



ANNUAL REPORT 2004

Nippon Shinyaku

Founded in the ancient capital Kyoto in 1919, Nippon Shinyaku is an R&D-oriented pharmaceutical company specializing in the development, manufacture, and sale of ethical drugs, particularly for the treatment of “contemporary diseases” such as cardiovascular, gastrointestinal, urological, and inflammatory and allergic diseases and for hematologic malignancies. Making good use of its technological know-how accumulated in the field of ethical drugs, the Company began the production of food additives in 1961, later expanding into fields such as functional food ingredients, and since then there has been steady growth in these business areas.

Since its establishment, Nippon Shinyaku has constantly pursued the creation of new top-quality pharmaceutical products and aggressively expanded its R&D activities. Basic research is conducted at our Discovery Research Laboratories in Kyoto and Tsukuba. Our office in Düsseldorf, Germany, and our U.S. subsidiary NS Pharma, Inc., in New Jersey, are engaged in the promotion of clinical studies and the collection of pharmaceutical and medical information in Europe and the United States, respectively.

The pharmaceuticals formulation plant at our Odawara Central Factory, which has one of the largest floor areas and one of the highest production capacities at the pharmaceutical industry in Japan, received the Nikkei Superior Trend-Setting Factories and Offices Awards (sponsored by the Nihon Keizai Shimbun) in 2002. The plant employs cutting-edge technology and sophisticated and highly efficient manufacturing systems.



Kyoto Headquarters

Forward-Looking Statements:

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

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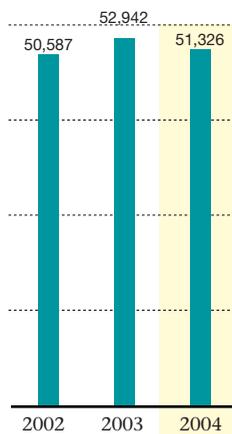
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Years ended March 31, 2004 and 2003	Millions of yen		Thousands of U.S. dollars (Note 2)
	2004	2003	2004
Net sales	¥ 51,326	¥ 52,942	\$484,208
Income before income taxes and minority interests	3,262	4,474	30,774
Net income	1,536	2,095	14,491
Amounts per share (in yen and U.S. dollars):			
Net income	¥ 21.50	¥ 29.20	\$ 0.20
Shareholders' equity (Note 1)	949.86	891.97	8.96
Total assets	¥104,008	¥109,549	\$981,208
Shareholders' equity	65,396	61,614	616,943
Investments in plant and equipment	1,829	4,370	17,255
R&D expenses	8,263	7,885	77,953

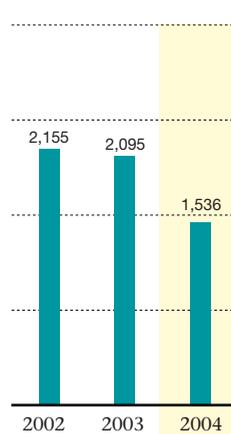
Notes: 1. Calculated on the basis of the average of the balances at the beginning and at the end of the term.

2. U.S. dollar amounts are converted from yen amounts at the rate of U.S.\$1=¥106, the approximate exchange rate on March 31, 2004.

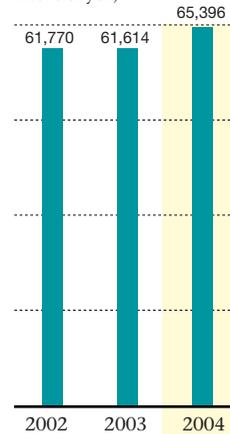
Consolidated Net Sales
(Millions of yen)



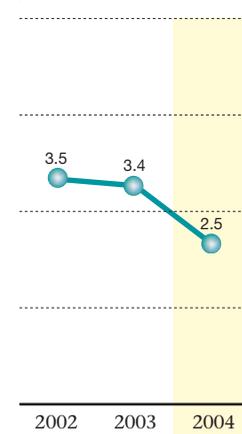
Consolidated Net Income
(Millions of yen)



Consolidated Shareholders' Equity
(Millions of yen)



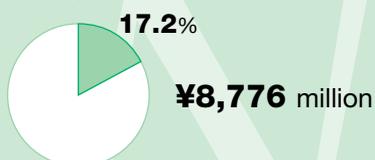
Consolidated Return on Average Equity
(%)



Pharmaceuticals



Nervous and Respiratory Drugs



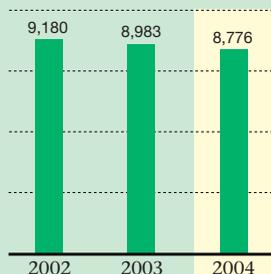
◆ Main Products

Hypen®(etodolac)
Non-Steroidal Anti-inflammatory and Analgesic Agent

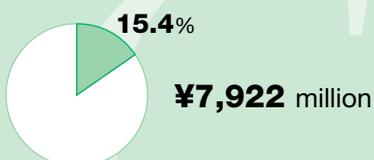
Cephadol®(difenidol hydrochloride)
Antivertigo Agent

Orcl®(actarit)
Antirheumatic Agent

◆ Sales (Millions of yen)



Cardiovascular and Metabolic Drugs



◆ Main Products

Selectol®(celiprolol hydrochloride)
Remedy for Hypertension and Angina Pectoris

Leftose®(lysozyme hydrochloride)
Antihemorrhagic and Anti-inflammatory Enzyme

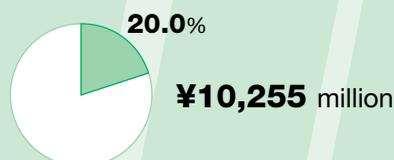
Glycoran®(metformin hydrochloride)
Remedy for Diabetes

Odric®(ACE inhibitor)
Anti-hypertensive Agent

◆ Sales (Millions of yen)



Urological Drugs



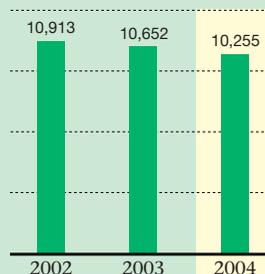
◆ Main Products

Bladderon®(flavoxate hydrochloride)
Remedy for Pollakisuria

Eviprostat®(herbal extracts)
Remedy for Prostatic Hypertrophy

Urocalun®(quercus salicina extract)
Remedy for Urinary Calculus

◆ Sales (Millions of yen)



Foodstuffs

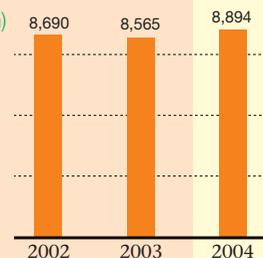


◆ Main Products

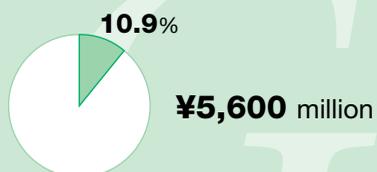
Protein preparations
Food quality preservatives
Seasonings & spices
Health food ingredients

◆ Sales

(Millions of yen)



Gastrointestinal Drugs



◆ Main Products

Gaslon N[®] (irsogladine maleate)
Remedy for Gastric Ulcer and Gastritis

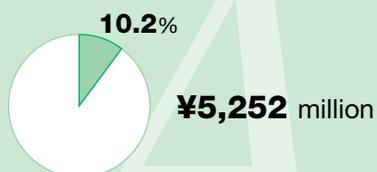
Portolac[®] (lactitol hydrate)
Antihyperammonemia Agent

Azunol[®] Gargle 4%
Mouthwash Agent

◆ Sales (Millions of yen)



Anticancer Drugs



◆ Main Products

Cylocide[®] (cytarabine)
Remedy for Acute Leukemia and Solid Cancer

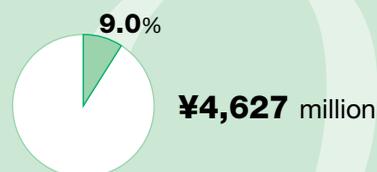
Cylocide[®]N (cytarabine)
Remedy for Acute Leukemia
– Induction therapy for relapse and refractory cases
– Consolidation therapy
Remedy for Malignant Lymphoma

Estracyt[®] (estramustine sodium phosphate)
Remedy for Prostatic Cancer

◆ Sales (Millions of yen)



Others

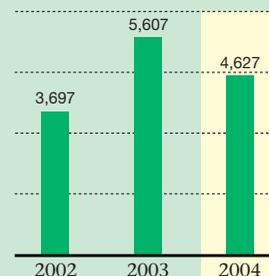


◆ Main Products

Livostin[®] Nasal Spray
(levocabastine hydrochloride)
Remedy for Allergic Rhinitis

Livostin[®] Eye Drops
(levocabastine hydrochloride)
Remedy for Allergic Conjunctivitis

◆ Sales (Millions of yen)



Urajirogashi (*Quercus salicina*)



Akamegashiwa (*Mallotus Japonicus*)

Message from the President



Kazuto Hatsuyama
President

The phenomenon of aging population combined with the declining birth rate among the population is common to almost all the world's advanced industrialized societies. This problem is especially acute in Japan, and has sparked a nationwide debate over how to secure the financial resources required to sustain the existing social security system. Public concern has been particularly intense regarding the question of how to ensure the comfortable life promised to the nation's elderly citizens under the existing pension plans, while also providing the financial resources necessary to operate the medical care system for the population as a whole. Attempts to devise a solution to this issue have grown into a major political bone of contention.

