The cover illustration is from "The Mysterious Blue Elephant," a picturebook published through the Nippon Shinyaku Children's Literary Awards contest. For more information about the contest, please refer to page 27 of this report.
Nippon Shinyaku at a Glance

Helping people lead healthier, happier lives

Nippon Shinyaku has provided products that help people lead healthier and happier lives through our pharmaceuticals business—part of our company since day one—and our functional food business, which operates under the belief that food is a form of medicine.

In the pharmaceuticals segment, we believe that our mission is to continually develop novel and unique medicines that benefit patients. In the functional food segment, we leverage our expertise in pharmaceuticals to deliver proprietary functional food ingredients that are beneficial to society and that help people live healthier lives.

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Elpers®
\textsuperscript{1}Hydroxyurea
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Drugs for Inflammation and Allergy 62
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Vanabo®

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Triton®

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Preservatives 129
Garcinia Powder J
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Nokko®

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Others 168
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We leverage our expertise in safety and quality control to promote high quality medicines that are safe and effective and that are supported by objective evidence of efficacy.

In the functional food segment, we utilize the advanced manufacturing technologies developed in our pharmaceutical business to manufacture high-quality, pure and concentrated ingredients as well as new products from functional foods.

We are committed to responding to unmet medical needs.

In 2011, we introduced Vidaza®, a treatment for myelodysplastic syndrome (MDS), which is a disease of the blood and bone marrow. Vidaza® also received regulatory approval outside of Japan.

We supply preservatives that can be used for just about any application, including in various foods and minimize effects on flavor. Our extensive lineup can be used in a variety of applications.

The health-food ingredients offered to date include Hokkaido melon, haskap, and cantaloupe melons produced in Hokkaido, as well as juice extracts from these fruits, onion concentrate, extracts, and various pharmaceuticals.

We have grown the market for functional food ingredients, thanks to new evidence of efficacy.

Although the market for functional food ingredients has contracted in recent years, we remain committed to promoting our products’ health benefits and continue to develop new ingredients in order to meet patients’ needs.

Nippon Shinyaku has provided products that help people lead healthier and happier lives and has been growing ever since, responding to unmet medical needs and engaging in socially responsible activities. Our mission is to continually develop novel and unique medicines that benefit patients and functional food ingredients that are beneficial to society.

We are committed to responding to unmet medical needs and to leveraging our expertise in pharmaceuticals to deliver functional food ingredients that are beneficial to society and help people live healthier lives.

*Figures presented in this report are taken from Nippon Shinyaku’s Financial Report for the fiscal year ended March 31, 2012. As figures have been rounded, totals may not exactly equal the sum of their composite statistics.

Forward-looking statements:

Statements contained in the 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 uncertainty. Actual results may therefore differ from those in the forward-looking statements.
### Consolidated Financial Highlights

#### Summary of consolidated financial index

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<tbody>
<tr>
<td>Net sales</td>
<td>67,304</td>
<td>62,952</td>
<td>62,576</td>
<td>60,072</td>
<td>58,410</td>
<td>58,210</td>
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<td>R&amp;D expenses</td>
<td>5,564</td>
<td>10,813</td>
<td>10,559</td>
<td>10,845</td>
<td>11,780</td>
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<td>211</td>
<td>245</td>
<td>240</td>
<td>247</td>
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#### Functional food

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<td>211</td>
<td>245</td>
<td>240</td>
<td>247</td>
<td>203</td>
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</table>

#### Pharmaceuticals

<table>
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<tr>
<td>ESG indices</td>
<td>211</td>
<td>245</td>
<td>240</td>
<td>247</td>
<td>203</td>
</tr>
</tbody>
</table>

#### Principle financial index

- **Net sales**
- **Operating income**
- **Net income**
- **R&D expenses**
- **Dividend per share**

#### Notes:
- U.S. dollar amounts are converted from yen amounts at the rate of U.S.$1 = ¥82, the approximate exchange rate on March 31, 2012.
- ESG indices reflect environmental, social, and corporate governance initiatives.
- ESG indices are summarized in thousands of GJ, tons, and millions of yen.

#### Key financial metrics:
- **Ratio of net worth (%)**
- **Return on equity (%)**
- **Pay ratio (%)**

#### Revenue per share

- **Earnings per share (yen)**
- **Dividend per share (yen)**

#### Total assets / Net assets (millions of yen)

#### Ratio of net worth (%)
To Our Stakeholders

Business Results for the Fiscal Year Ended March 31, 2012

Helping People Lead Healthier, Happier Lives

Business Philosophy

Helping People Lead Healthier, Happier Lives

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

Shigenobu Maekawa
President

Focus on Marketing New Products with High Added-Value amid Challenging Business Conditions

The fiscal year ended March 31, 2012 was a difficult year for the Japanese economy, which was impacted by the Great East Japan Earthquake and other factors such as the strong yen and financial crisis in Europe.

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

Under the circumstances, the Nippon Shinyaku Group recorded net sales of ¥97,304 million (up 5.9% year-on-year), operating profits of ¥6,012 million (up 16.1% year-on-year), and ordinary income of ¥6,193 million (up 13.1% year-on-year). Net income was ¥3,715 million (down 6.1% year-on-year), due to factors such as an increase in income tax adjustments necessitated by changes to the effective tax rate.

In the pharmaceuticals segment, lower than normal patent costs affected sales of Livestan® allergy remedy and Baynov® remedy for allergies, while competition from other pharmaceuticals and generic drugs led to lower sales of Hypon™-non-steroidal anti-inflammatory agent. Sales from six products that we released to the market starting in 2008 contributed significantly to an overall increase in net sales. We recorded significant increases in sales of products designed to address unmet medical needs, including Lunabel® dysmenorrhea remedy, Adcirca® treatment agent for pulmonary arterial hypertension, and Vidaza® remedy for myelodysplastic syndrome released in March 2011. As a result, net sales amounted to ¥55,746 million (up 6.1% year-on-year).

In the functional food segment, both the processed food and health food sectors continued to be marked by challenging business conditions. However, we significantly increased our sales of health food ingredients together with nutritional ingredients and preservatives, and recorded strong sales of protein preparations. As a result, net sales in the functional food segment were ¥11,558 million (up 5.4% year-on-year).

Management Policy

Customers: Supply unique and high-quality products

We will develop and supply pharmaceuticals that are safe and effective to address patients’ needs, first and foremost for patients who suffer from diseases. We will develop and supply high-quality, functional foods that meet the needs of customers.

Code of Conduct

Challenge: Meet Challenges

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

In the pharmaceuticals business, we have been focusing on developing and supplying unique and high-quality pharmaceuticals that are safe and highly effective relative to other drugs, and that in some way contribute to a better quality of life for patients, first and foremost for patients who suffer from diseases and targeting the fields of urology and hematology that we specialize in. By focusing on the three pillars of drug discovery research, in-licensing, and product life cycle management, we are striving to expand the pipeline of product development to consistently bring new pharmaceuticals to market.

Investigation: Spirit of Investigation

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

Investigation: Spirit of Investigation

We will develop each employee through goal-setting and action-oriented processes.

Employees: Develop each employee

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

Speed: Speedy Action

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

Investigation: Spirit of Investigation

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

Financial Position

Assets, Debts, and Net Assets

For the fiscal year ended March 31, 2012, total assets increased by ¥3,567 million year-on-year to ¥106,304 million. Total debts increased by ¥693 million year-on-year to ¥21,738 million. Net assets increased by ¥2,873 million year-on-year to ¥84,566 million.

Cash Flows

For the fiscal year ended March 31, 2012, cash and cash equivalents increased by ¥1,523 million year-on-year to ¥19,665 million. Net cash from operating activities amounted to ¥3,658 million, while net cash used in investing activities amounted to ¥759 million. Net cash expended for financing activities amounted to ¥1,341 million.

Challenging Business Conditions

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

In the pharmaceuticals business, we have been focusing on developing and supplying unique and high-quality pharmaceuticals that are safe and highly effective relative to other drugs, and that in some way contribute to a better quality of life for patients, first and foremost for patients who suffer from diseases and targeting the fields of urology and hematology that we specialize in. By focusing on the three pillars of drug discovery research, in-licensing, and product life cycle management, we are striving to expand the pipeline of product development to consistently bring new pharmaceuticals to market.
To Our Stakeholders

Aiming to Be a Company with a Meaningful Existence

At Nippon Shinyaku, we aim to be a company with a meaningful existence in healthcare, through business activities that are rooted in our business philosophy and guided by our management policy and codes of conduct. We pursue this vision by endeavoring to reinvent ourselves centering on five target areas, and secure growth through the process of reinvention.

In terms of sales, we are seeking to achieve balanced growth between our new and existing products. For marketing and informational activities, we are employing efficient and scientific approaches to managing our products and improving productivity among our medical representatives.

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

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

Nippon Shinyaku embraces a code of conduct: Meet Challenges, Speedy Action, and Spirit of Investigation. By making rapid and correct business decisions based on careful investigation and analysis, we will actively allocate our business resources to priority areas, while expanding our human resource development so that all employees can positively approach their work with pride and motivation. At the same time, we are renewing our personnel policies in an effort to boost employee motivation and facilitate their growth.

