipment. The subsidiary utilizes the system to provide stable supplies of high quality and reliable pharmaceuticals to the market.

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

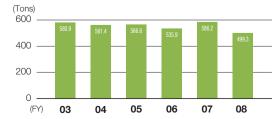


- \* The 5 plants are the head office facilities, Odawara Plant, Chitose Synthesis and Functional Food plants, Morioka Plant, and the Eastern Drug Discovery Laboratories.
- \* CO<sub>2</sub> emissions are calculated based on consumption of electricity, city gas (including LPG), crude oil (including kerosine), and gasoline and light oil.
- \* The basic emission unit: Total emissions (Tons)/Net sales (Millions of yen)
- \* The basic emission unit has been calcuated for the five plants.

#### **Electric Power Use**



#### **Waste Generated**



# Marketing



**Toshihiko Sago**Managing Director: General Manager, Marketing Division

Achieving efficient and scientific product management, we will improve the productivity of each of our medical representatives (MRs) and achieve balanced growth based on existing and new products.

#### **Marketing Strategies**

Although Japan's pharmaceuticals market faces a tough environment, Nippon Shinyaku's five-year medium-term management plan getting underway in the current fiscal year will see the Company enter a period of high growth never experienced before because of the many planned new products launches. Of course, this growth will depend on whether or not the group of new drugs will be able to develop sales to a level equal to the size of the latent markets. However, this does not mean we will be concentrating our resources only on new products. To enable the sales of new products to contribute to overall sales growth, the sales of high-margin existing products must not decline. Therefore, one of our main themes is achieving balance growth with contributions from both new products and high-margin existing products.

#### **Marketing Strategies for Fiscal 2009**

To begin with, in fiscal 2009 we will be working to achieve over a short period of time our targeted market shares and peak sales for new products launched that are expected to become major sources of income in the future. This category includes LUNABELL®, a treatment for dysmenorrhea resulting from endometriosis launched in July 2008; Cialis® (tadalafil), an ED remedy introduced in July 2009; and the allergic rhinitis remedy that we plan to launch in winter 2009.

Second, to prevent the 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 even though there is not much promise for growth. The first category includes Eviprostat®, our remedy for benign prostatic hypertrophy, and Gaslon N®, 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 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 "Royal customers" (excellent customers), aiming to achieve stable sales growth for existing products.

By steadily carrying out marketing activities based on these strategies, we will become a "significant company" in the eyes of society while posting growth. We will achieve this by improving the productivity of each MR and realizing growth based on a good balance between new and existing products.



Review of Operations

# Functional Food Company



**Hiroshi Adachi**Director: COO, Functional Food Company

Along with the progressive aging of society, the fields of "neutraceuticals" and "nutrition" are growing. Responding to the needs of the age by supplying the market with highly original products, we are endeavoring to achieve steady business expansion.

#### **Business Strategies**

Taking care to maintain the deep trust and expectations and the high reputation built over many years of business, we are aiming to expand and grow our business as well as improve profitability. Establishing strong R&D, manufacturing, quality assurance, and marketing systems, we will strengthen our organizational capabilities and focus on the following business fields.

As our first target, we will look at the processed food industries, including the meat-processing industries, seafood paste products, and bread and confectionery industries. Because of the progressive aging of society and lower birthrates in Japan, we will not be able to avoid the coming shifts in market trends from growth to saturation to contraction. However, since the scale of the market is large, we will still aim to achieve sales growth based on our protein preparations and preservatives.

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

Another promising field is nutrition. Although the market for liquid and other nutritional foods (clinical nutrition 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 our 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 and reduce hospitalization periods. 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 the fields we have mentioned, we will expand our business based on the premise of supplying high quality products. We also will endeavor to further improve our profitability. In addition to expanding our businesses in existing fields, we will work to build operations in new fields, such as the nutritional ingredients that the functional food company has begun to supply to the market. Finally, as an enterprise essential to our society, we will aim to win the trust of society and to be respected.

### Corporate Governance

#### **Basic Policies and Management System**

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

To provide corporate governance, the Company has selected the statutory auditor system, which relies on a system build 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 Corporation Law, the Company's internal control system is managed using a system determined in accordance with basic policies decided by the Board of Directors. The internal control 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 cornerstone systems of the company's management—internal control, compliance, and risk management.

#### Compliance

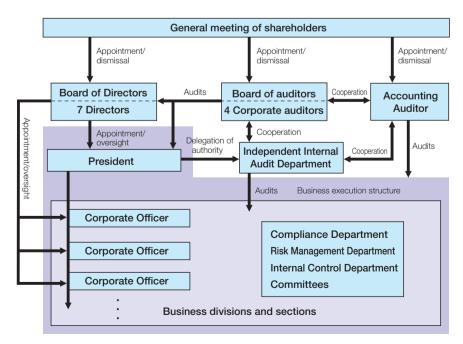
Nippon Shinyaku promotes compliance on an organizational basis. In addition to formulating a Group Charter Of Business Conduct, compliance is overseen by a Compliance Officer who is appointed

from among the directors of the Company. Moreover, compliance departments have been set up throughout the Company and carry out educational, training, and awareness activities. In fiscal 2008, 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 company spirit. Furthermore, to enable the Company to discover and deal with illegal behavior on an internal basis, compliance hotlines were 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 produced 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 2008, the Group's risk reduction activities focused on initial responses in the case of major disasters, achieving stable product supply systems, and measures to prevent failure of IT equipment.