In anticipation of this dramatic change in the medical care environment, pharmaceutical companies around the world have been transforming themselves at a dizzying pace. The key forces driving these changes are the globalization of the pharmaceutical business and the expansion of new drugs research and development pipeline. Each company has been taking whatever steps it can to reinforce its base of operations so as to weather the coming storm.

The pharmaceuticals industry, being closely interconnected with people's lives on a long-term and daily basis, is still growing and developing, and this development will continue for as long as human beings seek further improvements in their quality of life – particularly in lengthening their lifespan while maintaining an adequate degree of health, as well as properly-functioning physical and mental faculties for as long as possible.

In consideration of this background, we can confidently predict that the pharmaceuticals market will continue to both expand and diversify far into the future. In these circumstances, in addition to performing our basic duties of ensuring that the Company responds effectively to the changing business environment and keeping a firm hand on the management rudder so as to secure stable earnings, we will work to widen Nippon Shinyaku's drug development pipeline with the aim of growing the Company in the long term.

The demands being made on pharmaceuticals companies by those in the medical frontline – both doctors and patients – run the whole gamut from treatments for diseases and other medical problems, through preventatives to lifestyle drugs, and the market as a whole has been expanding. At the same time, however, R&D expenses have also been rising, to the point where it is often too costly or too risky for a single company to develop a particular new drug by itself.

Companies have therefore been forming business alliances for specific purposes, or have been merging. Joint development projects involving government bodies and academic institutions, as well as alliances with companies in other industries, are also frequently being seen. The market is not only demanding the development of revolutionary new treatments for medical complaints, but also improvements at the drug formulation stage in response to the needs of patients, including drugs that are easier to take and have fewer

or weaker side-effects. Pharmaceutical companies must thus approach the development of new drugs from a multiplicity of angles.

For the past several years, Nippon Shinyaku has followed an R&D policy featuring five themes: 1) developing new breakthrough drugs based on in-house research, 2) developing new drugs on the basis of compounds introduced from other companies, 3) developing improved new drugs through the modification of existing compounds, 4) adding new indications to the Company's own products, and 5) improving the formulation of the Company's products.

This system has worked well, as evidenced by our plans for bringing new drugs to market during the current business year, which include treatments for hematologic malignancies, and various drugs such as anti-diabetic agent in smaller pills or capsules for easier swallowing. From here onward, we hope to launch at least one new drug on the market each year.

In one of our particular fields of special competence – treatments for urological problems – we are planning the release of drugs to treat overactive bladder. Also in the pipeline is a drug to treat alcohol dependence, a medical problem that has wider social implications beyond the affected individual, and development of a drug for the treatment of neoplastic meningitis is also full underway. The Swiss pharmaceutical giant F. Hoffmann-La Roche Ltd., with which we have a development agreement, is already conducting full-fledged development in overseas of a treatment for dyslipidemia. If successful, this drug would become a major strategic product for us on the global market.

In the field of functional food ingredients, we are posting steady growth in sales of health foods and added ingredients for use at the food processing stage, and strong expansion is expected in this market niche in the future.

In its research and development activities, Nippon Shinyaku will continue to display the innovative, entrepreneurial spirit that has been the Company's watchword since its establishment. We will aim always to be at the cutting edge of research into drugs that address the most urgent unmet needs in each generation.

At Nippon Shinyaku, we intend to maintain the Company's strong presence in the market as a unique enterprise that provides high-quality pharmaceutical products, and thereby make a valuable contribution to the progress of medical treatment. By so doing, we are confident that we will earn the trust of the public and fulfill the expectations of our shareholders and investors.



Kazuto Hatsuyama
President



Drug Development Policy

Along with the rapid progress in clarification of mechanisms underlying diseases at the gene level, prevention and therapeutics are now expected even for diseases whose causes are unclear, and for which therapeutics were considered difficult. Nippon Shinyaku is conducting research and development activities by incorporating excellent expertise for new drug development obtained in various therapeutic fields and new scientific knowledge and technology. Now that the sequencing of the human genome has been completed and drug development based on utilizing genomic information has begun, the development has been aimed at substantial therapeutics and prevention of the onset of diseases. Nippon Shinyaku is also taking on this challenge, primarily through research conducted at the Discovery Research Laboratories in Tsukuba City, Ibaraki Prefecture, in collaboration with external partners, to prepare and maintain basic technology and to introduce cutting-edge technology. Research and development activities have been focused on urology, and also on other therapeutic fields including inflammation and allergies and hematologic malignancies. In these fields, we have targeted diseases for which more effective therapeutic drugs are desired. International clinical studies are being promoted to achieve rapid development and approval.

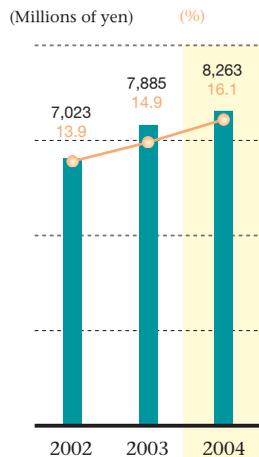
Results of Activities

In FY2003, Nippon Shinyaku invested around ¥8.2 billion, or 16% of total sales, in research and development. Compounds originated by Nippon Shinyaku are highly evaluated by overseas firms. We have out-licensed NS-8 for the treatment of overactive bladder to Apogepha Arzneimittel GmbH, Germany and NS-220 for the treatment for dyslipidemia to F. Hoffmann-La Roche Ltd., Switzerland, and full-fledged development is scheduled to begin. We are looking for a new licensing partner for HMN-214 to treat solid cancer, for which the administration has been completed in Phase I trials in the United States, after the termination of the licensing agreement with Biogen IDEC Inc.

The non-narcotic analgesic NS-315 has progressed to Phase III, while NS-126 for allergic rhinitis and bronchial asthma has progressed to Phase II, and NS-9 for liver cancer has progressed to Phase I in the U.S. We have also started Phase I trials on NS-101 for neoplastic meningitis.

Of the newly in-licensed compounds, we have started clinical trials on NS-11 (acamprosate) for the treatment of alcohol dependence.

Consolidated R&D Expenses Ratio to Net Sales



Drug Development Organization and Function

Domestic

We have around 440 R&D staff members and the collaborative efforts by our Kyoto and Tsukuba Research Laboratories have enabled us to build up our pipeline through rapid creation and development of in-house compounds and in-licensing, and are strengthening our genomics-based drug discovery research, including investigations into protein structure and function.

At the Discovery Research Laboratories in Kyoto, which are Nippon Shinyaku's main R&D facilities, we explore novel compounds and syntheses in line with our drug discovery strategy, and conduct pharmacological and toxicological studies to generate compounds ready for clinical testing. We also perform research to apply our proprietary drug formulation technologies to new drug development and work to improve existing drugs so that they better meet the needs of the healthcare professionals and the requirement of patients. In addition, we are working to improve the drug formulation technologies. We have developed a solid dispersion method that does not require organic solvents and uses a twin-screw extruder to enable the simultaneous control of mechanical pressure and heating operations. We have established formulation technologies for wax matrixes and inclusion compounds. We have also developed a rotary disk extruder technology that provides a new manufacturing process for solid dispersions.

At the Discovery Research Laboratories in Tsukuba, we are investigating target genes and proteins using DNA microarray techniques, and are exploring novel lead compounds using throughput screening and combinatorial chemistry techniques. In our genomics-based drug discovery research conducted in partnership with external organizations, we have been involved in the construction of the specialized beamline facility SPring-8 and the establishment of a protein structural analysis system through a joint project with 22 major pharmaceutical manufacturers. We are also participating in the Reverse Proteomics Research Institute, which is made up of 11 firms, and intend to further our genomics-based drug discovery by utilizing the results of this Institute's research, which is aimed at investigating and evaluating the interactions between commonly used low molecular weight pharmaceuticals and proteins derived from human full-length cDNA selected for the purposes of drug discovery research.



Discovery Research Laboratories in Kyoto



Discovery Research Laboratories in Tsukuba

Kumiko Noda (*Discovery Research Laboratory / Pharmacology Dept.*)

I belong to the Biotechnology Research Department, which primarily carries out drug-discovery research and follow-up research on existing products.

I conduct a wide variety of tests to investigate the action mechanism of pharmaceuticals as well as their side effects. In addition, I sometimes get hints that lead to the discovery of unique varieties. I expect the discovery of new substances will lead to the development of groundbreaking pharmaceuticals. In this way, I am working hard to develop new pharmaceuticals that can be quickly commercialized for the benefit of society.





NS Pharma, Inc. in New Jersey



The Düsseldorf Office

International

Nippon Shinyaku is working to collect information on the latest drug development technologies and novel development compounds from Western pharmaceutical majors, venture firms, and research institutions, via our offices in Düsseldorf, Germany and our U.S. subsidiary NS Pharma, Inc. These overseas operations also act as clinical development sites in Europe and the U.S., and play an important role in Nippon Shinyaku being able to conduct its own clinical trials.