Executing Our Management Policy to Achieve Sustainable Growth Together with Society

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

In our CSR initiatives, we endeavor to strike a balance between social contributions through our business activities, and social contributions outside of business. Our initiatives separate from business activities include sponsorship of the Nippon Shinyaku Children’s Literary Awards contest and the Shining Future for Children Fund, which organizes a fundraising drive to provide vaccines for needy children in developing countries. We send employees to teach workshops for elementary school students in the community, and arrange for our corporate baseball team to conduct baseball clinics for youth. We are also involved in initiatives to preserve and maintain Kyoto culture, and operate the Yamashina Botanical Research Institute, which is open to the public.

Increased Sales and Profits

In the pharmaceuticals segment, we forecast increased sales in the next fiscal year, despite the effects of the April 2012 revisions to pharmaceutical prices under the National Insurance System, and the government’s policy to promote generic drug prescriptions. The drivers of increased sales are the further growth of Vidaza® remedy for myelodysplastic syndrome and Lunabel® dysmenorrhea remedy, which both contributed greatly during the current fiscal year, as well as Eriaxis* (14-day) treatment for allergic rhinitis launched in June 2012.

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

With the above in mind, we expect net sales of ¥99,100 million, operating profits of ¥6,400 million, ordinary income of ¥6,600 million, and net income of ¥4,200 million.

Dividends

Returning Profits to Shareholders

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

For the fiscal year ended March 31, 2013, we issued an annual cash dividend of ¥19 per share, comprising an interim dividend of ¥10 per share and year-end dividend of ¥9 per share.

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

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

**Responding to Unmet Medical Needs**

**Vidaza® — Japan’s First Treatment for Myelodysplastic Syndrome**

Myelodysplastic syndrome (MDS) is a group of intractable hematological disorders that often progress to leukemia. Vidaza® is an epoch-making novel drug developed in the United States that has been proven to be very effective in the treatment of MDS.

We launched Vidaza® in March 2011, and since then, we have engaged in information provision activities aimed at its further penetration in the market.

**Launch of Vidaza® Sales**

In March 2011, Nippon Shinyaku began selling Vidaza®, a remedy for MDS. This drug has been demonstrated to be highly effective in the treatment of MDS, and its release was much anticipated in Japan. As of March 31, 2012, we have supplied Vidaza® to some 550 medical institutions throughout the country, including university hospitals and training facilities affiliated with the Japanese Society of Hematology. Net sales of the drug have also grown to about ¥4,600 million.

**Number of Medical Institutions Supplied**

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>150</td>
</tr>
<tr>
<td>2011</td>
<td>550</td>
</tr>
</tbody>
</table>

**Launch of the Novel Drug in Japan As Quickly As Possible**

**Marketing Approval Obtained in January 2011**

Thanks to its comparatively mild side effects and strong efficacy, Vidaza® carried with it strong expectations for improving patient quality of life.

**Arrival of the Long-Awaited Novel MDS Drug Vidaza®**

Vidaza® represents a new type of MDS drug developed in the United States. In addition to killing cancerous cells, the drug is also effective at inhibiting DNA methylation, which epigenetically adjusts the on-off switch of genes. In an international phase III clinical trial (AZA-001) targeting high-risk MDS patients, treatment with Vidaza® significantly extended patient life compared to the group receiving conventional chemotherapy and also doubled the two-year survival rate**1** from 26% to 51%. Vidaza® has also been confirmed to help diaplay leukemia of the onco-laden.

The primary side effect of the drug was bone-marrow suppression**2**, but the severity and occurrence rate were comparable to the control group, while non-hematological toxicity**3** was in general mild in nature.

**What is MDS?**

MDS is a group of disorders in which abnormalities in the hematopoietic stem cells found in bone marrow affect one, two or all three types of blood cells: red blood cells, white blood cells and platelets – resulting in a decrease in the number of blood cells. In MDS, the marrow may also produce immature blood cells, or blasts, and a rise in these cells could lead to acute myeloid leukemia (AML), making MDS a disease with a very poor prognosis. MDS appears mostly in the elderly and it has been designated as an intractable disease in Japan. One of the treatment options for MDS is a hematopoietic stem cell transplant. However, since MDS is a disease that most often affects the physically weak elderly and is accompanied by complications, in actuality there are only a limited number of cases where a transplant is feasible, due to loss of physical strength and the side effects. As a result, the development of a new treatment was eagerly anticipated.

**Careful Consideration for a Completely New Drug**

Since Vidaza® was a first-in-class**4** treatment for MDS and because of limited clinical data in Japan, we decided to take a careful approach to providing information while selecting cases for administration. We provided information on the drug’s efficacy and safety to training facilities affiliated with the Japanese Society of Hematology with a strong clinical track record in blood cancers, based on the insight gained from the international phase III clinical trial conducted in 15 countries and 79 facilities in Europe and North America (AZA-001) as well as the clinical trial conducted in Japan. Additionally, we organized a series of lectures across Japan held by physicians that participated in the clinical trial and MDS specialist leaders as part of our effort to convey information on the proper usage of the drug.

**Future Plans**

Vidaza® has received strong remarks from clinical practitioners as an effective additional treatment option for MDS, which until now only had a limited number of treatment methods. However, MDS is a group of disorders with differing patient backgrounds, and so detailed information must be provided based on the status of each case. In addition, we are examining ways to quickly channel new information gathered about Vidaza® to medical professionals by establishing evidence for new administration methods in combination with a stem-cell transplant or other drugs. Beginning in FY 2012, we also plan to enhance the information on the drug that we are currently providing over the Internet.

---

**Number of deaths: Azacitidine – 82; Conventional care – 113**

**Hazard ratio = 0.58 [95% CI: 0.43–0.77]**

**2-year Survival rate**

**Conventional care group**

- 2-year Survival rate: 26.2% (95% CI: 17.4–36.5)
- Kaplan-Meier curve of survival time (efficacy analysis set): Log-rank test p=0.0001
- Median survival = 13.0 months
- Hazard ratio = 0.58 [95% CI: 0.43–0.77]
- Number of deaths: Conventional care – 113

**Azacitidine (in the chart to right) is the generic name for Vidaza®.**

---

1: Two-year survival rate after the start of treatment
2: Reduction in the number of blood cells produced in the bone marrow
3: A side-effect of anti-cancer drugs in which organs other than the target organ are affected
4: An original, highly useful, novel pharmaceutical that significantly changes existing treatment regimens
Although the environment surrounding the pharmaceutical industry is becoming more challenging, we are implementing strategies with a focus on our new drug product lineup based on strategic R&D management defined in our 4th Medium-term Management Plan.

In fiscal 2012, we will further promote market penetration of therapeutic agent Vidaza®, a treatment for MDS, which contributed significantly to sales growth in fiscal 2011. In addition, in June 2012, we released an upgraded version of our existing drug Erizas®, a treatment of allergic rhinitis. Until now, powder capsules had to be refilled after each use, but the new version now comes loaded with powder for 14 days of use and a counter for the number of remaining uses. We expect to increase our revenues from new drug products by about 40% thanks to greater penetration in the market.

The growth in sales of our new drug products will absorb the affects of declining standard NHI prices and is expected to increase net sales of our pharmaceuticals business by 2.8% year on year to ¥57,300 million.

Moreover, we aim to apply for an additional indication of Tramal® for chronic pain as a non-narcotic analgesic as well as conduct a phase III trial of long-acting oral analgesic NS-24 in hopes of marketing drug products from our pipeline in a prompt and steady manner (please see page 14).

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

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

Market conditions remain challenging. Net Sales

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales (millions of yen)</th>
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<tbody>
<tr>
<td>2010</td>
<td>52,165</td>
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<tr>
<td>2011</td>
<td>55,746</td>
</tr>
<tr>
<td>2012</td>
<td>52,554</td>
</tr>
</tbody>
</table>

Meanwhile, in response to aging society and changes in disease composition, key growth drivers are gradually shifting from existing products for lifestyle diseases to specialty drugs aimed at addressing unmet medical needs. Amidst this change, new drugs such as anti-cancer agents, diabetic medicine with a new mechanism of action, and combination preparations of antihypertensive compounds are being released one after another, thereby invigorating the prescription drug market. In addition, demand for disease areas such as cancer and rheumatism has risen for the market as a whole.

In fiscal 2011, Japan’s prescription drug market was valued at some ¥9 trillion on a NHI price basis. Due in part to the lack of NHI price revisions, the market grew by 5.5% year on year in fiscal 2011. However, legislative changes such as ongoing and enhanced policies to minimize medical expenses were seen as the country’s social security costs continue to rise. Examples include strategies to promote use of generic drugs and additional NHI price cuts for long-term listed drugs. As such, Japan’s domestic market remains challenging.