#### **Corporate Governance Structure**



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



#### President

#### Shigenobu Maekawa

#### **Managing Director**

#### Toshihiko Sago

(General Manager, Marketing Division)

#### **Directors**

#### Junichi Yano, Ph. D.

(General Manager, Research & Development Division)

#### Yoshiro Yura

(General Manager, CSR & Human Resource Division)

#### **Corporate Auditors**

#### Youichi Toriyama

#### Hajime Nishikawa

#### **Corporate Officers**

#### Kazushige Itabashi

(General Manager, Business Development & Licensing Division)

#### **Toru Sakata**

(General Manager, Marketing Promotion Division)

#### Yoshinori Sato

(General Manager, Marketing Planning Division)

#### Hiroshi Adachi

(COO, Functional Food Company)

#### **Tsugio Tanaka**

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

#### Yojiro Ukai

#### Taro Sakurai

(General Manager, Finance & Accounting Dept.)

#### Akira Matsuura, Ph. D.

(General Manager, Discovery Research Laboratories)

#### Hirokata Harada

(General Manager, Planning Division)

#### Kazuo Fukushima

(General Manager, Corporate Planning Division)

#### Yasuo Tanabe

#### Takeshi Nomura

(General Manager, Osaka Business Office)

#### Kiyotaka Konno, Ph. D.

(General Manager, Clinical Development)

#### Yoshitaka Fukuda

(General Manager, Personnel Division)

### 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 essential to society through our environmentally conscious management of pharmaceuticals and functional food businesses 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 as the Company will meet the expectations of society, be trusted, and be considered a "significant company."

#### **Increasing the Value of Human Resources**

In the healthcare field, when the work a company does is considered essential to society, employees take pride in the purpose behind their jobs and find them rewarding. In addition, they have the satisfaction of growing through the pursuit of their work. We also recognize our employees as one group of stakeholders, and have introduced various systems to increase their work satisfaction. Taken together, we feel these factors introduce an upward spiral to increase the value of our human resources. In turn, this added value is reflected in a further increase in our corporate value.

#### **Environmental Initiatives**

Under the Board of Directors, Nippon Shinyaku has established an Environment Committee to deal with eight key environmental issues, including cutting carbon dioxide emissions and reducing waste generated. The Environment Committee sets goals for each issue and works systematically to achieve them. Specific measures include low-energy-consumption equipment, lowering the final disposal rate, and reducing the evaporation of halogen compounds.

#### **Social Contribution Initiatives**

Nippon Shinyaku proactively implements a variety of social contribution activities in response to requests from various groups made to its head office, plants, and offices. For example, the Company takes part in the Yellow Ribbon drive run by the Japan Endometriosis Association, supports the Orange Balloon Project promoted by the Japanese Society for Palliative Medicine, and sends lecturers to educate elementary students about the environment at the request of the Kyoto Chamber of Commerce and Industry. In commemoration of the 90th anniversary of the founding of Nippon Shinyaku in 2009, the Company held its first Nippon Shinyaku Children's Literary Awards contest, which was carried out broadly throughout Japan through medical institutions and public facilities.



At-school instruction program



Nippon Shinyaku Children's Literary Awards contests

#### Nippon Shinyaku Group Code of Conduct

- I. Following our business philosophy and principles, we are constantly aware of our corporate social responsibility and conduct ourselves with a high sense of ethics.
- II. As employees of a company that handles products affecting people's lives, we seek creatively to improve product quality and the quality of our work.
- III. We respect the rights and personalities of individuals, maintaining a safe and comfortable work environment.
- IV. We promote environmental activities, and make efforts to maintain and improve those activities.
- V. We communicate with stakeholders and build a relationship of trust through the timely and appropriate disclosure of corporate information and other activities.
- VI. We maintain sound and proper relationships with politicians, government officials, and customers and vendors, pursuing free competition in a fair and transparent manner.
- VII. We are fully aware of the value of company assets, including information assets, and handle them in a proper manner.
- VIII. We do not accept any improper or illegal requests from antisocial forces and organizations that threaten the social order or its security.
- IX. As members of society, we voluntarily participate in social contribution activities.
- X. When overseas, we observe international rules and local laws, carrying out our business activities with respect for local culture and customs.



# **Financial Section**

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# Six-Year Summary (Consolidated)

NIPPON SHINYAKU CO., LTD. and Consolidated Subsidiaries Years ended March 31

	Millions of Yen								
	2009	2008	2007	2006	2005	2004			
Net sales	¥63,072	¥ 59,450	¥ 56,321	¥ 53,947	¥54,252	¥ 51,326			
Income before income taxes and									
minority interests	7,686	6,879	5,290	3,285	9,630	3,262			
Net income	4,500	4,031	2,900	1,612	5,639	1,536			
Amounts per share (in yen):									
Basic net income	¥ 66.56	¥ 59.57	¥ 42.73	¥ 22.84	¥ 81.22	¥ 21.50			
Cash dividends applicable to the year	18.00	16.00	12.00	10.00	15.00	10.00			
Total assets	¥98,286	¥103,116	¥104,873	¥104,899	¥98,910	¥104,008			
Equity	76,193	76,804	76,070	75,412	70,010	65,396			
Capital investment	2,332	1,650	1,409	1,184	1,745	1,829			
R&D expenses	7,853	7,898	8,200	10,071	8,479	8,263			

### Management's Discussion and Analysis

#### I. Financial Strategy

Based on a policy of maximizing enterprise value, the Company builds up its research and development capabilities and strengthens its development pipeline, while reinforcing its fundamentals by maintaining a sufficient level of retained earnings to position it to withstand intensifying competition.

To ensure an appropriate level of return to shareholders, our payout ratio target is about 30% on a consolidated basis, depending on our business performance. We also have a basic policy of making continuous and stable annual dividend payments of at least ¥10 per share.

#### **II. Liquidity and Capital Resources**

Total assets declined ¥4,830 million from the previous fiscal year, to ¥98,286 million. The expansion in cash and cash equivalents, notes and accounts receivable, and other current assets was outweighed by a decline in investment securities.