Of the development compounds out-licensed to overseas firms, the quinolone antibacterial prulifloxacin, developed in Europe by Angelini ACRAF S.p.A., is scheduled to be approved in Italy in the near future, after which it will be filed in various other European countries. In addition, clinical trials on prulifloxacin are underway in South Korea by the licensing partner Yuhan Corp. Preparations for the start of clinical trials are underway by F. Hoffmann-La Roche Ltd. for NS-220 to treat dyslipidemia and by Apogepha Arzneimittel GmbH for NS-8 to treat overactive bladder. Irsogladine maleate (*Gaslon N*[®] in Japan) to treat gastric ulcer and gastritis is being developed in South Korea by Taejoon Pharmaceutical Co., Ltd.

Research and Development in the Foodstuffs Business

In 2003, Food Safety Basic Law was constituted, a milestone piece of legislation that constitutes the first major revision of the nation's legal statutes relating to food safety since the original passage of the Food Sanitation Law in 1947. This legislation places more strict restrictions than hitherto on the business operations of companies in the foodstuffs industry, and this has been compounded by difficulties in obtaining a sufficient supply of beef and chicken as a result of the discovery of BSE in the United States and the severe outbreak of avian influenza in East Asia. Nippon Shinyaku, for its part, responded positively to the difficulties facing its customers in this sector by taking care to accurately ascertain market needs and directing production development efforts towards meetings those needs.

In the field of food preservatives, we started R&D into preservatives for foods with pH factors ranging from neutral to alkaline. Products successfully brought to market included *Protec R-1*, an anti-mold agent for steamed buns; *NewRestol TK*, for preserving the freshness of cream; and *NewSutan PKL*, for meat products. We are currently focusing effort on the development of agents for preserving the freshness of vegetables used in boxed lunches and other ready-to-eat meals, as well as retarding color-fading in such vegetables.

In nutraceuticals, we carried out the necessary work preparatory to application for inclusion of our extracts of *Akamegashiwa* (*Mallotus japonicus*) and *Urajirogashi* (*Quercus salicina*) on the list of foods officially recognized as "Foods for Specified Health Use." At the same time, we continued to actively approach numerous companies with proposals for production of foods using our extracts under OEM contract. Also commenced during the reporting term was the test production of pumpkin and mushroom extracts.

Drugs under Development

Looking at our novel drugs under development, including licensed in and out compounds, we currently have four compounds, domestic and overseas, that have been filed; three compounds at Phase III; two at Phase II; five at Phase I; and one being prepared for clinical development. Of these, six compounds were originated at our own research laboratories. If development proceeds according to plan, we expect these compounds to become mainstay products for Nippon Shinyaku in the early part of the 21st century. Every year in the future, we plan to launch at least one new drug and are working on the development of these and other compounds. The following table shows our pipeline compounds, as of May 31, 2004.

◆ R&D compounds

(As of June 25, 2004)

< Domestic >

Stage	Product name (Generic name)	Therapeutic field	Indications	Development
Pre-registration	Urespan (temiverine hydrochloride)	urological	overactive bladder	original
Pre-registration	Amnoid (tamibarotene)	chemotherapeutics	acute promyelocytic leukemia	licensed-in from Toko Pharmaceutical Ind. Co., Ltd.
Pre-registration	Trisenox (arsenic trioxide)	chemotherapeutics	refractory / relapsed acute promyelocytic leukemia	licensed-in from Cell Therapeutics Inc.

Stage	Code No. (Generic name)	Therapeutic field	Indications	Development
Phase III	RAK-591 (etodolac)	inflammation / allergy	temporomandibular arthrosis (new indication)	licensed-in from Wyeth
Phase III	NS-315 (tramadol hydrochloride)	inflammation / allergy	non-narcotic analgesic (postoperative and cancer pain)	licensed-in from Grünenthal GmbH
Phase II	TRK-091 (tramadol hydrochloride SR)	inflammation / allergy	non-narcotic analgesic (low back pain)	co-developed with Toray Industries, Inc.
Phase II	NS-126	inflammation / allergy	allergic rhinitis bronchial asthma	co-developed with SSP Co., Ltd.
Phase I	NS-8	urological	overactive bladder	original
Phase I	NS-101 (cytarabine)	chemotherapeutics	neoplastic meningitis	licensed-in from SkyePharma Inc.
Phase I	NS-11 (acamprosate)	Others	alcohol dependence	licensed-in from Merck Sante S.A.S.

< Overseas >

Stage	Code No. (Generic name)	Therapeutic field	Indications	Licensee
Pre-registration	NM441 (prulifloxacin)	chemotherapeutics	bacterial infections	Angelini ACRAF SpA
Phase III				Yuhan Corporation
Phase I	NS-8	urological	overactive bladder	Apogepha Arzneimittel GmbH
Phase I	HMN-214	chemotherapeutics	solid tumor	—
Phase I	NS-9	chemotherapeutics	hepatic cancer	—
Pre-clinical	NS-220	cardiovascular	dyslipidemia	F.Hoffmann-La Roche Ltd.



Producing Granulated Form Facility



Printing and Inspection



Packaging



Automatic Conveying System



Control of Quality



Odawara Central Factory

Nippon Shinyaku has two plants for the production of pharmaceuticals formulation – the Odawara Central Factory and the Synthesis Plant in the Chitose Create Park – and two plants for production of extracts and other food ingredients – the Chitose Foodstuffs Plant and the Morioka Factory.

The Odawara Central Factory, our main pharmaceuticals plant located in the city of Odawara in Kanagawa Prefecture, approximately 70 kilometers southwest of central Tokyo, began operation in 1964. A new drug preparation wing was completed in 2001, and the plant is fully equipped with the production facilities and up-to-date production control systems required to stay competitive in today's global pharmaceutical manufacturing environment. The plant produces a very wide range of drugs in tablet form, granulated form, capsules, and injectable form. The plant's hygiene and cleanliness standards are up to international standards, production lines are state-of-the-art, and all internal transportation of raw materials, packaging materials, and pharmaceutical intermediates is carried out by automatic conveying systems.

The entire production system is computer-controlled, ensuring product quality with a very high degree of reliability. In 2002, the achievements of plant staffs in raising productivity earned the plant an award in the Nikkei Superior Trend-Setting Factories and Offices Awards competition. The staffs are now working to obtain certification under the ISO 14001 standard for environmental management systems.

Our other pharmaceuticals plant, the Chitose Synthesis Plant, located in Chitose City, near Sapporo in Japan's northernmost main island of Hokkaido, was completed in 1999. The plant principally manufactures pharmaceuticals bulk substance for the treatment of gastritis and gastric ulcers, for the treatments for rheumatism and so on. It is also responsible for producing the active pharmaceutical bulk substance for new drug products whose launch is planned in the near future. With a view to the future export to Europe and the U.S. of active pharmaceutical bulk substance,

measures have been taken to ensure that the plant meets international standards for good manufacturing practices (GMP). ISO 14001 certification for environmental management systems was acquired in 2002.

The Chitose Foodstuffs Plant, situated next-door to the Chitose Synthesis Plant, began operation in 1990, mainly producing extracts from onions and red peppers. Recently, the plant has begun production of concentrated fruit juices using fruit grown locally in Hokkaido, as well as various health food ingredients.

Our other plant involved in foodstuffs-related products – the Morioka Factory, in Iwate Prefecture, northern Japan – began operation in 1966 with the manufacture of extracts from various spices, shelflife expanders and other forms of food additives. The plant has recently diversified into the production of health food ingredients.

By means of these four plants, in addition to the effective utilization of the plant operated by our pharmaceuticals manufacturing subsidiary SHIOE PHARMACEUTICAL CO., LTD. at Amagasaki in Hyogo Prefecture and the foodstuffs plant operated by our subsidiary Tajima Shokuhin Kogyo Co., Ltd., also in Hyogo Prefecture, we have in place a highly efficient overall production system.



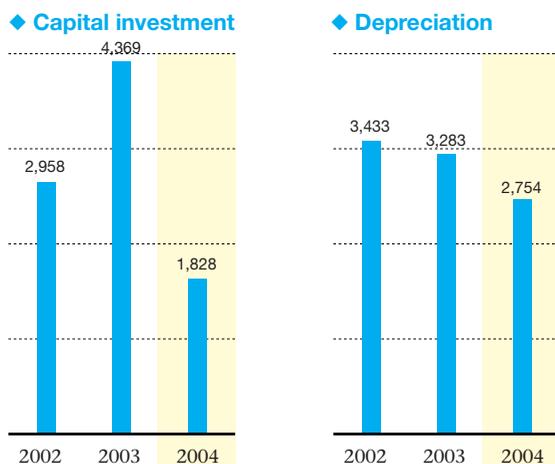
Chitose Synthesis Plant /
Chitose Foodstuffs Plant



Morioka Factory

Capital Investment and Depreciation

(consolidated accounts basis; millions of yen)



Yousuke Hayashi (Odawara Central Factory / Quality Control Dept.)

I am responsible for quality control testing. My job is to take products from the production line and test them to make sure that they conform to standards. This constitutes the final check at the plant level, and is therefore a heavy responsibility, but it is a worthwhile one because it ensures the high quality of our pharmaceutical products.



The Front Line — Our Medical Representatives



Nippon Shinyaku's marketing activities are handled by 22 branch offices scattered across Japan, containing 72 sections staffed by a current total of approximately 530 medical representatives. Our adoption of a simplified, more horizontal organizational structure incorporating a hierarchy of only three separate levels – branch manager, section head, and medical representative – has enabled us to achieve faster decision-making and a freer flow of information. We plan to increase the number of medical representatives to 600 in the near future.