Market Conditions

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

Our pharmaceuticals business saw a decline in sales for certain long-term listed drugs and allergy-related drugs from the influence of this season’s pollen amounts. However, our new lineup of drug products that have been brought to market in a steady stream, in particular our core products, have seen a significant increase in sales. Current fiscal year sales of Vidaza®, a treatment for myelodysplastic syndrome (MDS) that was released in March 2011, grew significantly, as did Lunabell®, combination tablets for dysmenorrhea, Adcirca®, a drug for pulmonary arterial hypertension, and Gaslon N®, a remedy for gastric ulcers and gastritis. As a result, pharmaceutical business net sales rose 6.1% year on year to ¥55,746 million.
**Business Segment**

**Pharmaceuticals**

### Research & Development

**Nippon Shinyaku’s R&D Vision**

Nippon Shinyaku has determined five fields of medicine on which to focus its primary R&D efforts: oncology, hematology, obstetrics and gynecology, pharmacology, and orthopedics. With an emphasis on these specialty fields, we aim to provide products to address patient needs through in-house drug discovery and manufacturing, licensing from other companies, and product life cycle management (PLCM). In particular, we are driven by a sense of responsibility to meet the challenges of developing treatments for rare diseases and intractable diseases currently without a cure.

#### Drug Discovery Research

With a focus on our core medical specialty of oncology and hemological diseases, and through elucidating the causes of new ailments, the development of our unique and proprietary drugs is conducted with an emphasis on speed.

#### Licensing-in Activity

We work actively to license in both marketed drugs is conducted with an emphasis on speed.

### Development of New Technology

Nippon Shinyaku is actively engaged in advanced research centered on genomic drug discovery and nucleic acid drugs at Discovery Research Laboratories in Tsukuba, Ibaraki Prefecture. In particular, we are focused on the development of pharmaceuticals based on a new therapeutic principle which emphasizes the relationship between gene functions and mutations with diseases.

*1: To analyze the connection between a disease and genes as a method of identifying the target for drug discovery

*2: Pharmaceuticals that control the function of specific genes. A portion of the drug molecule includes the structural component of genes, nucleic acid.

### Development of the R&D Pipeline

In March 2013, we filed an application for the marketing approval of NS-11 (Acamprosate calcium), a drug for supporting maintenance of abstinence from alcohol in patients with alcohol dependence. Alcohol dependence syndrome is one of the psychosomatic disease syndromes, recovery from which requires abstaining from alcohol for the remainder of one’s life. NS-11 is a remedy that acts on the central nervous system in suppressing the desire for alcohol in patients. Its significant efficacy in the improvement of success rate of abstinence in comparison to the placebo*2 group was verified in a clinical trial conducted in Japan. Promptly making this treatment available to medical institutions will contribute greatly to the treatment of alcohol dependence syndrome in Japan.

In addition, we are also preparing an application for an additional indication of chronic pain for NS-11 (Tramadol), a novel analgesic agent. Moreover, the development of clinical trial phase III is also being steadily implemented. (See the table on the right for additional details.) Going forward, we will continue to develop a structure for the continuous launch of promising treatments.

#### Recently we have launched two products while development is steadily underway on promising new drugs

We strive for the development of high-quality products through appropriate allocation of management resources for drug discovery research, licensing in activities, and PLCM, with a clear definition of R&D targets. As a result of our efforts, in fiscal 2016, we launched “Tumebar” for the treatment of cancer pain and “Abideza,” a remedy for nephrotic syndrome (NHS).

We are currently developing promising new drugs including NS-11, a drug for supporting maintenance of abstinence from alcohol in patients with alcohol dependence, which has been submitted for a New Drug Application. In the future, we will engage actively in the development of therapeutics for diseases that have yet to see an established cure. In order to provide therapeutic products for patients as quickly as possible, we aim to achieve early approval by accelerating our clinical development process and improving success rates of clinical trials.

### Pipeline: Domestic

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Designation</th>
<th>Expected Field</th>
<th>Indications</th>
<th>Origin</th>
<th>Development</th>
<th>Phase</th>
<th>Market</th>
<th>Approval</th>
<th>Status</th>
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<tr>
<td>NS-11 (Acamprosate calcium)</td>
<td>Acamprosate calcium</td>
<td>Patient medical therapy</td>
<td>Alcohol dependence syndrome</td>
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<td>Japan</td>
<td>2011</td>
<td>Approved</td>
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<tr>
<td>NS-355 (Lyn1 inhibitor)</td>
<td>Lyn kinase inhibitor</td>
<td>Cancer</td>
<td>Lyn tyrosine kinase inhibition</td>
<td>Nippon Shinyaku</td>
<td>Licensed</td>
<td>III</td>
<td>Japan</td>
<td>2011</td>
<td>Approved</td>
</tr>
<tr>
<td>N-118 (Bafetinib)</td>
<td>Bcr-Abl tyrosine kinase inhibitor</td>
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### Pipeline: Overseas

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<td>Licensed</td>
<td>III</td>
<td>Japan</td>
<td>2011</td>
<td>Approved</td>
</tr>
</tbody>
</table>

#### Acknowledgment

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

Business Segment

Pharmaceuticals

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

We are committed to maximizing our new drug product lineup which we have been developing continuously since fiscal 2008.

For example, Vidaza®, a much anticipated treatment for MDS brought to market in Japan in March 2011, was made available at an early date through an accelerated delivery plan. This medication yields greater results as the treatment cycle repeat. To increase its market penetration, we will be hosting seminars and using the Internet to further enhance our information dissemination efforts, in addition to providing information on treatment cycles, as it is important to provide appropriate information based on actual clinical results from KOLs. Moreover, we will strengthen our information collection system for appropriate product use and in turn relay this back to patients and medical professionals in charge of hematological malignancies.

Also, following Adoxa®, a new drug for pulmonary arterial hypertension released in December 2009, we have been developing a number of drugs with different mechanisms of action to be launched in the same field.

Through their market penetration we aim to become a leader in the treatment of hematological malignancies related drug products and approximately 50 regional academic staff located at each of our branch offices in Japan. Also, we provide information to hematologists and pharmacists through hematological malignancy KOLs, at academic seminars, etc. In MR activities, we will continue to strive for timely dissemination of information that matches the needs of medical experts as well as improve the quality and quantity of information provided.

Clear awareness of and strict emphasis on compliance

We are strongly aware of compliance with regulations and are committed to its thorough implementation. To abide by the Transparency Guideline addressing the relationship between company activities and medical institutions, we formulated a BCP for business continuity and contingency planning for our branch offices, which is reviewed every month on an ongoing basis. Moreover, based on the 4th Medium-term Management Plan, we have established a BCP for our branch offices in Japan. This BCP is designed to cover the potential impact of an earthquake and other sudden events on our business, and is reviewed on an annual basis.

*1  Pharmaceutical Drug Marketing
*2  Voluntary standards necessary to define the amount and quality of information provided.
*3  Good Manufacturing Practice
*4  Business Continuity Plan
*5  Good Quality Practice
*6  Good Manufacturing Practice
*7  Good Veterinary Practice

Production

Core Measures

Revising inventory criteria and raw materials procurement, working toward stable supply

In order to provide high quality active pharmaceutical ingredients and finished products at a steady pace, it is crucial for raw materials to be procured with consistency. Since our establishment, we have adopted a policy to hedge risk by sourcing raw materials from two separate suppliers for pharmaceutical products used to treat rare diseases as well as anti-cancer agents that have no substitution and possess a great influence on society. In the current fiscal year, we upgraded certain outdated production equipment. In addition, based on the 4th Medium-term Management Plan, we formulated a BCP for the Odawara Central Factory located in Western Kanagawa Prefecture. The Odawara Central Factory is situated within the zone expected to see heavy damage in the event an earthquake with a maximum seismic intensity of upper 6 strikes the Tokai region. As such, countermeasures have been planned and established, including equipment safety, IT, distribution, and storage of products and raw materials, in order to minimize damage and resume factory operations within two months of the anticipated disaster.

In addition to the above measures, following the Great East Japan Earthquake, efforts have also been made to improve the earthquake resistance of buildings and equipment as well as increase product inventory.

Focused on reducing costs

We are implementing cost reduction efforts within each division in order to enhance our profit margin. In fiscal 2011, our Procurement Division reduced procurement costs by closely evaluating new suppliers and obtaining competitive bids, while the Manufacturing Division introduced measures, including staggered work schedules, that have greatly reduced overtime hours, thereby reducing personnel costs. Our Logistics Division also cut costs by re-evaluating its shipping providers. Meanwhile, we aim to develop our Consignment Manufacturing Business by utilizing one of Japan’s largest microparticle coating machines used to manufacture orally-disintegrating tablets which we installed at the Odawara Central Factory this fiscal year.

Advancing quality assurance and safety management

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

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

As for managing the safety of our pharmaceutical products, in addition to adhering to GDP*, we also collect, analyze, and evaluate data on side effects via medical institutions, medical professionals, and related companies within Japan and abroad, as well as from patients, their family, articles, and conference reports.

If an issue arises, we determine a response and report to the regulating authorities as well as provide feedback to medical professionals and patients.