Liabilities contracted  $\pm 4,223$  million year on year, to  $\pm 21,942$  million. The declines in current portion of long-term debt and deferred tax liabilities more than offset the increase in trade payables and other current liabilities.

Total equity at fiscal year end amounted to ¥76,344 million.

The equity ratio climbed 3.0 percentage points from a year earlier, to 77.5%.

Net cash provided by operating activities totaled ¥6,370 million. The main components of cash inflows were income before income taxes and depreciation and amortization expenses, while the major

outflows were income tax payments, decreases in notes and accounts payable, increases in notes and accounts receivable, and a decrease in the liability for retirement benefits.

Net cash used in investing activities totaled ¥3,566 million. The major factors in cash outflows were expenditures on long-term prepaid expenses and the acquisition of property, plant and equipment. The principal cash inflow was proceeds from the redemption of marketable securities.

Net cash used in financing activities totaled ¥2,300 million. The chief components were dividend payments and repayments of long-term debt.

As a result, cash and cash equivalents at the fiscal year end increased ¥292 million year-on-year, to ¥15,446 million.

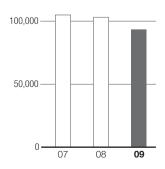
The Company will continue to prioritize a sound financial position, appropriate levels of liquidity and availability of necessary funding for business activities.

#### Consolidated Cash Flows (Millions of yen)

	2007	2008	2009
Net cash provided by operating activities	4,201	7,347	6,370
Net cash used in investing activities	(4,259)	(1,070)	(3,566)
Net cash used in financing activities	(2,448)	(2,150)	(2,300)
Cash and cash equivalents, end of year	11,313	15,154	15,446

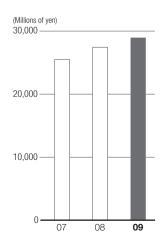
# Consolidated Total Assets

(Millions of yen) 150,000



#### Consolidated Equity Ratio

# Consolidated Cost of Sales



#### III. Results of Operations (consolidated)

The pharmaceutical industry faced severe business conditions in the fiscal year under review. In April 2008, the Japanese government implemented an average reduction of 5.2% in the standard prices of pharmaceuticals under the NHI (national health insurance) plan. In addition, there was another change of prescription format for the promotion of greater use of generic drugs. Although the hikes in raw material price began to slow at the start of the second half in the functional food product industry, price competition continued to intensify. As a result, the business environment for the processed food and health food industries remained difficult.

Despite these difficult circumstances, the Nippon Shinyaku Group continued to pursue firm marketing activities during the fiscal year under review. As a result, consolidated net sales rose 6.1% year on year, to ¥63,072 million while operating income increased by 16.8% to ¥7,547 million. Net income grew 11.6% from a year earlier, to ¥4.500 million.

Earnings by segment were as follows.

#### Pharmaceutical business

In the pharmaceuticals business, sales of such products as our non-steroidal analgesic and anti-inflammatory agent Hypen® and Bladderon®, a remedy for pollakisuria, suffered from competition from other products and other factors. In contrast, sales increased for Eviprostat®, a remedy for benign prostatic hypertrophy for which the Company launched a new formulation with a double amount of the active ingredient in July 2008. Other products that posted sales

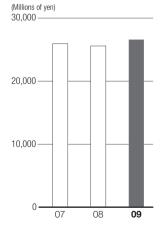
growth included Baynas®, a remedy for allergic rhinitis, and Azunol® Gargle 4%, a gargling solution containing Azulene. LUNABELL®, a treatment for dysmenorrhea resulting from endometriosis that was launched in July 2008, also contributed to sales. In addition, the Company earned industrial property revenues from out-licenses. Overall, sales of the pharmaceuticals business totaled ¥50,358 million, advancing 3.5% year on year.

#### **Functional Food business**

In the functional food business, despite lagging sales of health food ingredients, sales of food preservatives grew firmly as did sales of protein preparations, our lineup of which has been strengthened. Our newly added line of nutrition ingredients also contributed to sales. Overall, sales of the functional food business totaled ¥12,714 million, rising 17.8% year on year.

The functional food business took steps in its production operations during the fiscal year under review to further develop the business. Aiming to reduce manufacturing costs and increase competitiveness through the concentration of production bases, the business added a food additive formulation production plant at consolidated subsidiary Tajima Shokuhin Kogyo Co., Ltd. in August 2008.

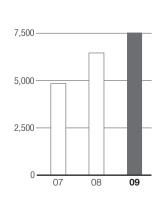
#### Consolidated Selling, General and Administrative Expenses



# Consolidated Operating Income

(Millions of yen)

10,000

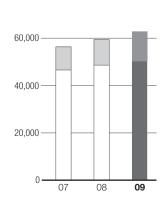


# Consolidated Sales by Industry Segment

(Millions of yen)

80,000

Pharmaceuticals



## Consolidated Balance Sheets

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries March 31, 2009 and 2008