To maximize the efficiency of our medical representatives' visits to clinics, hospitals and so on all over Japan, we have focused on four therapeutic categories – urological problems, inflammation and allergies, cardiovascular problems, and hematologic malignancies. The relative weightings of these four categories – in terms both of the amount of production devoted to drugs in these categories and to the number of medical representatives trained to specialize in them – has been determined on the basis of detailed analyses of doctors' prescriptions. This allows us to devote the most appropriate amount of management resources to each drug category, to accurately estimate sales of drugs to be launched within the next decade, and to plan future new drug R&D strategies.

Our medical representatives attend training sessions held each month as part of a continuously evolving course, enabling them to acquire a detailed knowledge of the diseases and complaints within their field of specialization, and of the drugs available or in the R&D pipeline. Particularly in the case of hematological malignancies, we have implemented a program to forge stronger bonds of trust between our medical representatives and the doctors with whom they interact. It is essential that our medical representatives and the doctors they deal with establish a sophisticated information exchange relationship in the field of hematological malignancies, which require treatment at an early stage.

Our medical representatives will make the most of the knowledge and experience they have acquired thus far, to further refine their familiarity with the latest academic studies in their area of specialization, and to increase the frequency of their visits to each doctor and the number of presentations on new drugs that they make. We believe that such measures will inevitably lead to growth in sales over the long term.

Fumito Nishino (*Kyoto Business Office*)

The job of medical representative brings with it a large amount of responsibility, in that as a representative of the Company I must visit medical institutions and meet individually with doctors, who are experts in their chosen fields, to exchange information about illnesses and products. I must compile my own action plans, while the Company has an in-house sales data system for managing physician data. Each medical representative is equipped with a notebook computer offering mobile capabilities. Whenever I receive a favorable response from doctors regarding our drugs, I get the feeling that I am playing an active role in medical treatment, and this serves as one of the largest incentives for doing this kind of work.



Licenses and Joint Developments

July 2003: Development work with Schering A.G. terminated on NS-7, a treatment for acute-phase cerebrovascular diseases

October 2003: Signed license-out agreement with Apogepha Arzneimittel GmbH of Germany on NS-8, a treatment for overactive bladder

License-out agreement concluded with F. Hoffmann-La Roche Ltd. of Switzerland on NS-220, a treatment for dyslipidemia

January 2004: Terminated license-out arrangement with Biogen IDEC Inc. of the United States for anticancer agent HMN-214

March 2004: License-in agreement terminated with Seikagaku Corporation regarding NS-7201, a treatment for interstitial cystitis

Mr. Hatsuyama, President of Nippon Shinyaku and Dr. Franz B. Humer, Chairman & CEO of F. Hoffmann-La Roche, at the license-out agreement ceremony



Other News

August 2003: Introduced a new corporate pension plan (cash balance plan)

December 2003: Defined contribution pension plan (Japanese-style 401k) adopted

April 2004: Received the government's approval for the termination of agency operation of the Welfare Pension Fund regarding employees' prior service, and established a corporate pension fund

June 2004: Construction completed of new Tokyo office building at Nihonbashi, in the capital's business center



Nihonbashi Sakura-dori BLDG.

Board of Directors and Corporate Auditors

As of June 29, 2004



[Photo]

(Front from left)

Chairman
Hiroshi Ichinose

President
Kazuto Hatsuyama

(Back from left)

Managing Director
Naoki Shimidzu

Managing Director
Yoshiaki Asano

Managing Director
Kouzo Kaneki

Managing Director
Hiroshi Satani

Chairman Hiroshi Ichinose

President Kazuto Hatsuyama

Managing Directors Naoki Shimidzu, Ph. D.
(General Manager, Research & Development Division)

Yoshiaki Asano
(General Manager, Functional Food Division)

Kouzo Kaneki
(General Manager, Tokyo Branch Office)

Hiroshi Satani
(General Manager, Marketing Division)

Directors

Kouichi Ushimaru
(General Manager, Production Division)

Nobuyoshi Sumi, Dr. med. vet.
(General Manager, International Business & Resource Procurement Division)

Yoshihisa Shibata, Ph. D.
(General Manager, Regulatory & Post Marketing Surveillance Division)

Takuji Hata
(General Manager, Corporate Strategy Division)

Corporate Auditors

Youichi Toriyama

Sadayasu Nagai

Kenji Ohishi

Yasuo Tanabe

Corporate Officers

Shigenobu Maekawa
(General Manager, Corporate Planning Dept.)

Seishiro Harano
(General Manager, Finance & Accounting Dept.)

Akira Miura
(General Manager, Human Resources Dept.)

Tetsuya Yonekawa
(General Manager, Odawara Central Factory)

Junichi Yano, Ph. D.
(General Manager, Research & Development Dept.)

Kichiro Inoue
(General Manager, Discovery Research Laboratories)

Kazushige Itabashi
(General Manager, Licensing & Business Development Dept.)

Toshihiko Sagou
(General Manager, Tokyo Business Office)

Hideo Arai
(General Manager, Nagoya Business Office)

Yoshitake Nakazawa
(General Manager, Osaka Business Office)

Years ended March 31	Millions of yen					
	2004	2003	2002	2001	2000	1999
Net sales	¥51,326	¥52,942	¥50,587	¥50,949	¥49,127	¥48,177
Income before income taxes and minority interests	3,262	4,474	4,534	6,245	2,721	6,721
Net income	1,536	2,095	2,155	3,117	978	2,418
Amounts per share (in yen):						
Net income	¥21.50	¥29.20	¥30.68	¥44.37	¥13.93	¥34.42
Cash dividends applicable to the year	10.00	10.00	10.00	10.00	10.00	10.00
Total assets	¥104,008	¥109,549	¥103,871	¥110,143	¥98,365	¥90,124
Shareholders' equity	65,396	61,614	61,770	61,788	55,354	49,966
Investments in plant and equipment	1,829	4,370	2,959	8,886	3,190	3,020
R&D expenses	8,263	7,885	7,023	6,618	6,735	7,078

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Consolidated Total Assets

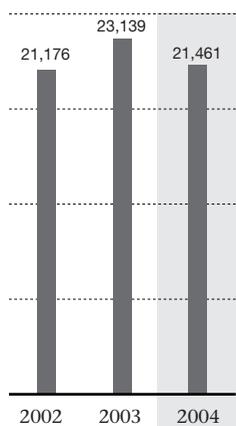
(Millions of yen)

**Consolidated Stockholders' Equity Ratio**

(%)

**Consolidated Cost of Sales**

(Millions of yen)

**Financial Strategy**

The management of Nippon Shinyaku constantly work to improve the Company's competitiveness in research and development through the appropriate allocation of management resources, in response to the continuous appearance of innovative technologies. At the same time, we take steps to ensure the soundness of the Company's financial position by retaining a sufficient level of internal reserves to reinforce our capital base with a view to future business expansion and the ability to invest in R&D whenever necessary. At the same time, the adequate return of profit to our shareholders is also one of our top management priorities. To this end, we follow a fundamental policy of making uninterrupted and stable dividend payments that fairly reflect the Company's performance and the value of its shares.

Liquidity and Capital Resources

The total assets of Nippon Shinyaku at the end of the reporting term stood at ¥104,008 million (US\$981,208 thousand), a decline of ¥5,540 million from the previous term-end. Of this, current assets came to ¥58,010 million (US\$547,264 thousand), a year-on-year decline of ¥5,565 million. The primary cause of this decrease in current assets was a fall in cash and deposits as a result of the redemption of convertible bonds in the amount of ¥7,000 million. Noncurrent assets stood at ¥45,998 million (US\$433,944 thousand), approximately the same as the previous term-end.

Meanwhile, total liabilities came to ¥38,461 million (US\$362,840 thousand), a decline of ¥9,328 million from the previous year, thanks principally to a decrease in the amount of current liabilities as a result of the aforementioned redemption of convertible bonds.

Shareholders' equity rose ¥3,783 million over the previous term-end, to ¥65,396 million, largely as a result of the recognition of unrealized gains on available-for-sale securities in line with the recovery of prices on the stock market. The equity ratio (shareholders' equity as a percentage of total assets) improved to 62.9% from 56.3% for the previous term.

Turning to cash flows, net cash provided by operating activities amounted to ¥4,068 million (US\$38,377 thousand), owing to an increase in income taxes. Net cash used in investing activities amounted to ¥2,273 million (US\$21,443 thousand) as a result of continuing payments for the construction of the Company's new Tokyo office building. Net cash used in financing activities came to ¥7,630 million (US\$71,981 thousand) as a result of the redemption of

Consolidated Cash Flows (Millions of yen)

	2002	2003	2004
Net cash provided by operating activities	1,155	6,327	4,068
Net cash used in investing activities	(725)	(6,081)	(2,273)
Net cash provided by (used in) financing activities	(797)	3,847	(7,630)
Cash and cash equivalents, end of year	21,879	25,910	20,032

convertible bonds. As a consequence of the foregoing, cash and cash equivalents at term-end amounted to ¥20,032 million (US\$188,981 thousand), a decline of ¥5,878 million from the level at the end of the previous term.