*  Good Distribution Practice
*  Production and quality management standards for pharmaceutical products
*  Safety management standards for pharmaceutical products after marketing approval

Stabilizing existing businesses while actively expanding new ones

Our most important mission is to provide a steady stream of high quality pharmaceutical-drug products. For this reason, we have developed a robust and sound supply chain, procuring raw materials used in our main products from two different suppliers, ensuring the steady operation of production equipment, and implementing high standards of GDP*. Furthermore, in the 4th Medium-term Management Plan (2009-2013), we have formulated policies to prevent business continuity risks due to the failed procurement of raw materials and suspension of operations at our factories. In fiscal 2009, we established a BCP for the Odawara Central Factory and systematically implemented risk aversion strategies for the entire supply chain. Moreover, the Great East Japan Earthquake that struck in March 2011 served as an opportunity for us to revise this BCP and enhance building and facility earthquake resistance in fiscal 2011. This also gave us an opportunity to identify drug products that impact society and increase their stockpiles. While we are implementing strategies to ensure stable business operations, we have also taken a proactive stance toward expanding our Consignment Manufacturing Business with the hope of effectively utilizing current facilities at the Odawara Central Factory with the aim of generating greater profits. Through opening up the avenue of consignment manufacturing, which will make effective use of existing facilities including microparticle coating machines purchased in fiscal 2011, we hope to further expand our business operations going forward.

Tetsuya Yuno
Director, General Manager, Sales and Marketing Division

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

15

16
Nippon Shinyaku has been in the business of functional food since 1961 with the belief that “medicine and food have the same origin.” Focused primarily on the Japanese market, we provide a range of products including functional ingredients to maintain and improve health in the health foods market, spices, preservatives, and protein preparations to the processed foods market, and nutritional ingredients for food products for the elderly.

### Sales Conditions

**Dramatically improved sales of health food ingredients boosted revenue**

While difficult times persist for Functional Food Company, we are exploring new business opportunities by strengthening flagship products as we develop new ones. In FY 2011, these efforts dramatically improved sales of health food ingredients like collagen and hyaluronic acid, nutritional ingredients like caseinates, and preservatives like the new “Mikaku Fine Z.” The efforts also boosted sales of protein preparations like dried albumen and soy proteins. This saw consolidated sales rise 5.4% year-on-year to ¥11.558 billion.

### Main Strategy

**Develop safe, high-quality functional food and ingredients**

Functional Food Company’s products include seasonings and spices, preservatives, protein preparations, health food ingredients, nutritional ingredients, sterilizers, cleansers, and wheat products. These are used as auxiliary ingredients in processed foods and health foods, and are used in keeping factories sanitary.

Created using a variety of techniques developed over many years through the pharmaceuticals business, these products undergo strict quality control and are well received and trusted by the processed foods and health foods industries.

In recent years, as the population ages and thinks more about its health, we are working to enhance our functional food and ingredients for the nutraceutical and nutrition industries.

“As foods that directly impact health, Nippon Shinyaku’s functional food ingredients must always be safe, quality products.” This has been our motto since we began our functional food business as a pharmaceuticals manufacturer. To accomplish this, we apply advanced techniques, strict quality control, GLP*1 in R&D, and GMP in production, which have been developed in pharmaceutical manufacturing.

### Business Segment

#### Functional Food

**Market Conditions**

Consumers are saving more and seeking safety and security of food

Continuing deflation, recent consumer tendencies to save, and increasing pressure to lower prices have put the processed foods market in dire straits.

Especially in Japan, where simply making new products no longer guarantees sales, processed food manufacturers are fighting for their very survival.

Consumer frugality is now slowing even the once solid growth in the health foods industry.

Processed food manufacturers now face unprecedented consumer demand for information—including information about ingredient sources for better traceability and pesticide management information—to improve safety and security of food.

**Sales Conditions**

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### Prospects for FY 2012

In addition to putting more new products on the market, we will be starting new business ventures.

Sales for next year are projected to be ¥11.8 billion, a 2.1% increase year-on-year.

While hard times are expected to continue next year in the food industry, we will be expanding our functional food business by putting new products, such as highly water-soluble health product ingredients and shelf life extenders that minimally affect taste, on the market to address user demand and the needs of the times.

We will also be rolling out business in new overseas markets.

*1 Standard for conduct of nonclinical safety studies of drugs

**Hiroshi Adachi**

Director, COO, Functional Food Company

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

As a company dealing in functional food and ingredients under our philosophy “helping people lead healthier, happier lives,” we make the most of our advanced manufacturing techniques and quality control expertise honed through many years of pharmaceutical business to improve our customers’ health by providing highly-original functional food and ingredients that benefit society.

As a functional food manufacturer within Nippon Shinyaku, we make safety and trust a top priority as we conduct R&D into natural food ingredients and create a variety of functional food and ingredients. What people want from foods is constantly changing. Functional Food Company meets the needs of the times with precision, providing highly-original functional food and ingredients that benefit society.
CSR Management

Appropriate Conduct of Sales Activities

Adherence to JPSMA Promotion Code and Fair Competition Code
Medical representatives work with medical professionals to ensure the proper use of pharmaceuticals by gathering and providing information regarding the quality, effectiveness, and safety of pharmaceuticals. Medical representatives work with doctors with medical professionals for the prevention of drug therapies, and must adhere to high ethical standards. Nippon Shinyaku implements its own guidelines for sales activities that are based on the Japan Pharmaceuticals Manufacturers Association (JPSMA), Promotion Code and Fair Competition Code of the Ethical Pharmaceutical Drug Manufacturing Industry. The internal guidelines follow our standards for conduct in activities that ensure the promotion of pharmaceuticals.

In Fiscal 2017, we revised our guidelines to respond to changes in the Fair Competition Code covering the promotion of food and beverages, and sales activities affecting these areas. We also conducted education to inform employees of the changes, and will continue adhering to these guidelines in Fiscal 2017 to ensure that our activities are properly executed.

Transparency Guideline
In January 2011, the JPSMA published new guidelines on transparency in the relationship between corporate activities and medical institutions. In accordance with the approach of this guideline, Nippon Shinyaku initiated an internal project to implement transparency guidelines in Fiscal 2011, to draw up and implement transparency guidelines and establish an internal system for information disclosure. Under the guideline, information disclosure is aimed at ensuring the transparency of our relations with medical institutions or contributing to the advancement of life sciences, and informing stakeholders that we adhere to high ethical standards in performing our corporate activities.

Fostering Human Resources and a Welcoming Labor Environment

Our Approach to Human Resources and Labor Management
We recognize our utmost priority to develop each employee, since they are the driving force behind our corporate activities. We have been expanding our human resources management for the development of the growth of employees, and are now an enterprise in order to restructure the organization and strengthen our business foundations, so that we may be a corporation that values employees and provides employment. Furthermore, in order to establish sustainable growth, we are pursuing workplace diversity, in line with the growing expectation towards diversity due to aging demographics and diverse cultures. We are also seeking to create investment opportunities for a workplace culture where every single employee—each with diverse values—can flourish and be independent.

Occupational Health and Safety
Nippon Shinyaku is committed to securing employee health and safety, and complying with industrial safety and health law in order to create comfortable working conditions, and are committed to promoting certified initiatives for health and safety.

The Chita Central Factory has established an occupational health and safety management system (OHSMS) since Fiscal 1995. The system conforms to guidance (OHSAS) guidelines and occupational health and safety management systems (OHSMS) 18001 and 18001 standards, and dictates the plant to implement risk management. The head office’s area implemented its assessment in March 2017, and began conducting FallBuilding risk assessments in Fiscal 2017. These assessments are used to identify potential risks and harmful effects in the workplace beforehand, in order to implement suitable safety measures.

Occupational Accident Record

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*1 Includes members of the corporate baseball team

Contributions to Society

Our Approach to Social Contribution
Nippon Shinyaku believes that it is necessary to strike a balance in our CSR initiatives between contributing to society through our business activities and contributing to society through non-business activities.

In terms of contributions through our business activities, we provide extremely safe and effective pharmaceutical products to patients in need, while also developing superior quality functional food that meet the needs of consumers. In terms of our non-business activities, the Nippon Shinyaku Children’s Literary Awards and our youth baseball clinics are initiatives directed toward supporting the healthy development of children and young adults. Similarly, other projects include efforts to preserve and protect the rich culture of Japan and our biodiversity through animal initiatives. Nippon Shinyaku fervently pursues initiatives towards nature and the environment, along with projects to deepen communication and exchange with society.

Environmental Conservation

Basic Environmental Policy
As a corporate citizen and as a help for people and local businesses in regions where Nippon Shinyaku operates, we wish to work with society by reestablishing a policy for sustainable conservation of the environment, and setting goals for the entire company in Europe.

1. We will establish and operate an internal organization responsible for environmental management, with the following mission and goals:
   a. To establish and operate a policy for sustainable conservation of the environment, and to set goals for the entire company in Europe.
   b. To continually assess and review the environmental management system, and to set goals for the entire company in Europe.
   c. To establish and operate a policy for sustainable conservation of the environment, and to set goals for the entire company in Europe.

2. We will comply with environmental regulations and prepare internal rules and procedures necessary for environmental management, and green procurement.