	Millions	Millions of Yen	
	2009	2008	U.S. Dollars (Note 1
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	¥ 15,446	¥ 15,154	\$ 157,612
Time deposits	40	80	408
Marketable securities (Note 3)	1,000	600	10,204
Notes and accounts receivable:	,		·
Trade notes	300	253	3,061
Trade accounts	27,332	26,783	278,898
Other	317	229	3,235
Total notes and accounts receivable	27,949	27,265	285,194
Inventories (Note 4)	10,832	10,596	110,531
Deferred tax assets (Note 10)	1,617	1,743	16,500
Other current assets	710	843	7,245
Allowance for doubtful accounts	(16)		(163
Total current assets	57,578	56,281	587,531
DOODEDTY DI ANT AND FOLIDAENT (Note 5)-			
	0.400	0.470	00.000
Land	8,162	8,172	•
Land Buildings and structures	25,641	24,884	261,643
Land Buildings and structures Machinery and equipment	25,641 12,208	24,884 11,961	261,643 124,571
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures	25,641 12,208 9,197	24,884 11,961 9,009	261,643 124,571 93,847
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress	25,641 12,208 9,197 114	24,884 11,961 9,009 229	261,643 124,571 93,847 1,163
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress Total	25,641 12,208 9,197 114 55,322	24,884 11,961 9,009 229 54,255	261,643 124,571 93,847 1,163 564,510
Buildings and structures  Machinery and equipment  Tools, furniture and fixtures  Construction in progress  Total  Accumulated depreciation	25,641 12,208 9,197 114 55,322 (34,916)	24,884 11,961 9,009 229 54,255 (33,950)	261,643 124,571 93,847 1,163 564,510 (356,286
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress Total	25,641 12,208 9,197 114 55,322	24,884 11,961 9,009 229 54,255	261,643 124,571 93,847 1,163 564,510 (356,286
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress  Total Accumulated depreciation	25,641 12,208 9,197 114 55,322 (34,916)	24,884 11,961 9,009 229 54,255 (33,950)	261,643 124,571 93,847 1,163 564,510 (356,286
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress  Total Accumulated depreciation  Net property, plant and equipment	25,641 12,208 9,197 114 55,322 (34,916)	24,884 11,961 9,009 229 54,255 (33,950)	261,643 124,571 93,847 1,163 564,510 (356,286 208,224
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress  Total Accumulated depreciation  Net property, plant and equipment  INVESTMENTS AND OTHER ASSETS:	25,641 12,208 9,197 114 55,322 (34,916) 20,406	24,884 11,961 9,009 229 54,255 (33,950) 20,305	261,643 124,571 93,847 1,163 564,510 (356,286 208,224
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress  Total Accumulated depreciation  Net property, plant and equipment  INVESTMENTS AND OTHER ASSETS: Investment securities (Note 3)	25,641 12,208 9,197 114 55,322 (34,916) 20,406	24,884 11,961 9,009 229 54,255 (33,950) 20,305	261,643 124,571 93,847 1,163 564,510 (356,286 208,224
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress  Total Accumulated depreciation Net property, plant and equipment  INVESTMENTS AND OTHER ASSETS: Investment securities (Note 3) Long-term prepaid expenses	25,641 12,208 9,197 114 55,322 (34,916) 20,406	24,884 11,961 9,009 229 54,255 (33,950) 20,305	261,643 124,571 93,847 1,163 564,510 (356,286 208,224 117,673 62,918 1,684
Land Buildings and structures Machinery and equipment Tools, furniture and fixtures Construction in progress  Total Accumulated depreciation  Net property, plant and equipment  INVESTMENTS AND OTHER ASSETS: Investment securities (Note 3) Long-term prepaid expenses Deferred tax assets (Note 10)	25,641 12,208 9,197 114 55,322 (34,916) 20,406	24,884 11,961 9,009 229 54,255 (33,950) 20,305 19,212 4,527 56	83,286 261,643 124,571 93,847 1,163 564,510 (356,286 208,224 117,673 62,918 1,684 24,888 207,163

	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
	2009	2008	2009
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Short-term borrowings (Note 5)		¥ 30	
Current portion of long-term debt (Note 5)	¥ 70	1,163	\$ 714
Notes and accounts payable:			
Trade notes	1,168	820	11,919
Trade accounts	3,264	4,241	33,306
Other payables	663	404	6,765
Total notes and accounts payable	5,095	5,465	51,990
Income taxes payable	1,551	1,649	15,827
Accrued expenses	5,984	6,054	61,061
Deposits from customers	281	263	2,867
Other current liabilities	541	447	5,521
Total current liabilities	13,522	15,071	137,980
LONG-TERM LIABILITIES:			
Long-term debt (Note 5)	182	59	1,857
Liability for retirement benefits (Note 6)	8,009	8,537	81,724
Negative goodwill		1	
Deferred tax liability (Note 10)		2,207	
Other long-term liabilities	229	290	2,337
Total long-term liabilities	8,420	11,094	85,918
CONTINGENT LIABILITIES (Note 11)			
<b>EQUITY</b> (Notes 7 and 14):			
Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares	5,174	5,174	52,796
Capital surplus	4,444	4,441	45,347
Retained earnings	65,554	62,271	668,918
Unrealized gain on available-for-sale securities	3,032	6,822	30,939
Deferred gain on derivatives under hedge accounting	1		10
Foreign currency translation adjustments	(26)	(4)	(265)
Treasury stock – at cost, 2,674,288 shares in 2009 and 2,606,466			
shares in 2008	(1,986)	(1,900)	(20,265)
Total	76,193	76,804	777,480
Minority interests	151	147	1,540
Total equity	76,344	76,951	779,020
TOTAL	¥98,286	¥103,116	\$1,002,918

## Consolidated Statements of Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2009 and 2008

	Millions	of Yen	Thousands of U.S. Dollars (Note 1)
	2009	2008	2009
NET SALES (Note 15)	¥63,072	¥59,450	\$643,592
COST AND EXPENSES (Note 15):			
Cost of sales	28,914	27,378	295,041
Selling, general and administrative expenses (Note 8)	26,611	25,611	271,541
Total	55,525	52,989	566,582
Operating income (Note 15)	7,547	6,461	77,010
OTHER INCOME (EXPENSES):			
Interest and dividend income	471	403	4,806
Interest expenses	(15)	(28)	(153)
Gain on sales of property, plant and equipment		19	
Other - net	(317)	24	(3,235)
Other income - net	139	418	1,418
INCOME BEFORE INCOME TAXES AND MINORITY INTERESTS	7,686	6,879	78,428
INCOME TAXES (Note 10):			
Current	2,819	2,510	28,765
Deferred	362	335	3,694
Total income taxes	3,181	2,845	32,459
MINORITY INTERESTS IN NET INCOME	5	3	51
NET INCOME	¥ 4,500	¥ 4,031	\$ 45,918
	Ye	en	U.S. Dollars (Note 1)
AMOUNTS PER COMMON SHARE (Notes 2.o and 13):			
Basic net income	¥66.56	¥59.57	\$0.68
Cash dividends applicable to the year	18.00	16.00	0.18