The management of Nippon Shinyaku constantly works to maintain the health of the Company's balance sheet while ensuring sufficient cash liquidity and sources of funds for working capital.

Business Performance

The business environment of companies in the pharmaceuticals industry remained difficult during the reporting period, owing to the depletion of the government's financial resources required to supplement patients' medical insurance payments. As a result, following the raising of the patient's contribution ratio for treatment costs from 20% to 30% in April 2003, in April 2004 another round of reductions in drug prices under the National Health Insurance system was pushed through as part of an ongoing initiative to cut back on medical expenses. Amid this difficult business environment, Nippon Shinyaku's sales for the term declined by 3.1% from the previous year, to ¥51,326 million (US\$484,208 thousand) in spite of all our efforts.

At the level of profits, declines in the cost of sales and the depreciation burden were more than offset by increases in selling, general and administrative expenses as well as research and developments expenses, leading to a 18.6% year-on-year fall in operating income, to ¥3,475 million (US\$32,783 thousand), and a 27.1% drop in income before income taxes and minority interests, to ¥3,262 million. Net income posted a sharp decline of 26.7% from the previous term, at ¥1,536 million (US\$14,491 thousand).

Business Performance by Segment

Pharmaceuticals

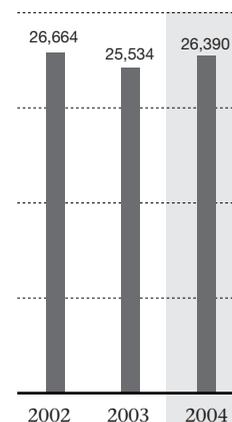
During the reporting period, sales growth was recorded by mainstay products including the non-steroidal anti-inflammatory and non-steroidal anti-inflammatory and analgesic agent *Hypen*[®], remedy for pollakisuria *Bladderon*[®], remedy for acute leukemia *Cylocide*[®], and the mouthwash agent *Azumol*[®] Gargle 4%, containing sodium azulene sulfonate. Against this, declines were suffered in sales of remedy for prostatic hypertrophy *Eviprostat*[®], remedy for hypertension and angina pectoris *Selectol*[®], remedy for gastric ulcer and gastritis *Gaslon N*[®]. In addition, particularly steep falls in sales were recorded by *Livostin*[®] Eye Drops, for the treatment of allergic conjunctivitis, and of *Livostin*[®] Nasal Spray, for the treatment of allergic rhinitis, due to the decreased amount of hay fever-causing pollen during the term under review. As a result of these factors, total sales registered a year-on-year decline of 4.4%, to ¥42,432 million.

Foodstuffs

In spite of a deterioration in the overall market for foodstuffs, the Company's Foodstuffs Business during the reporting term succeeded in recording increased sales of health food ingredients. As a result, total sales of this segment rose by 3.8% year-on-year, to ¥8,894 million.

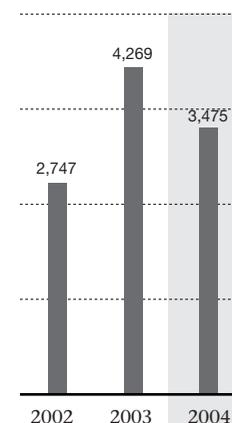
Consolidated Selling, general and administrative expense

(Millions of yen)



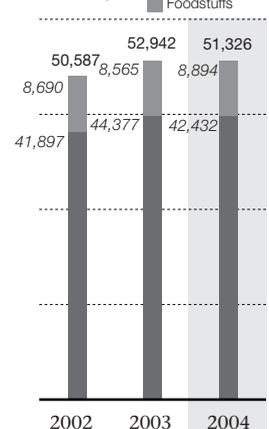
Consolidated Operating Income

(Millions of yen)



Consolidated Sales by Industry Segment

(Millions of yen)



Consolidated Balance Sheets

March 31, 2004 and 2003	Millions of yen		Thousands of U.S. dollars (Note 1)
	2004	2003	2004
Assets			
Current assets:			
Cash and cash equivalents	¥ 20,032	¥ 25,910	\$ 188,981
Time deposits	100	90	943
Marketable securities (Note 3)	2,301		21,707
Notes and accounts receivable:			
Trade notes	1,253	1,556	11,821
Trade accounts	22,443	24,266	211,726
Other	92	180	868
Allowance for doubtful receivables and sales returns		(23)	
Total notes and accounts receivable, net	23,788	25,979	224,415
Inventories (Note 4)	8,924	8,543	84,189
Deferred tax assets (Note 10)	1,543	1,550	14,557
Other current assets	1,322	1,504	12,472
Total current assets	58,010	63,576	547,264
Property, plant and equipment (Note 5):			
Land	8,823	8,800	83,236
Buildings and structures	25,102	24,899	236,811
Machinery and equipment	11,614	11,775	109,566
Tools, furniture and fixtures	9,579	9,550	90,368
Construction in progress	958	33	9,038
Total	56,076	55,057	529,019
Accumulated depreciation	(31,620)	(30,056)	(298,302)
Net property, plant and equipment	24,456	25,001	230,717
Investments and other assets:			
Investment securities (Note 3)	14,124	10,416	133,245
Long-term prepaid expenses	2,679	3,475	25,274
Deferred tax assets (Note 10)	2,091	4,168	19,727
Other assets	2,648	2,913	24,981
Total investments and other assets	21,542	20,972	203,227
Total	¥104,008	¥109,549	\$ 981,208

See notes to consolidated financial statements.

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2004	2003	2004
Liabilities and Shareholders' Equity			
Current liabilities:			
Short-term borrowings (Note 5)	¥ 4,030	¥ 4,250	\$ 38,019
Current portion of long-term debt (Note 5)	1,297	7,087	12,236
Notes and accounts payable:			
Trade notes	417	402	3,934
Trade accounts	2,989	3,118	28,198
Construction	927	336	8,746
Total notes and accounts payable	4,333	3,856	40,878
Income taxes payable	1,309	3,127	12,349
Accrued expenses	5,326	5,691	50,245
Deposits from customers	260	248	2,453
Other current liabilities	597	831	5,632
Total current liabilities	17,152	25,090	161,812
Long-term liabilities:			
Long-term debt (Note 5)	4,951	5,748	46,708
Liability for retirement benefits (Note 6)	16,357	16,934	154,311
Negative goodwill	1	17	9
Total long-term liabilities	21,309	22,699	201,028
Minority interests	151	146	1,425
Contingent liabilities (Note 11)			
Shareholders' equity (Notes 7 and 14):			
Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares ...	5,174	5,174	48,811
Capital surplus	4,439	4,439	41,877
Retained earnings	51,621	50,837	486,991
Unrealized gain on available-for-sale securities	5,049	1,912	47,632
Foreign currency translation adjustments	(9)	(3)	(85)
Treasury stock – at cost, 1,458,891 shares in 2004 and 1,239,255 shares in 2003.....	(878)	(745)	(8,283)
Total shareholders' equity	65,396	61,614	616,943
Total	¥104,008	¥109,549	\$981,208

Consolidated Statements of Income

Years ended March 31, 2004 and 2003	Millions of yen		Thousands of U.S. dollars (Note 1)
	2004	2003	2004
Net sales (Note 15)	¥51,326	¥52,942	\$484,208
Cost and expenses (Note 15):			
Cost of sales	21,461	23,139	202,463
Selling, general and administrative expenses (Note 8)	26,390	25,534	248,962
Total	47,851	48,673	451,425
Operating income (Note 15)	3,475	4,269	32,783
Other income (expenses):			
Interest and dividend income	168	163	1,585
Interest expenses	(220)	(182)	(2,075)
Gain on sales of property, plant and equipment	2	460	19
Other – net	(163)	(236)	(1,538)
Other income (expenses) – net	(213)	205	(2,009)
Income before income taxes and minority interests	3,262	4,474	30,774
Income taxes (Note 10):			
Current	1,818	3,854	17,151
Deferred	(99)	(1,479)	(934)
Total	1,719	2,375	16,217
Minority interests	7	4	66
Net income	¥ 1,536	¥ 2,095	\$ 14,491

	Yen		U.S. dollars
Amounts per common share (Notes 2.n and 13):			
Basic net income	¥21.50	¥29.20	\$0.20
Diluted net income		27.80	
Cash dividends applicable to the year	10.00	10.00	0.09

See notes to consolidated financial statements.