3. We will ensure and maintain all facilities in compliance with the requirements of environmental conservation and all its responsible managers.

4. We will actively communicate with local communities and share information on the results of our environmental management initiatives.

Acquisition of ISO 14001 Certification
Nippon Shinyaku has acquired ISO 14001 certification at all production facilities with a significant environmental impact, covering the Chita Pharmaceutical Plant, Chita Functional Food Plant, and Otsu Laboratory. We contract with an external audit organization to conduct third-party audits of our environmental management systems, and implement internal audits of our business facilities.

A medical audit and regular audit by an outside audit organization in Fiscal 2017 found no major instances of non-compliance and deficiencies, but some instances of minor environmental risks. We addressed these problems at the earliest possible moment and have implemented action plans to resolve the noted improvements.

Moving forward, we will continue to improve our environmental management systems in order to reduce the environmental impact of our business activities.
Aiming to be a company that meets society's expectations and secures the confidence and recognition of society

With the growing importance of CSR in corporate activities, corporations are expected to fulfill many social responsibilities. The Nippon Shinyaku Group has made a clear commitment to CSR that guides us to enhance our competitiveness and management performance. We are confident in meeting our social responsibilities by providing appropriate information to society and everyone involved in society.

Moving forward, the Nippon Shinyaku Group will endeavor to continuously develop pharmaceuticals and biologicals in line with the social expectations and needs of society. The Group aims to be a company that meets the expectations of society and secures the confidence and recognition of society.

Yoshiro Yura
Director, General Manager, Administration Division

Information Disclosure and Dialogue with Stakeholders

Nippon Shinyaku is committed to disclosure and appropriate disclosure of corporate information as an essential factor for the health of the market. In accordance with the regulations of the Financial Instruments and Exchange Act and in light of social expectations, we actively disclose information on our corporate activities, which we then publish on our corporate website.

We operate an information disclosure committee that discussions critical issues with the Board of Directors and top management. The committee sets principles and guidelines for disclosing information to society, determines the release date and time for disclosing information, and maintains a liaison with the Tokyo Stock Exchange for disclosure and other matters. Important information that meets the disclosure criteria is released timely. Our company has established disclosure guidelines that meet the Tokyo Stock Exchange’s requirements as well as the Timely Disclosure Network (TDnet) operated by the TSE. We rapidly disclose material information on our website and through our press releases, which we then publish on our corporate website.

Standing Alongside Patients and Medical Professionals

Educating Consumers about Allergies through our Website

In order to contribute to the better health of society, we are actively providing information. We have an informative website on allergic rhinitis and other related matters. On our “Talking about Allergies” website, you will find comprehensive information about the causes and solutions for allergic rhinitis. Our website also provides information on seasonal and year-round pollens, which helps to guide you in your daily lives.

Offering Advice through our Drug Consultants

In order to ensure the quality of life for patients using medical products, our Drug Consultants provide advice on how to appropriately use our products. In terms of information, we provide items such as our “Common Inquiries” website, which incorporates information management features. Our website includes accurate and easy-to-understand information to the public.

Conclusions

In order to fulfill the high ethical standards we have set for our business, we are actively pursuing social initiatives on our own. We contribute to society, protect the environment, and engage in dialogue with our stakeholders, including patients, business partners, users, shareholders, investors, and employees.

In the future, we will actively disclose information and engage in dialogue with our stakeholders. We will continue to contribute to the sustainable growth of society.
Quality Assurance and Reliability

Pharmaceutical Products Reliability Assurance

- Nonclinical tests
- Clinical trials
- Post-marketing data
- Marketing quality assurance based on GVP

**Swift, Stable Product Supply**

At Nippon Shinyaku, we have implemented a production framework dedicated to reducing manufacturing time and ensuring stable and efficient individual employee working conditions in our manufacturing site. We have also adopted a Business Continuity Plan (BCP) in the event of any disaster, so that disruptions to the supply of products to patients may be avoided. In addition, we have diversified our storage locations for product inventory, and are working with various partner companies to bolster our support framework. The Great East Japan Earthquake in 2011 prompted us to reassess our resources, and in fiscal 2011 of the initial measures surrounding our new priorities. We have also reviewed and strengthened our management of key personnel such as head and considered ways to prevent any shortages of these key personnel.

_3) To ensure optimal performance in the case of a disaster, a system for a direct telephone that can be used by key personnel is in place._

In Partnership with Employees

**Providing Productive, Employee-Friendly Workplaces**

Nippon Shinyaku places on the highest priority the health and well-being of all employees, and our efforts reflect our business principles. Nippon Shinyaku's CSR PROMISE "Growth For Each and Every Employee" reflects our commitment to providing an employee-friendly workplace.

Nippon Shinyaku strives to create a workplace in which all employees can feel secure and comfortable, and in which employees are able to work productively, resting regularly, and leading a fruitful lifestyle that increases their capabilities for orally dissolving medicines.

At Nippon Shinyaku, we follow these stipulations and appoint the supervisor-general, a quality assurance manager, and a safety management chief as the top-level management in charge of the corporate safety management structure with openness and accessibility for all of its participants.

Diverse, Inclusive Work Environment

Nippon Shinya's diversity management is one of the social responsibilities incumbent upon us as a corporation. Consequently, since fiscal 2007, we have carried out a dual system for hiring newly-graduated individuals with disabilities. This system includes features such as providing a number of consultants for disabled workers. The aim is to help workers with disabilities become productive and take on an active role in the company.

**Safeguarding Reliability and Safety**

Nippon Shinyaku has incorporated a career development system called CAST (Career Approach SysTem). As an in-house employment planning system, CAST helps employees to plan their careers as they move forward in their company, considering the aspirations of both parties, the interests of employees, and the company's policies. Terakoya Academy's objective is to build a clear workplace structure and openness and accessibility for all of its participants.

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CSR Activities Report

Joining with Society and Local Communities

The Nippon Shinyaku Children’s Literary Awards

Nippon Shinyaku works to ensure the spirited growth of the children who will inherit our world. With this in mind, and to celebrate our 90th anniversary as a company, Nippon Shinyaku Children’s Literary Awards in 2009.

The Nippon Shinyaku Children’s Literary Awards work with the support of the Japan Junior Writers Association to call for works of art from visual artists and literature from young writers. The category and both works of art are made into picture books. Approximately 100 of these books are then distributed free to medical institutions, children’s hospitals, and public libraries, as well as libraries and elementary schools in Kyoto (the city of the company’s head office), and Osaka (the site of our Central Factory). Also, visitors to our website are able to see electronic versions of the books and then read about them as they browse the pages. In addition, through the Nippon Shinyaku Children’s Literary Awards, we cooperated with another project to contribute to local communities. This project was called the Children’s City – Mini-Kyoto 2011. In this event, we cooperated with another project to contribute to local communities.

The Nippon Shinyaku Children’s Literary Awards in 2009, we collect donations from employees to support the Japan Juvenile Writers Association to call for works of art as the Nippon Shinyaku Children’s Literary Awards in 2009. Furthermore, through our Shining Future for Children Foundation, we support the Kyoto Children’s Center NPO and other groups. Nippon Shinyaku participated in this project and use their own faculties to get by. The event is called the Children’s City – Mini-Kyoto 2011. In this event, we cooperated with another project to contribute to local communities.

Initiatives to Preserve Biodiversity

The Nippon Shinyaku Shining Future for Children’s Biodiversity Institute was founded in 1998 at the Yama- shimizu Pilot Farm and is an important part of our R&D initiatives. It is the only biodiversity institute in Japan that protects the natural environment. We launched a project to support the construction of Nippon Shinyaku’s Shining Future for Children’s Biodiversity Institute. Also among the plants preserved and cultivated at the institute are several kimura and their tea leaves. The institute is also a member of a number of societies and use these leaves to help the local community. The institute is also a member of a number of societies and use these leaves to help the local community.

Disease Education Activities

Correlation: The most common cause of death in Japan. As a part of cancer treatment, it is important to find ways for patients to avoid inducing new cancer. Nippon Shinyaku is part of The Cancer Pain Relief Network that drives to spread information and educate patients on Womein’s Cancer Pain Relief. Similarly, we support the Ministry of Health, Labour and Welfare’s Orange Ribbon Project for increasing awareness of palliative care.

This significant number of women endure endometrial cancer, though relatively few of them are aware that endometrial cancer or other diseases can provide palliative care. Our support promotes early education campaign speaking about the disease. It disseminates accurate information on endometrial cancer and the disease. In fiscal 2011, we supported a smart phone app “Telling About Endometrial Cancer” website with functionality for teaching about endometrial cancer. We also supported a seminar held during women’s health week (March 1–8). An independent magazine called Kyô, originally started in 1967, this publication centers on health, illness, and the patient experience. Kyô and Nippon Shinyaku have worked closely together to raise awareness of endometrial cancer and other gynecological issues.

Supporting Education through Sports

In fiscal 2011, the Nippon Shinyaku Children’s Literary Awards in 2010, we received donations from employees to support the Japan Juvenile Writers Association to call for works of art as the Nippon Shinyaku Children’s Literary Awards in 2009.