# Consolidated Statements of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2009 and 2008

	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 (Loss) on Derivatives under Hedge Accounting	Foreign Currency Translation Adjustments	Treasury Stock	Total	Minority Interests	Total Equity
BALANCE, APRIL 1, 2007	67,704	¥5,174	¥4,441	¥59,120	¥ 9,168	¥ 1		¥(1,834)	¥76,070	¥144	¥76,214
Net income				4,031					4,031		4,031
Cash dividends, ¥13.00 per share				(880)					(880)		(880)
Purchase of treasury stock	(61)							(68)	(68)		(68)
Disposal of treasury stock	2							2	2		2
Net change in the year					(2,346)	(1)	¥(4)		(2,351)	3	(2,348)
BALANCE, MARCH 31, 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 in 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

				Thou	usands of U.S	S. Dollars (No	ote 1)			
	Common Stock	Capital Surplus	Retained Earnings	Unrealized Gain on Available- for-sale Securities	Deferred Gain (Loss) on Derivatives under Hedge Accounting	Foreign Currency	Treasury Stock	Total	Minority Interests	Total Equity
BALANCE, MARCH 31, 2008	\$52,796	\$45,316	\$635,418	\$ 69,612		\$(41)	\$(19,387)	\$783,714	\$1,500	\$785,214
Net income			45,918					45,918		45,918
Cash dividends, \$0.18 per share			(12,418)					(12,418)		(12,418)
Purchase of treasury stock							(939)	(939)		(939)
Disposal of treasury stock		31					61	92		92
Net change in the year				(38,673)	\$10	(224)		(38,887)	40	(38,847)
BALANCE, MARCH 31, 2009	\$52,796	\$45,347	\$668,918	\$30,939	\$10	\$(265)	\$(20,265)	\$777,480	\$1,540	\$779,020

## Consolidated Statements of Cash Flows

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2009 and 2008

	Millions	of Yen	Thousands of U.S. Dollars (Note 1)	
	2009	2008	2009	
OPERATING ACTIVITIES:				
ncome before income taxes and minority interests	¥ 7,686	¥ 6,879	\$ 78,428	
Adjustments for:				
Income taxes - paid	(2,918)	(2,240)	(29,776	
Depreciation and amortization	2,875	2,848	29,337	
Changes in assets and liabilities:				
(Increase) decrease in notes and accounts receivable	(684)	1,233	6,979	
Increase in inventories	(235)	(1,826)	(2,398	
Decrease in other current assets	104	104	1,062	
(Decrease) increase in notes and accounts payable	(628)	1,012	(6,408	
Increase (decrease) in other current liabilities	94	(25)	959	
Decrease in liability for retirement benefits	(527)	(827)	(5,378	
Other - net	603	189	6,153	
Total adjustments	(1,316)	468	(13,428	
Net cash provided by operating activities	6,370	7,347	65,000	
INVESTING ACTIVITIES:  Proceeds from redemption of marketable securities	600	700	6,122	
Capital expenditures	(2,025)	(1,778)	(20,663	
Purchases of investment securities	(38)	(2,126)	(388	
Proceeds from redemption and sales of investment securities	48	2,290	490	
Purchases of software	(128)	(154)	(1,306	
Acquisition of the license rights	(2,207)	(210)	(22,52	
Other - net	184	208	1,878	
Net cash used in investing activities	(3,566)	(1,070)	(36,388	
	(0,000)	(1,070)	(00,000	
FINANCING ACTIVITIES:  Decrease in short-term borrowings	(30)		(306	
Proceeds from long-term debt	200		2,041	
Repayments of long-term debt	(1,170)	(1,205)	(11,939	
Cash dividends paid	(1,170)		• •	
·		(879)	(12,428	
Increase of treasury stock	(82)	(66)	(837	
Net cash used in financing activities  FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS	(2,300)	(2,150)	(23,469	
	(212)	(286)	(2,163	
NET INCREASE IN CASH AND CASH EQUIVALENTS	292	3,841	2,980	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	15,154	11,313	154,632	

### 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.

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 ¥98 to \$1, the approximate rate of exchange at March 31, 2009. 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, 2009 include the accounts of the Company and its significant three 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.

The difference between the cost of an acquisition and the fair value of the net assets of the acquired subsidiary at the date of acquisition is reported as negative goodwill in the accompanying consolidated balance sheets and is being amortized over a period of five years.

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

- b. Cash Equivalents Cash equivalents are short-term investments that are readily convertible into cash and that are exposed to insignificant risk of changes in value. Cash equivalents include time deposits, certificate of deposits 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 be 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 (from seven to nine years in 2008) 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 circumstance 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 the receivables outstanding.
- i. Leases In March 2007, the Accounting Standards Board of Japan (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 note 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 do not transfer ownership of the leased property to the lessee as operating lease transactions. There was no effect of this change to income before income taxes and minority interests.

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.
- I. 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 were 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. All derivative financial instruments are used for hedging purposes that qualify for hedge accounting because of high correlation and effectiveness between the hedging instruments and the hedged items, which are deferred until maturity of the hedged transactions.
- 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.