Consolidated Statements of Shareholders' Equity

Years ended March 31, 2004 and 2003	Thousands	Millions of yen					
	Outstanding number of shares of common stock	Common stock	Capital surplus	Retained earnings	Unrealized gain on available-for-sale securities	Foreign currency translation adjustments	Treasury stock
Balance at April 1, 2002	70,228	¥5,174	¥4,439	¥49,492	¥2,676	¥ 4	¥ (15)
Net income				2,095			
Cash dividends, ¥10.00 per share				(702)			
Bonuses to directors and corporate auditors				(48)			
Net decrease in unrealized gain on available-for-sale securities					(764)		
Net decrease in foreign currency translation adjustments						(7)	
Repurchase of treasury stock	(1,216)						(730)
Balance at March 31, 2003	69,012	5,174	4,439	50,837	1,912	(3)	(745)
Net income				1,536			
Cash dividends, ¥10.00 per share				(690)			
Bonuses to directors and corporate auditors				(62)			
Net increase in unrealized gain on available-for-sale securities					3,137		
Net decrease in foreign currency translation adjustments						(6)	
Repurchase of treasury stock	(220)						(134)
Disposal of treasury stock	1						1
Balance at March 31, 2004	68,793	¥5,174	¥4,439	¥51,621	¥5,049	¥(9)	¥(878)

	Thousands of U.S. dollars (Note 1)					
	Common stock	Capital surplus	Retained earnings	Unrealized gain on available-for-sale securities	Foreign currency translation adjustments	Treasury stock
Balance at March 31, 2003	\$48,811	\$41,877	\$479,594	\$18,038	\$(28)	\$(7,028)
Net income			14,491			
Cash dividends, \$0.09 per share			(6,509)			
Bonuses to directors and corporate auditors			(585)			
Net increase in unrealized gain on available-for-sale securities.....				29,594		
Net decrease in foreign currency translation adjustments					(57)	
Repurchase of treasury stock						(1,264)
Disposal of treasury stock						9
Balance at March 31, 2004	\$48,811	\$41,877	\$486,991	\$47,632	\$(85)	\$(8,283)

See notes to consolidated financial statements.

Consolidated Statements of Cash Flows

Years ended March 31, 2004 and 2003	Millions of yen		Thousands of U.S. dollars (Note 1)
	2004	2003	2004
Operating activities:			
Income before income taxes and minority interests	¥ 3,262	¥ 4,474	\$ 30,774
Adjustments for:			
Income taxes – paid.....	(3,637)	(982)	(34,311)
Depreciation and amortization	3,155	3,626	29,764
Gain on sales of property, plant and equipment.....	(2)	(460)	(19)
Changes in assets and liabilities:			
Decrease in notes and accounts receivable.....	2,214	1,018	20,887
Decrease (increase) in inventories	(381)	158	(3,594)
Decrease (increase) in other current assets	182	(629)	1,717
Increase (decrease) in notes and accounts payable	(114)	83	(1,076)
Decrease in other current liabilities	(234)	(381)	(2,208)
Increase (decrease) in liability for retirement benefits	(576)	217	(5,434)
Other, net	199	(797)	1,877
Total adjustments	806	1,853	7,603
Net cash provided by operating activities	4,068	6,327	38,377
Investing activities:			
Proceeds from sales of property, plant and equipment	5	611	47
Proceeds from redemption of marketable securities		1,000	
Capital expenditures	(1,307)	(5,459)	(12,330)
Purchases of investment securities	(696)	(419)	(6,566)
Increase in time deposits.....	(10)	(30)	(94)
Purchases of software	(48)	(98)	(453)
Payment of royalty.....	(219)	(1,675)	(2,066)
Other, net	2	(11)	19
Net cash used in investing activities	(2,273)	(6,081)	(21,443)
Financing activities:			
Net decrease in short-term bank loans	(220)		(2,075)
Proceeds from long-term bank loans	740	5,350	6,981
Redemption of convertible bonds.....	(7,000)		(66,038)
Repayments of long-term debt	(324)	(70)	(3,056)
Cash dividends paid	(691)	(702)	(6,519)
Increase of treasury stock	(133)	(730)	(1,255)
Other, net	(2)	(1)	(19)
Net cash provided by (used in) financing activities	(7,630)	3,847	(71,981)
Foreign currency translation adjustments			
on cash and cash equivalents	(43)	(62)	(406)
Net increase (decrease) in cash and cash equivalents	(5,878)	4,031	(55,453)
Cash and cash equivalents, beginning of year	25,910	21,879	244,434
Cash and cash equivalents, end of year	¥20,032	¥25,910	\$ 188,981

See 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 Securities and Exchange Law and its related accounting regulations, and in conformity with accounting principles generally accepted in Japan, which are different in certain respects as to application and disclosure requirements of International Financial Reporting Standards.

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form which is more familiar to readers outside Japan. In addition, certain reclassifications have been made in the 2003 financial statements to conform to the classifications used in 2004.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Nippon Shinyaku Co., Ltd. (the "Company") is incorporated and operates. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been made at the rate of ¥106 to \$1, the approximate rate of exchange at March 31, 2004. 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 include the accounts of the Company and its significant two domestic and one overseas subsidiaries (together, the "Companies"). Consolidation of the remaining subsidiary would not have a material effect on the accompanying consolidated financial statements. Under the control or influence concept, those companies in which the Company, directly or indirectly, is able to exercise control over operations are fully consolidated, and those companies over which the Companies have the ability to exercise significant influence are accounted for by the equity method.

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

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 and short-term investments, 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 those securities not classified as held-to-maturity securities, are reported at fair value, with unrealized gains and losses, net of applicable taxes, reported as a separate component of shareholders' 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. All other 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 are stated principally at cost determined by the average method.

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 7 to 9 years for machinery and equipment, and from 4 to 6 years for tools, furniture and fixtures.

f. Retirement and Pension Plans — The Company has non-contributory and contributory defined benefit pension plans and unfunded retirement benefit plan for employees. Consolidated domestic subsidiaries have unfunded retirement benefit plans.

Effective April 1, 2000, the Companies adopted a new accounting standard for employees' retirement benefits and accounted for the liability for retirement benefits based on projected benefit obligations and plan assets at the balance sheet date. The transitional credit of ¥845 million determined as of April 1, 2000 is being amortized over five years.

On August 1, 2003, the Company resolved to integrate the corporate portion of its contributory funded defined benefit pension plan established at the discretion of the Company under the Japanese Welfare Pension Insurance Law, non-contributory defined benefit pension plan and part of the unfunded retirement benefit plan to introduce a cash balance pension plan. The employees of the Company are covered by the contributory funded defined benefit pension plan until April 1, 2004 when approval by the Ministry of Health, Labor and Welfare to transfer the substitutional portion of past pension obligations to the government was obtained and the cash balance pension plan was implemented. See Notes 6 and 14. a. Under the cash balance pension plan, 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.

On December 1, 2003, the Company introduced a defined contribution pension plan to allow qualified persons aged from 60 to 64 to receive post retirement benefits at their discretion.

Retirement benefits to directors and corporate auditors are provided at the amount which would be required if such individuals were to retire at the balance sheet date.

g. 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.

h. Leases — All leases, except those of the overseas subsidiary, are accounted for as operating leases. Under Japanese accounting standards for leases, finance leases that are deemed to transfer ownership of the leased property to the lessee are to be capitalized, while other finance leases are permitted to be accounted for as operating lease transactions if certain "as if capitalized" information is disclosed in the notes to the lessee's consolidated financial statements.

- i. 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.
- j. Appropriations of Retained Earnings** — Appropriations of retained earnings are reflected in the consolidated financial statements for the following year upon shareholders' approval.
- k. 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 statement of income to the extent that they are not hedged by forward exchange contracts.
- l. 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 shareholders' equity, which is translated at historical rates. Differences arising from such translation are reported as a separate component of shareholders' equity.
- m. 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.
- n. 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.
- Diluted net income per share reflects the potential dilution that could occur if securities were converted into common stock. Diluted net income per share of common stock assumes full conversion of the outstanding convertible bonds at the beginning of the year (or at the time of issuance) with an applicable adjustment for related interest expense, net of tax.
- 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.
- o. New Accounting Pronouncements** — In August 2002, the Business Accounting Council issued a Statement of Opinion, "Accounting for Impairment of Fixed Assets", and in October 2003 the Accounting Standards Board of Japan (ASB) issued ASB Guidance No.6, "Guidance for Accounting Standard for Impairment of Fixed Assets". These new pronouncements are effective for fiscal years beginning on or after April 1, 2005 with early adoption permitted for fiscal years ending on or after March 31, 2004.
- The new accounting standard requires an entity to review its long-lived assets for impairment whenever events or changes in circumstances indicate that 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.

The Company expects to adopt these pronouncements as of April 1, 2005 and is currently in the process of assessing the effect of adoption of these pronouncements.

3. MARKETABLE AND INVESTMENT SECURITIES

Marketable and investment securities as of March 31, 2004 and 2003 consisted of the following:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Current:			
Government and corporate bonds	¥ 2,001		\$ 18,877
Trust fund investments	300		2,830
Total.....	¥ 2,301		\$ 21,707
Non-current:			
Equity securities.....	¥12,218	¥ 6,706	\$115,264
Government and corporate bonds	1,906	3,410	17,981
Trust fund investments.....		300	
Total.....	¥14,124	¥10,416	\$133,245

Information regarding each category of securities classified as available-for-sale and held-to-maturity at March 31, 2004 and 2003 were as follows:

March 31, 2004	Millions of yen			
	Cost	Unrealized gain	Unrealized loss	Fair value
Securities classified as:				
Available-for-sale:				
Equity securities	¥3,205	¥8,572	¥16	¥11,761
Debt securities	5	1		6
Held-to-maturity	3,901	28		3,929
Millions of yen				
March 31, 2003	Cost	Unrealized gain	Unrealized loss	Fair value
Securities classified as:				
Available-for-sale:				
Equity securities	¥3,009	¥3,351	¥112	¥6,248
Debt securities	5	1		6
Held-to-maturity	3,404	57		3,461