Activities to Preserve and Maintain the Culture of Kyoto

In 2011, the Nippon Shinyaku Children’s Literary Awards in 2010, we received donations from employees to support the Japan Juvenile Writers Association to call for works of art as the Nippon Shinyaku Children’s Literary Awards in 2009.
**Environmental Conservation Activities**

### 3rd Nippon Shinyaku Environmental Targets

<table>
<thead>
<tr>
<th>Objective</th>
<th>Targets</th>
<th>FY 2011 Results</th>
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<tbody>
<tr>
<td><strong>Environment</strong></td>
<td><strong>Reduce</strong></td>
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<td><strong>Environmental Accounting</strong></td>
<td><strong>Energy</strong></td>
<td><strong>14,453,000</strong></td>
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</table>

### CSR Activities Report

#### Promote an Environmentally Friendly Organization System

- **Environmental Management System:**
  - Continuously improve the environmental performance by maintaining ISO 14001 certification (EMS) and building a global environmental management system.

- **Environmental Management Committee:**
  - Comprised of the presidents of Nippon Shinyaku Corporation, its affiliates, and other independent entities responsible for the management of environmental protection.

#### Promote Environmental Conservation Education and Awareness

- **Environmental Education:**
  - Each of our main business locations decided on an environmental education theme and carried out employee instruction programs to raise awareness of environmental conservation.

#### Reduce Resource and Energy Consumption

- **Resource Use:**
  - With a FY 2011 final landfill waste ratio of 0.4%, we were able to meet our zero landfilled waste goal.

#### Promote Green Purchasing and Procurement Practices

- **Materials Procurement:**
  - We continued to focus on reducing and eliminating the environmental impact of our products through improved product designs and packaging.

#### Implement Environmental Conservation Activities

- **Pollution Prevention Costs:**
  - We reduced waste volume to 462 tons at our main business locations, down from 1,072 tons in FY 2011.

#### Achieve Zero Emissions

- **Environmental Remediation Costs:**
  - We reduced emissions of 9,568 tons from FY 1990.

#### Appropriately Disclose Information

- **Social Activity Costs:**
  - We increased the disclosure of information through our corporate website.

#### Actively Participate in Activities to Give Back to the Areas

- **Upstream and Downstream Costs:**
  - We are currently working to introduce the KES Environmental Management System (KES EMS) to our head office.

#### Continually Improve the Results of Our Environmental Conservation Activities

- **Company-Wide Energy Conservation/Energy Efficiency Measures:**
  - We are working to reduce our energy consumption by implementing ISO 14001 certification (EMS) maintenance and operation, green space conservation, personnel expenses for the Environmental Management Division.

#### Proper Waste Disposal Efforts

- **Proper Waste Disposal:**
  - We are currently working to introduce the KES Environmental Management System (KES EMS) to our head office.

#### Implement Environmental Conservation Initiatives for Our Community

- **Proper Waste Disposal:**
  - We are currently working to introduce the KES Environmental Management System (KES EMS) to our head office.

#### Promote an Environmental Conservation Culture

- **Proper Waste Disposal:**
  - We are currently working to introduce the KES Environmental Management System (KES EMS) to our head office.

#### Environmental Conservation Costs

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<td>48,585</td>
<td>59,011</td>
<td>57,401</td>
<td>64,706</td>
<td>70,147</td>
<td>89,135</td>
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#### Environmental Conservation Benefits

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CSR

CSR Activities Report

<table>
<thead>
<tr>
<th>Reducing CO2 Emissions</th>
<th>Targets</th>
<th>Hold FY 2013 CO2 emissions at or below FY 1990 levels.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2011 Results</td>
<td></td>
<td>At 9,568 tons, we achieved our goal of improving on FY 1990's level of 10,569 tons.</td>
</tr>
</tbody>
</table>

Energy Conservation Efforts

Nippon Shinyaku is continuously endeavoring to conserve energy and reduce emissions of CO2. These efforts include switching to green air conditioning units in all company offices, encouraging employees to drive appropriately for the season (following Japan's so-called 'cool biz' and 'warm biz' dress codes), and promoting use of trains, lighting, elevator, and office equipment usage.

Following the disruptions from the Great East Japan Earthquake, domestic companies have been required to conserve electricity. In June 2011, Nippon Shinyaku created an Energy Efficiency and Conservation Promotion Committee. The committee drafted Energy Conservation Guidelines and promotes increased energy conservation efforts company-wide, including efforts to continue cutting back on air conditioning, lighting, elevator, and office equipment usage. Results from these efforts led to total CO2 emissions of 10,846 tons, a 9.5% reduction from the fiscal 1990 amount of 11,780 tons.

Introducing Environmental Friendly Vehicles in our Sales Fleet

Our fleet of over 100 vehicles comprises two types: a new type set for 15% reductions in CO2 emissions based on 2010 criteria for our fleet of sales force vehicles, and new vehicles as we have gradually phased in high gas efficiency, low CO2 catalogs. At the end of fiscal 2011, 15% out of our sales force cars are now environmentally friendly models (either low emissions or hybrid vehicles). In addition, we upgraded our environmental preservation activities to promoting use of trains instead of vehicles, or Tokyo Desk, where the public transportation system is highly developed. At this time, we are also maximizing the use of electric vehicles in our fleet moving forward.

Proper Management of Chemical Substances

Our company has designated substances under the PRTR Act, usage amounts of Class 1 designated chemical substances under the PRTR Act. Along with this, we worked to keep our facilities up to date and properly managed.

Results of Initiatives

For materials related to our research laboratories, we set and reviewed a house-regulation following relevant laws with regard to substances of concern, such as genetically modified organisms and regulated species, in addition to a variety of other chemical substances, such as those designated under the PRTR Act. Along with this, we worked to keep our facilities up to date and properly managed.

We submitted legal notifications for our business locations that exceeded our legal limits for the fiscal 2011 usage of chlorine, chloroform, and carbon tetrachloride: 1,109 kg, 285 kg, and 677 kg, respectively, for chloroform. In addition, we implemented a series of measures to prevent emissions of n-hexane, newly subject to reporting as of fiscal 2011 under the revised PRTR Act enforcement order, was 3,200 kg.

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Proper Management of Chemical Substances

Targets | Promote the proper management of chemical substances designated under the PRTR Act.

FY 2011 Results | Following on from FY 2010, we achieved zero emissions with a 0.4% final landfill waste ratio.

Results of Initiatives

The amount of waste generated in fiscal 2011 was 9,568 tons, or 18 ton reductions from fiscal 2010 in the amount of landfill waste. This is an increase of landfill waste while maintaining achievement of zero emissions from fiscal 2011. Nippon Shinyaku continues to steadily reduce the amount of landfill waste at its four business locations (Kyo, 2005; Osaka, 2006; 2007; and Tokyo) as it promotes further reduction of landfill waste.

Proper Management of Chemical Substances

Targets | Promote the proper management of chemical substances designated under the PRTR Act.

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Framework for Corporate Governance

Nippon Shinyaku employs a system of auditors, with the general meeting of shareholders appointing and dismissing them. The company also employs Deloitte Touche Tohmatsu LLC as an accounting auditor, to help raise the effectiveness and efficiency of its business. Since fiscal 2008, Nippon Shinyaku has been establishing a framework to ensure the proper execution of the business.

Compliance Initiatives

Group-wide compliance initiatives are formulated and implemented by the managers in each department. Training that focuses on teaching compliance to employees of Nippon Shinyaku and Group companies can report on or raise the effectiveness and efficiency of our business. Since fiscal 2008, Nippon Shinyaku has been establishing a framework to ensure the proper execution of the business.

E-mail/Website

Nippon Shinyaku also implemented a risk awareness survey for each department for the particular risk is instructed to respond and take action. If the employee determines that there is a particularly high level of risk, he or she notifies the supervising manager, who in turn notifies the risk management department and the director in charge of risk management.

Employees may report any matters concerning compliance, including cases where employees were subjected to undue or unreasonable pressure. Employees can also report matters that they do not understand such as prohibited activities, conflict of interests, and illegal activities. Feedback for reporting employee is provided to the employee when reported.