# 3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2009 and 2008 consisted of the following:

	Millions of Yen		Thousands of U.S. Dollars			
	2	2009	2	1008	- 2	2009
Current:						
Government and corporate bonds	¥	900	¥	600	\$	9,184
Trust fund investments		100				1,020
Total	¥	1,000	¥	600	\$	10,204
Non-current:						
Equity securities	¥1	0,837	¥1	7,516	\$1	10,581
Government and corporate bonds		499		1,399		5,092
Trust fund investments		196		297		2,000
Total	¥1	1,532	¥1	9,212	\$1	17,673

Information regarding each category of securities classified as available-for-sale and held-to-maturity at March 31, 2009 and 2008 were as follows:

	Millions of Yen				
March 31, 2009	Cost	Unrealized Gain	Unrealized Loss	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	

	Millions of Yen				
March 31, 2008	Cost	Unrealized Gain	Unrealized Loss	Fair Value	
Securities classified as:					
Available-for-sale:					
Equity securities	¥5,904	¥11,253		¥17,157	
Government and					
corporate bonds	100		¥ 1	99	
Trust fund investments	300		3	297	
Held-to-maturity	1,899		20	1,879	

	Thousands of U.S. Dollars			
March 31, 2009	Cost	Unrealized Gain	Unrealized Loss	Fair Value
Securities classified as:				
Available-for-sale:				
Equity securities	\$56,735	\$50,112		\$106,847
Government and				
corporate bonds	1,020			1,020
Trust fund investments	3,061		\$ 51	3,010
Held-to-maturity	13,265		245	13,020

Available-for-sale securities whose fair value is not readily determinable as of March 31, 2009 and 2008 were as follows:

	Carrying Amount			
	Millions	Millions of Yen		
	2009	2008	2009	
Available-for-sale -				
Equity securities	¥366	¥359	\$3,735	

Proceeds from sales of available-for-sale securities for the years ended March 31, 2009 and 2008 were ¥48 million (\$490 thousand) and ¥170 million, respectively. Gross realized gains on these sales, computed on the moving average cost basis, were ¥27 million (\$276 thousand) and ¥147 million for the years ended March 31, 2009 and 2008, respectively. Gross realized loss on these sales, computed on the moving average cost basis, was immaterial for the year ended March 31, 2009.

The carrying values of debt securities by contractual maturities for securities classified as available-for-sale and held-to maturity at March 31, 2009 were as follows:

	Millions	Millions of Yen		f U.S. Dollars
	Available for Sale	Held to Maturity	Available for Sale	Held to Maturity
Due in one year or less	¥100	¥ 900	\$1,020	\$ 9,184
Due after one year				
through five years	94	499	959	5,091
Total	¥194	¥1,399	\$1,979	\$14,275

#### 4. INVENTORIES

Inventories at March 31, 2009 and 2008 consisted of the following:

	Million	Thousands of U.S. Dollars	
	2009	2008	2009
Finished products and merchandise	¥ 6,051	¥ 6,348	\$ 61,745
Work in process	1,171	1,233	11,949
Raw materials	3,610	3,015	36,837
Total	¥10,832	¥10,596	\$110,531

# 5. SHORT-TERM BORROWINGS AND LONG-TERM DEBT

Short-term borrowings consisted of bank overdrafts, due within one year.

The weighted average annual interest rate for short-term bank loans was 1.0% at March 31, 2008.

Short-term borrowings at March 31, 2009 and 2008 consisted of the following:

	Millions	Millions of Yen		
	2009	2008	2009	
Loans from banks				
(1.0% at 2008)		¥30		

Long-term debt at March 31, 2009 and 2008 consisted of the following:

	Millions	of Yen	Thousands of U.S. Dollars
	2009	2008	2009
Loans from financial institutions,			
0.90% to 2.0%,			
due serially to January 2014	¥252	¥ 1,222	\$2,571
Less current portion	(70)	(1,163)	(714)
Long-term debt, less current portion	¥182	¥ 59	\$1,857

Annual maturities of long-term debt at March 31, 2009 were as follows:

Year Ending March	Millions of Yen	Thousands of U.S. Dollars
2010	¥ 70	\$ 714
2011	50	510
2012	50	510
2013	48	490
2014	34	347
Total	¥252	\$2,571

At March 31, 2009, the following assets were pledged as collateral for certain long-term debt (including current portion):

	Millions of Yen	Thousands of U.S. Dollars
Property, plant and equipment,		
net of accumulated depreciation	¥347	\$3,541
Related liabilities:		
Current portion of long-term debt	¥ 30	\$ 306
Long-term debt (excluding current portion)	¥ 28	\$ 286

#### 6. RETIREMENT BENEFITS

The liability for employees' retirement benefits at March 31, 2009 and 2008 consisted of the following:

	Millions	of Yen	Thousands of U.S. Dollars
	2009	2008	2009
Projected benefit obligation	¥ 26,100	¥ 25,700	\$ 266,326
Fair value of plan assets	(10,630)	(11,235)	(108,469)
Unrecognized actuarial loss	(7,034)	(5,456)	(71,776)
Unrecognized prior service cost	(427)	(472)	(4,357)
Net liability	¥ 8,009	¥ 8,537	\$ 81,724

The components of net periodic benefit costs for the years ended March 31, 2009 and 2008 are as follows:

	Millions	of Yen	Thousands of U.S. Dollars
	2009	2008	2009
Service cost	¥ 880	¥ 883	\$ 8,980
Interest cost	510	512	5,204
Expected return on plan assets	(447)	(460)	(4,561)
Recognized actuarial loss	522	420	5,326
Amortization of prior service cost	45	45	459
Premiums for defined contribution			
pension plan and other	74	43	755
Net periodic benefit costs	¥1,584	¥1,443	\$16,163

Assumptions used for the years ended March 31, 2009 and 2008 are set forth as follows:

	2009	2008
Discount rate	2.0%	2.0%
Expected rate of return on plan assets	4.0%	4.0%
Recognition period of actuarial gain/loss	15years	15years
Amortization period of prior service cost	15years	15years

#### 7. EQUITY

Since May 1, 2006, Japanese companies have been 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 the Board of Directors, (2) having independent auditors, (3) having the 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 paidin capital (a component of capital surplus) depending on the equity account charged upon the payment of such dividends until the total of aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock. Under the Companies Act, the total amount of additional paid-in capital and legal reserve may be reversed without limitation. The Companies Act also provides that common stock, legal reserve, additional paid-in capital, other capital surplus and retained earnings can be transferred among the accounts under certain conditions upon resolution of the shareholders.