March 31, 2004	Thousands of U.S. dollars			
	Cost	Unrealized gain	Unrealized loss	Fair value
Securities classified as:				
Available-for-sale:				
Equity securities	\$30,236	\$80,868	\$151	\$110,953
Debt securities	47	10		57
Held-to-maturity	36,802	264		37,066

Available-for-sale securities whose fair value is not readily determinable as of March 31, 2004 and 2003 were as follows:

March 31	Carrying amount		
	Millions of yen	2003	Thousands of U.S. dollars
2004	2003	2004	
Available-for-sale:			
Equity securities	¥457	¥458	\$4,311
Trust fund investments.....	300	300	2,830
Total.....	¥757	¥758	\$7,141

The carrying values of debt securities by contractual maturities for securities classified as available-for-sale and held-to-maturity at March 31, 2004 are as follows:

March 31, 2004	Millions of yen		Thousands of U.S. dollars	
	Available for Sale	Held to Maturity	Available for Sale	Held to Maturity
Due in one year or less	¥300	¥2,001	\$2,830	\$18,877
Due after one year through five years.....	¥ 6	¥1,900	\$ 57	\$17,925

4. INVENTORIES

Inventories at March 31, 2004 and 2003 consisted of the following:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Finished products and merchandise.....	¥4,841	¥4,335	\$45,670
Work in process	1,969	1,601	18,576
Raw materials.....	2,114	2,607	19,943
Total.....	¥8,924	¥8,543	\$84,189

5. SHORT-TERM BORROWINGS AND LONG-TERM DEBT

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

The weighted average annual interest rates for short-term bank loans at March 31, 2004 and 2003 were 0.67% and 0.71%, respectively.

Short-term borrowings at March 31, 2004 and 2003 consisted of the following:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Loans from banks, 0.59% to 1.375% (2004) and 0.59% to 1.375% (2003)	¥4,030	¥4,000	\$38,019
Loans from other financial institutions, 1.375% (2003)		250	
Total.....	¥4,030	¥4,250	\$38,019

Long-term debt at March 31, 2004 and 2003 consisted of the following:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Unsecured 1.6% yen convertible bonds, due March 2004.....		¥ 7,000	
Loan from a financial institution, 0.86% to 2.3% (2004) and 0.9% to 2.3% (2003), due November 2012.....	¥6,243	5,827	\$58,897
Capital lease obligations	5	8	47
Total.....	6,248	12,835	58,944
Less current portion.....	(1,297)	(7,087)	(12,236)
Long-term debt, less current portion	¥4,951	¥ 5,748	\$46,708

Annual maturities of long-term debt at March 31, 2004 were as follows:

Year ending March 31	Millions of yen	Thousands of U.S. dollars
2005	¥1,297	\$12,236
2006	1,297	12,236
2007	1,237	11,670
2008	1,195	11,272
2009	1,163	10,972
2010 and thereafter	59	558
Total.....	¥6,248	\$58,944

At March 31, 2004, the following assets were pledged as collateral for certain short-term borrowings and long-term debt (including current portion):

	Millions of yen	Thousands of U.S. dollars
Property, plant and equipment, net of accumulated depreciation	¥6,646	\$ 62,698
Related liabilities:		
Short-term borrowings.....	¥3,460	\$ 32,642
Current portion of long-term debt	¥1,147	\$ 10,821
Long-term debt (excluding current portion)	¥4,366	\$ 41,189

6. RETIREMENT BENEFITS

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 non-contributory and contributory trustee pension plans which fund a portion of the Company's retirement benefits. The contributory funded defined benefit pension plan, which is established under the Japanese Welfare Pension Insurance Law, covers a substitutional portion of the governmental pension program managed by the Company on behalf of the government and a corporate portion established at the discretion of the Company.

In accordance with the Defined Benefit Pension Plan

Law enacted in April 2002, the Company applied for an exemption from obligation to pay benefits for future employee services related to the substitutional portion which would result in the transfer of the pension obligations and related assets to the government upon approval. The Company obtained approval for exemption from the future obligation by the Ministry of Health, Labor and Welfare on February 25, 2003. The substitutional portion of the plan assets which will be transferred to the government in the subsequent year is measured to be approximately ¥4,659 million (\$43,953 thousand) as at March 31, 2004. If such substitutional portion of the plan assets would be transferred to the government on March 31, 2004, income before income taxes and minority interests would have increased by approximately ¥3,769 million (\$35,557 thousand). See Note 14.a.

The liability for employees' retirement benefits at March 31, 2004 and 2003 consisted of the following:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Projected benefit obligation...	¥34,524	¥31,217	\$325,698
Fair value of plan assets	(11,652)	(10,484)	(109,924)
Unrecognized actuarial loss ...	(7,918)	(6,561)	(74,698)
Unrecognized transitional credit	169	338	1,594
Unrecognized prior service cost	964	1,736	9,094
Prepaid pension cost		407	
Net liability	¥16,087	¥16,653	\$151,764

The components of net periodic benefit costs for the years ended March 31, 2004 and 2003 are as follows:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Service cost	¥ 911	¥1,591	\$ 8,594
Interest cost	789	773	7,443
Expected return on plan assets	(575)	(603)	(5,424)
Amortization of transitional credit	(169)	(169)	(1,594)
Recognized actuarial loss	468	351	4,415
Amortization of prior service cost	(95)	(51)	(896)
Net periodic benefit costs	¥1,329	¥1,892	\$12,538

Assumptions used for the years ended March 31, 2004 and

2003 are set forth as follows:

	2004	2003
Discount rate.....	2.0%	2.5%
Expected rate of return on plan assets...	4.0%	5.5%
Recognition period of actuarial gain / loss	15 years	15 years
Amortization period of transitional credit	5 years	5 years
Amortization period of prior service cost	15 years	15 years

The liability for retirement benefits at March 31, 2004 and 2003 included ¥270 million (\$2,547 thousand) and ¥281 million, respectively, for directors' and corporate auditors' retirement benefits.

7. SHAREHOLDERS' EQUITY

Japanese companies are subject to the Japanese Commercial Code (the "Code") to which various amendments have become effective since October 1, 2001.

The Code was revised whereby common stock par value was eliminated resulting in all shares being recorded with no par value and at least 50% of the issue price of new shares is required to be recorded as common stock and the remaining net proceeds as additional paid-in capital (a component of capital surplus). The Code permits Japanese companies, upon approval of the Board of Directors, to issue shares to existing shareholders without consideration as a stock split. Such issuance of shares generally does not give rise to changes within the shareholders' accounts.

The revised Code also provides that an amount at least equal to 10% of the aggregate amount of cash dividends and certain other appropriations of retained earnings associated with cash outlays applicable to each period shall be appropriated as a legal reserve (a component of retained earnings) until such reserve and additional paid-in capital equal 25% of common stock. The amount of total additional paid-in capital and legal reserve that exceeds 25% of the common stock may be available for dividends by resolution of the shareholders. In addition, the Code permits the transfer of a portion of additional paid-in capital and legal reserve to the common stock by resolution of the Board of Directors.

The revised Code eliminated restrictions on the

repurchase and use of treasury stock allowing Japanese companies to repurchase treasury stock by a resolution of the shareholders at the general shareholders meeting and dispose of such treasury stock by resolution of the Board of Directors. The repurchased amount of treasury stock cannot exceed the amount available for future dividend plus amount of common stock, additional paid-in capital or legal reserve to be reduced in the case where such reduction was resolved at the general shareholders, meeting.

The amount of retained earnings available for dividends under the Code was ¥47,632 million (\$449,358 thousand) as of March 31, 2004, based on the amount recorded in the Company's general books of account. In addition to the provision that requires an appropriation for a legal reserve in connection with the cash payment, the Code imposes certain limitations on the amount of retained earnings available for dividends.

Dividends are approved by the shareholders at a meeting held subsequent to the fiscal year to which the dividends are applicable. Semiannual interim dividends may also be paid upon resolution of the Board of Directors, subject to certain limitations imposed by the Code.

At the general shareholders' meeting held on June 27, 2003, the Company's shareholders authorized the Company to repurchase up to 6 million shares of the Company's common stock (aggregate amount of ¥5,000 million) as treasury stock until the closing of the next general shareholders' meeting in accordance with the revised Code. The Company repurchased 195 thousand shares (aggregate amount of ¥117 million (\$1,104 thousand)) of the Company's common stock under this plan for the year ended March 31, 2004.

8. RESEARCH AND DEVELOPMENT COSTS

Research and development costs for the years ended March 31, 2004 and 2003 were ¥8,263 million (\$77,953 thousand) and ¥7,885 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, 2004 and 2003 were ¥1,243 million (\$11,726 thousand) and ¥1,230 million, respectively, including ¥193 million (\$1,821 thousand) and ¥184 million of lease payments under finance leases, respectively.

Pro forma information of leased property under finance leases that do not transfer ownership of the leased property to the lessee on an "as if capitalized" basis for the years ended March 31, 2004 and 2003 was as follows:

Machinery and equipment, and tools, furniture and fixtures:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Acquisition cost	¥139	¥118	\$1,311
Accumulated depreciation.....	77	54	726
Net leased property.....	¥ 62	¥ 64	\$ 585

Obligations under finance leases:

March 31	Millions of yen		Thousands of U.S. dollars
	2004	2003	2004
Due within one year	¥25	¥22	\$236
Due after one year.....	37	42	349
Total.....	¥62	¥64	\$585

Depreciation expense, which is not reflected in the accompanying consolidated statements of income, computed by the straight-line method was ¥23 million (\$217 thousand) and ¥24 million for the years ended March 31, 2004 and 2003, respectively.