Corporate Audit

Corporate Auditors are an effective framework for audits. In addition to reviewing documents and periodically meeting with the organizational structure for internal control, compliance, and risk management. To fulfill our accountability to all stakeholders, by securing the transparency of management and increasing corporate value, so that the transparency of management and increasing corporate value, so that...
Verification of details

Initiatives for Information Security

President

Corporate Auditors

Corporate Officers

Organization for Corporate Governance

In order to efficiently manage the Company, the Board of Auditors is responsible for each director responsible for executing separate areas of work in their respective departments as internal bodies. The Board of Directors is comprised of seven directors, with the President and Corporate Officers in charge of the business, the Board of Directors, and the Board of Auditors serving as the highest decision-making bodies for the Company. The Board of Directors and the Board of Auditors play an important role in ensuring the Company is properly operating. The Internal Audit Department works with the Board of Auditors to ensure the proper accounting procedures and evaluates internal controls for financial reporting. Nippon Shinyaku is committed to financial compliance and is working to strengthen the framework for securing occupational safety and health. Since fiscal 2008, Nippon Shinyaku has been quantifying risk and working to enhance the system for confirming the safety of employees, with a special focus on information security, guided by the basic policy and rules. Initiatives for information security are being discussed by the directors in charge of various departments, with a working group in charge of practical response. However, if the risk is determined to have a major impact signifying a crisis, the administrative department reports to the director in charge of risk management, who in turn notifies the supervising manager, who in turn notifies the risk management officer. In place if a risk or crisis arises, under Basic Risk Management Rules. Nippon Shinyaku has been promoting risk management education, in light of the increasing pervasiveness of social media and other factors, with a focus on teaching new employees about compliance concepts and approaches, and stressing the importance of compliance. In addition, we studied and analyzed IT risks and examined the effectiveness of our security policy. In fiscal 2011, Nippon Shinyaku formulated information security rules extending to all employees, and put up posters in each department. Nippon Shinyaku is implementing measures under a security policy to prevent unauthorized access, false identification and leakage. Moving forward, Nippon Shinyaku will continue to take initiatives for information security, guided by the basic policy and rules.
Operating Results

1. Fundamental Policy Regarding Profit Sharing

Under our strategy to increase corporate value, we strive to grow our business foundation by believing Nippon Shinyaku Group to expand the pipeline for product development, and enhancing selling margins to enable us to maintain a corporate position to achieve increasingly competitive results. We are also focusing on retuning profit share to shareholders to issue dividends linked to earnings and maintaining a consolidated payout ratio of around 50%. In some cases, we may include retention during fiscal years when calculating the payout ratio.

For the fiscal year ended March 31, 2012, we received an annual cash dividend of ¥19 per share, comprising an interim dividend of ¥19 per share and year-end dividend of ¥19 per share. For the fiscal year ending March 31, 2011, we are proposing an annual dividend of ¥19 per share, comprising an interim dividend of ¥19 per share and year-end dividend of ¥19 per share.

2. Financial Condition

Total assets increased by ¥1,524 million from March 31, 2011, to ¥1,524,678 million. While other current assets decreased, notes and accounts receivables together with cash and deposits increased in the current assets area by ¥5,583 million. Fixed assets decreased by ¥2,016 million since March 31, 2011. Liabilities increased by ¥1,059 million since March 31, 2011, to ¥1,059,272 million. Retained and accumulated profits decreased while income tax payable and other accumulated payable increased, so that current debts increased by ¥1,341 million. Net income amounted to ¥1,059 million since March 31, 2011. The equity ratio was 79.4%.

Net cash from operating activities amounted to ¥3,659 million. The main cash inflows were income before income taxes of ¥6,194 million and ordinary income of ¥1,059 million since March 31, 2011. Net cash used in investing activities amounted to ¥759 million. The main cash outflows were for the capital expenditures of ¥988 million, while the main cash inflows were income before income taxes of ¥6,194 million and ordinary income of ¥1,059 million.

Net cash from financing activities amounted to ¥1,341 million. The main cash inflows were proceeds from redemption of marketable securities of ¥240 million. The main cash outflows were for the capital expenditures of ¥988 million, while the main cash inflows were income before income taxes of ¥6,194 million and ordinary income of ¥1,059 million.

Following is a summary of the business results in each segment.

1. Pharmaceuticals

In the pharmaceutical segment, sales of Livostin®, allergy remedy, Baynas®, allergy remedy, for allergic rhinitis and severe atopic dermatitis remedy and Adrias® treatment agent for pulmonary arterial hypertension were up. Sales of Vidaza® remedy for myelodysplastic syndrome, which was released in March 2011, contributed significantly to net sales, which amounted to ¥16,623 million (up 13.1% year-on-year).

2. Functional Food

In the functional food segment, both the processed food and health food segments were marketed by challenging business conditions. However, we significantly increased our sales of functional food ingredients together with nutritional ingredients and fortifiers, and recorded strong sales of protein preparations. As a result, net sales in the functional food segment rose ¥11,438 million (up 4.9% year-on-year).

3. Summary of Consolidated Business Results

Business conditions remained challenging in the pharmaceutical and functional food segments, due to the continuing emphasis on measures to limit medical costs in the pharmaceutical sector, and the continued strong trend toward low-cost foods in the food sector.

Under the circumstances, the Nippon Shinyaku Group recorded net sales of ¥1,926 billion (up 3.9% year-on-year), operating profits of ¥160 billion (up 17.4% year-on-year), and ordinary income of ¥169 billion (up 12.1% per year). Net income was ¥17,716 million (up 1.1% year-on-year), due to factors such as an increase in investment adjustments contributed by changes to the effective tax rate.

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Business Risks

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

1. Regulatory Control Risks

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

2. R&D Risks

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

3. Side Effect Risks

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

4. Drug Price Revision Risks

The selling price of drugs can be very sensitive to changes in drug price standards under the national health insurance system. Drug price standards are generally revised downward every two years. Depending on the extent of the price decrease, it could impact the business results of the Nippon Shinyaku Group.

5. Manufacturing and Procurement Risks

The Nippon Shinyaku Group is improving its production efficiency by concentrating its manufacturing facilities. At the same time, if operations at manufacturing facilities cease due to a natural disaster or other circumstances, it could interrupt the supply of products and impact our business results.

In addition, if there are significant changes in the business environment, such as fluctuations in raw material costs, it could impact our business results.
## Consolidated Financial Statements