(c) Treasury stock and treasury stock acquisition rights

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

Under the Companies Act, stock acquisition rights, which were previously presented as a liability, are now presented as a separate component of equity.

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

#### 8. RESEARCH AND DEVELOPMENT COSTS

Research and development costs for the years ended March 31, 2009 and 2008 were ¥7,853 million (\$80,133 thousand) and ¥7,898 million, respectively.

#### 9. LEASES

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

Total rental expenses for the years ended March 31, 2009 and 2008 were ¥1,070 million (\$10,918 thousand) and ¥1,019 million, respectively, including ¥3 million (\$31 thousand) and ¥7 million of lease payments under finance leases, respectively.

As discussed in Note 2.i., the Companies account for leases which existed at the transition date and do not transfer ownership of the leased property to the lessee as operating lease transactions. Pro forma information of such leases existing at the transition date, such as acquisition cost, accumulated depreciation, obligations under finance leases, depreciation expense, on a "as if capitalized" basis for the years ended March 31, 2009 and 2008 was as follows.

Machinery and equipment, and tools, furniture and fixtures:

	Millions o	of Yen	Thousands of U.S. Dollars
	2009	2008	2009
Acquisition cost	¥15	¥15	\$153
Accumulated depreciation	8	5	82
Net leased property	¥ 7	¥10	\$ 71

Obligations under finance leases:

	Millions	of Yen	Thousands of U.S. Dollars
	2009	2008	2009
Due within one year	¥3	¥ 3	\$31
Due after one year	4	7	41
Total	¥7	¥10	\$72

Depreciation expense, which is not reflected in the accompanying consolidated statements of income, computed by the straight-line method was ¥3 million (\$31 thousand) and ¥7 million for the years ended March 31, 2009 and 2008, respectively.

#### 10. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in aggregate, resulted in a normal effective statutory tax rate of approximately 41% for the years ended March 31, 2009 and 2008. 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, 2009 and 2008 are as follows:

	Millions of Yen		Thousands of U.S. Dollars
	2009	2008	2009
Deferred Tax Assets:			
Retirement benefits	¥3,283	¥3,497	\$33,500
Accrued expenses	1,206	1,177	12,306
Property, plant and equipment	87	97	888
Other	1,060	1,111	10,816
Less valuation allowance	(585)	(450)	(5,969)
Deferred tax assets	5,051	5,432	51,541
Deferred Tax Liabilities: Unrealized gain on available-for-sale securities	1,874	4,427	19,122
Deferred gains on			
sales of property	1,327	1,334	13,541
Other	68	79	694
Deferred tax liabilities	3,269	5,840	33,357
Net deferred tax assets (liabilities)	¥1,782	¥ (408)	\$18,184

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, 2009 and 2008 is as follows:

	2009	2008
Normal effective statutory tax rate	41.0%	41.0%
Expenses not deductible for income tax purposes	4.4	4.7
Income not taxable for income tax purposes	(0.7)	(0.7)
Increase in valuation allowance	1.7	2.3
Tax credits for research and development costs	(5.4)	(5.6)
Other - net	0.4	(0.4)
Actual effective tax rate	41.4%	41.3%

#### 11. CONTINGENT LIABILITIES

At March 31, 2009, contingent liabilities were ¥364 million (\$3,714 thousand) representing loans guaranteed (jointly guaranteed with six unrelated companies). There is an agreement between the seven companies to equally share liability.

In addition to above, ¥10 million (\$102 thousand) of export bill receivables were discounted with a financial institution for which the Company is contingently liable at March 31, 2009.

#### 12. DERIVATIVES

The Companies do not enter into derivative for speculative purposes. 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 judgement by the purchase department. Such derivative transactions are entered into to hedge foreign currency exposures incorporated within the Company's business.

Because the counterparties to these derivatives are limited to major financial institutions, the Company does not anticipate any losses arising from credit risk.

The Companies have internal policies which restrict the use of derivatives only for the purpose of reducing market risks.

Forward exchange contracted amounts which are assigned to associated liabilities and are reflected in the consolidated balance sheets at year-end are not subject to the disclosure of market value information.

#### 13. NET INCOME PER SHARE

Net income per share ("EPS") for the years ended March 31, 2009 and 2008 is as follows:

	Yen in millions	Thousands of shares	Yen	U.S. Dollars
	Net income	Weighted average shares	Е	PS
For the year ended				
March 31, 2009 -				
Basic EPS				
Net income available				
to common				
shareholders	¥4,500	67,605	¥66.56	\$0.68
For the year ended				
March 31, 2008 -				
Basic EPS				
Net income available				
to common				
shareholders	¥4,031	67,667	¥59.57	

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

#### 14. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 26, 2009, the Company's shareholders approved the following: Payment of a year-end cash dividend of ¥9.00 (\$0.09) per share to holders of record at March 31, 2009 for a total of ¥608 million (\$6,204 thousand).