The minimum rental commitments under non-cancelable operating leases at March 31, 2004 and 2003 were as follows:

March 31	Millions of yen		Thousands of
	2004	2003	U.S. dollars
Due within one year	¥10	¥10	\$ 94
Due after one year.....	23	36	217
Total.....	¥33	¥46	\$311

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 42% for the years ended March 31, 2004 and 2003. The overseas subsidiary is subject to income tax of the country in which it operates.

On March 31, 2003, a tax reform law concerning enterprise tax was enacted in Japan which changed the normal effective statutory tax rate from 42% to 41%, effective for years beginning on or after April 1, 2004. The deferred tax assets and liabilities which will realize on or after April 1, 2004 are measured at the effective tax rate of 41% as at March 31, 2004 and 2003.

The tax effects of significant temporary differences which resulted in deferred tax assets and liabilities at March 31, 2004 and 2003 are as follows:

	Millions of yen		Thousands of
	2004	2003	U.S. dollars
Deferred Tax Assets:			
Retirement benefits	¥6,068	¥5,920	\$57,245
Accrued expenses	1,131	887	10,670
Property, plant and equipment	163	185	1,538
Other	904	1,169	8,529
Deferred tax assets	8,266	8,161	77,982
Deferred Tax Liabilities:			
Unrealized gain on available-for-sale securities	3,508	1,328	33,094
Deferred gains on sales of property	971	982	9,160
Other	153	133	1,444
Deferred tax liabilities.....	4,632	2,443	43,698
Net deferred tax assets	¥3,634	¥5,718	\$34,284

A reconciliation between the normal effective statutory tax rates for the years ended March 31, 2004 and 2003 and the actual effective tax rates reflected in the accompanying consolidated statements of income is as follows:

	Year ended March 31,	
	2004	2003
Normal effective statutory tax rate.....	42.0%	42.0%
Expenses not deductible for income tax purposes	12.8	8.9
Income not taxable for income tax purposes	(0.6)	(0.6)
Effect of tax rate reduction	1.2	3.0
Other – net	(2.7)	(0.2)
Actual effective tax rate	52.7%	53.1%

11. CONTINGENT LIABILITIES

At March 31, 2004, contingent liabilities were ¥889 million (\$8,387 thousand) of loans guaranteed (jointly guaranteed with six unrelated companies) and ¥7 million (\$66 thousand) of export bill receivables discounted and sold to a financial institution for which the Company is

contingently liable.

12. DERIVATIVES

The Company has no internal policies which regulate derivative transactions, since the Company's derivative transactions are specific foreign exchange forward contracts. However, it is the Company's basic practice not to use derivatives for trading or speculative purposes. The Company has entered into foreign exchange forward contracts to hedge foreign exchange risk specifically associated with imported merchandise, as requested by customers. 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.

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, 2004 and 2003 is as follows:

	Yen in millions	Thousands of shares	Yen	Dollars
	Net income	Weighted average shares	EPS	
For the year ended				
March 31, 2004:				
Basic EPS				
Net income available to common shareholders	¥1,483	68,958	¥21.50	\$0.20
For the year ended				
March 31, 2003:				
Basic EPS				
Net income available to common shareholders	¥2,039	69,865	¥29.20	
Effect of Dilutive Securities				
Convertible bonds ...	65	5,769		
Diluted EPS				
Net income for computation.....	¥2,105	75,634	¥27.80	

Diluted net income per share is not disclosed for the year ended March 31, 2004 because there are no convertible bonds outstanding at March 31, 2004.

14. SUBSEQUENT EVENTS

- a. The Company obtained approval for transfer of the substitutional portion of past pension obligations to the government by the Ministry of Health, Labor and Welfare on April 1, 2004. The actual transfer of the pension obligations and related assets to the government is to take place subsequently after the governments's approval. Based upon the above approval in April, 2004, the Company currently expects to recognize a gain on such transfer in the amount of ¥3,769 million (\$35,557 thousand) for the year ending March 31, 2005.
- b. At the general shareholders' meeting held on June 29, 2004, the Company's shareholders approved the following:
 - 1) Payment of a year-end cash dividend of ¥5.00 (\$0.05) per share to holders of record at March 31, 2004 for a total of ¥344 million (\$3,245 thousand).
 - 2) Payment of bonuses to directors and corporate auditors of ¥53 million (\$500 thousand).

15. SEGMENT INFORMATION

Information about industry segments of the Companies for the years ended March 31, 2004 and 2003 is as follows:

Industry Segments

a. Sales and Operating Income

	Millions of yen				Thousands of U.S. dollars			
	2004				2004			
	Pharmaceuticals	Foodstuffs	Eliminations/ Corporate	Consolidated	Pharmaceuticals	Foodstuffs	Eliminations/ Corporate	Consolidated
Sales to customers.....	¥42,432	¥8,894		¥51,326	\$400,302	\$83,906		\$484,208
Intersegment sales	4		¥ (4)		38		\$(38)	
Total sales	42,436	8,894	(4)	51,326	400,340	83,906	(38)	484,208
Operating expenses.....	39,125	8,730	(4)	47,851	369,104	82,359	(38)	451,425
Operating income	¥ 3,311	¥ 164	¥Nil	¥ 3,475	\$ 31,236	\$ 1,547	\$Nil	\$ 32,783

b. Assets, Depreciation and Capital Expenditures

	Millions of yen				Thousands of U.S. dollars			
	2004				2004			
	Pharmaceuticals	Foodstuffs	Eliminations/ Corporate	Consolidated	Pharmaceuticals	Foodstuffs	Eliminations/ Corporate	Consolidated
Assets.....	¥59,807	¥6,826	¥37,375	¥104,008	\$564,217	\$64,396	\$352,595	\$981,208
Depreciation	2,907	248		3,155	27,425	2,339		29,764
Capital expenditures.....	1,730	99		1,829	16,321	934		17,255

a. Sales and Operating Income

	Millions of yen			
	2003			
	Pharmaceuticals	Foodstuffs	Eliminations/ Corporate	Consolidated
Sales to customers.....	¥44,377	¥8,565		¥52,942
Intersegment sales	4		¥ (4)	
Total sales	44,381	8,565	(4)	52,942
Operating expenses.....	40,225	8,452	(4)	48,673
Operating income	¥ 4,156	¥ 113	¥Nil	¥ 4,269

b. Assets, Depreciation and Capital Expenditures

	Millions of yen			
	2003			
	Pharmaceuticals	Foodstuffs	Eliminations/ Corporate	Consolidated
Assets.....	¥62,574	¥6,713	¥40,262	¥109,549
Depreciation	3,359	267		3,626
Capital expenditures.....	3,978	392		4,370

Deloitte.

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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. and consolidated subsidiaries as of March 31, 2004 and 2003, and the related consolidated statements of income, shareholders' 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, 2004 and 2003, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in Japan.

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

Deloitte Touche Tohmatsu

June 29, 2004

Member of
Deloitte Touche Tohmatsu

Corporate Directory

Founded

October 1919

Date of Incorporation

September 1919

Paid-in Capital

¥5,174 million

Issued and Outstanding Number of Shares

70,251,484

Independent and Certified Public Accountants

Deloitte Touche Tohmatsu
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Transfer Agent

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Major Shareholders

Meiji Yasuda Life Insurance Company
Nippon Life Insurance Company
The Bank of Tokyo-Mitsubishi,
Limited
The Kyoto Bank, Limited
Japan Trustee Services Bank, Limited
The Tokio Marine and Fire Insurance
Company, Limited
State Street Bank and Trust Company
The Master Trust Bank of Japan,
Limited
Mitsubishi Corporation
The Daiichi Mutual Life Insurance
Company

(As of March 31, 2004)

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Chitose Create Park

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Morioka Factory

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Morioka 020-0133, Japan

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Germany
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(As of July 2004)

Overseas Subsidiary

NS Pharma, Inc.

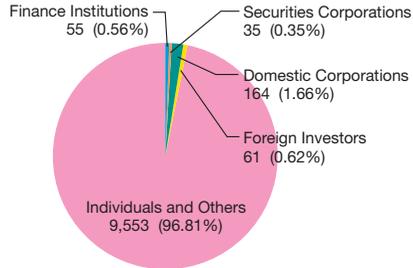
President: Shun Aruga

9 Campus Drive, 3rd Floor
Parsippany, NJ07054, U.S.A.
Phone: 973-285-7010
Fax: 973-267-4240

Distribution of Shareholders and Shares

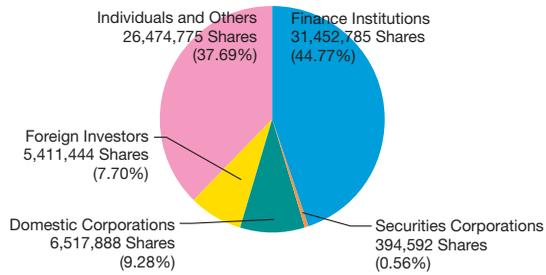
◆ Number of Shareholders

9,868 (100.00%)



◆ Number of Shares Issued

70,251,484 Shares (100.00%)



Stock Price Range

Stock price (Yen)