#### 15. SEGMENT INFORMATION

Information about industry segments of the Companies for the years ended March 31, 2009 and 2008 is as follows:

#### **Industry Segments**

#### a. Sales and Operating Income

		Millions	of Yen			Thousands of	U.S. Dollars	
		200	09			20	09	
	Pharmaceuticals	Functional Food	Eliminations/ Corporate	Consolidated	Pharmaceuticals	Functional Food	Eliminations/ Corporate	Consolidated
Sales to customers	¥50,358	¥12,714		¥63,072	\$513,857	\$129,735		\$643,592
Intersegment sales			¥Nil				¥Nil	
Total sales	50,358	12,714		63,072	513,857	129,735		643,592
Operating expenses	43,559	11,966		55,525	444,479	122,102		566,582
Operating income	¥ 6,799	¥ 748	¥Nil	¥ 7,547	\$ 69,378	\$ 7,633	¥Nil	\$ 77,010

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

		Millions	of Yen			Thousands of	U.S. Dollars	
		2009				2009		
	Pharmaceuticals	Functional Food	Eliminations/ Corporate	Consolidated	Pharmaceuticals	Functional Food	Eliminations/ Corporate	Consolidated
Assets	¥60,444	¥8,879	¥28,963	¥98,286	\$616,775	\$90,602	\$295,541	\$1,002,918
Depreciation	2,684	155	36	2,875	27,388	1,582	367	29,337
Capital expenditures	1,877	455		2,332	19,153	4,643		23,796

#### a. Sales and Operating Income

		Millions of Yen				
		2008				
	Pharmaceuticals	Functional Food	Eliminations/ Corporate	Consolidated		
Sales to customers	¥48,659	¥10,791		¥59,450		
Intersegment sales	2		¥(2)			
Total sales	48,661	10,791	(2)	59,450		
Operating expenses	42,219	10,772	(2)	52,989		
Operating income	¥ 6,442	¥ 19	¥Nil	¥ 6,461		

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

		Millions of Yen					
		2008					
	Pharmaceuticals	Functional Food	Eliminations/ Corporate	Consolidated			
Assets	¥60,047	¥8,635	¥34,434	¥103,116			
Depreciation	2,651	159	38	2,848			
Capital expenditures	1,397	253		1,650			

### Independent Auditors' Report

# Deloitte.

#### **Deloitte Touche Tohmatsu**

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

Tel: +81 (75) 222 0181 Fax: +81 (75) 231 2703 www.deloitte.com/ip

#### 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, 2009 and 2008, 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, 2009 and 2008, 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.

Deloite Touche Tohmaten

June 26, 2009

Member of Deloitte Touche Tohmatsu

#### Service Network

As of July 2009

#### **Head Office**

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

# Tokyo Branch Office & Tokyo Business Office

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#### **Osaka Business Office**

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#### **Other Domestic Business Offices**

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Overseas Office

#### **Düsseldorf Office**

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

# Research Laboratories Kyoto

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#### Tsukuba

3-14-1, Sakura, Tsukuba, Ibaraki 305-0003, Japan Phone: +81-298-50-6216 Facsimile: +81-298-50-6217

#### **Odawara Central Factory**

676-1, Kuwabara, Odawara 250-0861, Japan

# Chitose Synthesis Plant & Chitose Functional Food Plant

1007-81, Izumisawa, Chitose, Hokkaido 066-0051, Japan Domestic Subsidiaries

#### Sioe Pharmaceutical Co., Ltd.

3-1-11, Shioe, Amagasaki, Hyogo 661-0976, Japan Phone: +81-6-6499-2601 Facsimile: +81-6-6499-8205

#### Tajima Shokuhin Kogyo Co., Ltd.

435, Higashishiba, Hidaka-cho, Toyooka, Hyogo 669-5300, Japan Phone: +81-796-42-1095 Facsimile: +81-796-42-3763

#### Overseas Subsidiary

#### NS Pharma, Inc.

President: Yoshihiko Makita Mack-Cali Centre III-South Tower, 2nd Floor 140 East Ridgewood Avenue

Paramus, NJ 07652, U.S.A. Phone: +1-201-986-3860 Facsimile: +1-201-986-3865



### Corporate Data

As of July 2009

#### Founded

October 1919

#### **Date of Incorporation**

September 1919

#### Paid-in Capital

¥5,174 million

#### **Issued and Outstanding Number of Shares**

70.251.484

#### **Number of Shareholders**

5,791

#### **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 1-5, Dojima-hama 1-chome, Kita-ku Osaka 530-0004, Japan

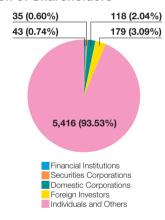
#### **Major Shareholders**

Meiji Yasuda Life Insurance Company Japan Trustee Services Bank, Limited Nippon Life Insurance Company The Bank of Tokyo-Mitsubishi UFJ, Ltd. The Kyoto Bank, Limited Tokio Marine & Nichido Fire Insurance Co., Ltd. Mitsubishi Corporation The Master Trust Bank of Japan, Limited Pursing Division of Donaldson, Lufkin & Jenrette Sec. Corporation

Nippon Shinyaku Employees' Stockholding

#### **Investor Information**

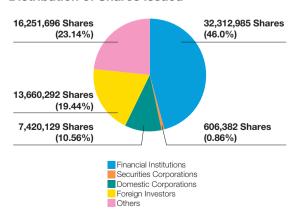
#### **Distribution of Shareholders**



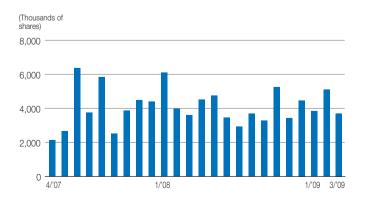
#### **Stock Price**



#### **Distribution of Shares Issued**



#### **Trading Volumes**





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