### Consolidated Balance Sheet

#### Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

March 31, 2012

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<thead>
<tr>
<th>ASSETS</th>
<th>2012</th>
<th>2011</th>
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</thead>
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<td>CURRENT ASSETS:</td>
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</tr>
<tr>
<td>Cash and cash equivalents (Note 10)</td>
<td>¥ 19,666</td>
<td>¥ 18,142</td>
<td>$ 239,829</td>
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<tr>
<td>Time deposits (Note 10)</td>
<td>322</td>
<td>72</td>
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<td>Marketable securities (Notes 3 and 10)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Notes and accounts receivables (Note 10):</td>
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<tr>
<td>Trade notes</td>
<td>240</td>
<td>199</td>
<td>2,927</td>
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<td>Trade accounts</td>
<td>31,748</td>
<td>27,375</td>
<td>387,171</td>
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<tr>
<td>Other</td>
<td>84</td>
<td>233</td>
<td>1,024</td>
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<tr>
<td>Total notes and accounts receivables</td>
<td>32,012</td>
<td>27,607</td>
<td>391,122</td>
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<td>Inventories (Note 4)</td>
<td>11,925</td>
<td>11,546</td>
<td>145,427</td>
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<td>Deferred tax assets (Note 9)</td>
<td>1,635</td>
<td>1,519</td>
<td>19,939</td>
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<tr>
<td>Other current assets</td>
<td>713</td>
<td>1,442</td>
<td>8,695</td>
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<td>Total current assets</td>
<td>¥ 66,533</td>
<td>¥ 60,750</td>
<td>¥ 808,939</td>
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<tr>
<td>PROPERTY, PLANT, AND EQUIPMENT:</td>
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<td></td>
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<tr>
<td>Land</td>
<td>8,031</td>
<td>8,119</td>
<td>97,839</td>
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<td>Buildings and structures</td>
<td>26,147</td>
<td>26,877</td>
<td>318,866</td>
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<tr>
<td>Machinery, equipment, and vehicles</td>
<td>12,177</td>
<td>12,146</td>
<td>153,378</td>
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<td>Tools, furniture, and fixtures</td>
<td>9,185</td>
<td>9,264</td>
<td>112,012</td>
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<td>Construction in progress</td>
<td>1</td>
<td>205</td>
<td>12</td>
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<td>Total</td>
<td>55,941</td>
<td>55,811</td>
<td>662,207</td>
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<tr>
<td>Accumulated depreciation</td>
<td>(58,109)</td>
<td>(56,998)</td>
<td>(654,695)</td>
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<tr>
<td>Net property, plant, and equipment</td>
<td>17,832</td>
<td>18,823</td>
<td>217,512</td>
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<td>INVESTMENTS AND OTHER ASSETS:</td>
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<tr>
<td>Investment securities (Notes 3 and 10)</td>
<td>11,710</td>
<td>11,903</td>
<td>136,220</td>
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<td>Long-term prepaid expenses</td>
<td>8,112</td>
<td>8,896</td>
<td>98,937</td>
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<td>Deferred tax assets (Note 9)</td>
<td>200</td>
<td>450</td>
<td>2,439</td>
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<tr>
<td>Other assets</td>
<td>2,654</td>
<td>2,846</td>
<td>32,366</td>
</tr>
<tr>
<td>Total investments and other assets</td>
<td>22,176</td>
<td>23,165</td>
<td>269,952</td>
</tr>
<tr>
<td>TOTAL</td>
<td>¥ 106,305</td>
<td>¥ 102,738</td>
<td>¥ 1,296,403</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>LIABILITIES AND EQUITY</th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
</tr>
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<tbody>
<tr>
<td>CURRENT LIABILITIES:</td>
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<td></td>
<td></td>
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<tr>
<td>Notes and accounts payables (Note 10):</td>
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<tr>
<td>Trade notes</td>
<td>¥ 1,414</td>
<td>¥ 1,160</td>
<td>$ 17,244</td>
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<tr>
<td>Total accounts payable</td>
<td>¥ 3,605</td>
<td>¥ 4,137</td>
<td>$ 43,963</td>
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<tr>
<td>Other</td>
<td>3,104</td>
<td>2,806</td>
<td>37,854</td>
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<tr>
<td>Total notes and accounts payables</td>
<td>8,123</td>
<td>8,133</td>
<td>99,961</td>
</tr>
<tr>
<td>Income taxes payable (Note 10)</td>
<td>1,294</td>
<td>959</td>
<td>15,780</td>
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<tr>
<td>Accrued expenses</td>
<td>3,531</td>
<td>3,345</td>
<td>43,061</td>
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<tr>
<td>Deposits from customers</td>
<td>386</td>
<td>295</td>
<td>3,732</td>
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<tr>
<td>Other current liabilities</td>
<td>708</td>
<td>562</td>
<td>8,634</td>
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<td>Total current liabilities</td>
<td>13,962</td>
<td>12,903</td>
<td>170,268</td>
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<tr>
<td>LONG-TERM LIABILITIES:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liability for retirement benefits (Note 5)</td>
<td>7,058</td>
<td>7,719</td>
<td>89,732</td>
</tr>
<tr>
<td>Other long-term liabilities</td>
<td>419</td>
<td>423</td>
<td>5,110</td>
</tr>
<tr>
<td>Total long-term liabilities</td>
<td>7,477</td>
<td>8,142</td>
<td>94,842</td>
</tr>
<tr>
<td>EQUITY (Notes 6 and 12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common stock, authorized, 200,000,000 shares; issued 70,251,484 shares</td>
<td>5,174</td>
<td>5,174</td>
<td>63,998</td>
</tr>
<tr>
<td>Capital surplus</td>
<td>4,441</td>
<td>4,441</td>
<td>54,207</td>
</tr>
<tr>
<td>Retained earnings</td>
<td>73,542</td>
<td>71,109</td>
<td>896,864</td>
</tr>
<tr>
<td>Treasury stock - at cost, 2,757,573 shares in 2012 and 2,740,568 shares in 2011</td>
<td>(2,054)</td>
<td>(2,059)</td>
<td>(25,317)</td>
</tr>
<tr>
<td>Accumulated other comprehensive income:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealized gain on available-for-sale securities</td>
<td>3,129</td>
<td>2,881</td>
<td>40,597</td>
</tr>
<tr>
<td>Deferred gain on derivatives under hedge accounting</td>
<td>2</td>
<td>2</td>
<td>24</td>
</tr>
<tr>
<td>Foreign currency translation adjustments</td>
<td>(41)</td>
<td>(36)</td>
<td>(500)</td>
</tr>
<tr>
<td>Total</td>
<td>84,375</td>
<td>81,515</td>
<td>1,028,963</td>
</tr>
<tr>
<td>Minority interests</td>
<td>191</td>
<td>176</td>
<td>2,330</td>
</tr>
<tr>
<td>Total equity</td>
<td>84,566</td>
<td>81,693</td>
<td>1,031,293</td>
</tr>
<tr>
<td>TOTAL</td>
<td>¥ 106,305</td>
<td>¥ 102,738</td>
<td>¥ 1,296,403</td>
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See notes to consolidated financial statements.
### Consolidated Statement of Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2012

<table>
<thead>
<tr>
<th></th>
<th>Millions of Yen</th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NET INCOME</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minority interests in net income</td>
<td>19 (16)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net income before minority interests</td>
<td>3,735</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>INCOME TAXES (Note 9):</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income before income taxes and minority interests</td>
<td>6,194</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>COST AND EXPENSES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest and dividend income</td>
<td>289</td>
<td>367</td>
<td></td>
<td>3,524</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(9)</td>
<td>105</td>
<td>(105)</td>
<td></td>
</tr>
<tr>
<td>Other - net</td>
<td>399</td>
<td>397</td>
<td>(1,237)</td>
<td></td>
</tr>
<tr>
<td><strong>OPERATING INCOME (Note 14):</strong></td>
<td>6,013</td>
<td>5,181</td>
<td>73,329</td>
<td></td>
</tr>
<tr>
<td><strong>NET SALES</strong> (Note 14)</td>
<td>67,303</td>
<td>63,525</td>
<td>820,792</td>
<td></td>
</tr>
<tr>
<td><strong>INCOME FROM OPERATING ACTIVITIES</strong></td>
<td>6,013</td>
<td>5,181</td>
<td>73,329</td>
<td></td>
</tr>
<tr>
<td><strong>INCOME FROM OPERATING ACTIVITIES</strong></td>
<td>6,013</td>
<td>5,181</td>
<td>73,329</td>
<td></td>
</tr>
<tr>
<td>Income and expenses, selling, general, and administrative expenses (Note 7)</td>
<td>230</td>
<td>181</td>
<td>397</td>
<td></td>
</tr>
<tr>
<td>Cost of sales</td>
<td>6,013</td>
<td>5,181</td>
<td>73,329</td>
<td></td>
</tr>
<tr>
<td>Operating income (Note 14)</td>
<td>6,013</td>
<td>5,181</td>
<td>73,329</td>
<td></td>
</tr>
</tbody>
</table>

### Consolidated Statement of Changes in Equity

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

<table>
<thead>
<tr>
<th></th>
<th>Milions of Yen</th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BALANCE, MARCH 31, 2011</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash dividends, ¥19.00 per share</td>
<td>(1,283)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net change during the year</td>
<td>718</td>
<td>(174)</td>
<td>3,716</td>
<td></td>
</tr>
<tr>
<td><strong>BALANCE, MARCH 31, 2010</strong></td>
<td>67,546</td>
<td>5,174</td>
<td>4,159</td>
<td>5,174</td>
</tr>
<tr>
<td>Net income</td>
<td>3,958</td>
<td>4,159</td>
<td>5,174</td>
<td></td>
</tr>
<tr>
<td>Cash dividends, ¥19.00 per share</td>
<td>(1,283)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BALANCE, MARCH 31, 2011</strong></td>
<td>64,092</td>
<td>5,174</td>
<td>4,159</td>
<td>5,174</td>
</tr>
<tr>
<td>Net change during the year</td>
<td>456</td>
<td>443</td>
<td>50,602</td>
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</tr>
<tr>
<td><strong>BALANCE, MARCH 31, 2012</strong></td>
<td>68,648</td>
<td>5,174</td>
<td>4,159</td>
<td>5,174</td>
</tr>
</tbody>
</table>

See notes to consolidated financial statements.

### Consolidated Statement of Comprehensive Income

Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NET INCOME BEFORE MINORITY INTERESTS</strong></td>
<td>1,715</td>
<td>3,795</td>
<td>45,549</td>
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</tr>
<tr>
<td><strong>OTHER COMPREHENSIVE INCOME (Note 11):</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealized gain (loss) on available-for-sale securities</td>
<td>448</td>
<td>1,314</td>
<td>5,463</td>
<td></td>
</tr>
<tr>
<td>Deferred loss on derivatives under hedge accounting</td>
<td>(11)</td>
<td>(11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total other comprehensive income</td>
<td>461</td>
<td>(1,326)</td>
<td>5,402</td>
<td></td>
</tr>
<tr>
<td><strong>COMPREHENSIVE INCOME (Note 11):</strong></td>
<td>1,776</td>
<td>2,479</td>
<td>45,951</td>
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<td>Owners of the parent</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Minority interests</td>
<td>19</td>
<td>17</td>
<td>232</td>
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</tbody>
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See notes to consolidated financial statements.
# Consolidated Statement of Cash Flows

**Nippon Shinyaku Co., Ltd. and Consolidated Subsidiaries**

**Consolidated Statement of Cash Flows**

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPERATING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income before income taxes and minority interests</td>
<td>¥1,194</td>
<td>¥1,033</td>
<td>$74,337</td>
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<tr>
<td>Adjustments for:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income taxes - paid</td>
<td>(1,311)</td>
<td>(1,321)</td>
<td>(18,671)</td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>2,946</td>
<td>3,116</td>
<td>35,951</td>
<td></td>
</tr>
<tr>
<td><strong>CHANGES IN ASSETS AND LIABILITIES:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase in trade notes and trade accounts receivables</td>
<td>¥(4,614)</td>
<td>¥(2,757)</td>
<td>¥53,282</td>
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</tr>
<tr>
<td>Increase in inventories</td>
<td>(17)</td>
<td>(52)</td>
<td>(4,398)</td>
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</tr>
<tr>
<td>Decrease in other current assets</td>
<td>610</td>
<td>461</td>
<td>7,459</td>
<td></td>
</tr>
<tr>
<td>Decrease in other current liabilities</td>
<td>(27)</td>
<td>605</td>
<td>(3,390)</td>
<td></td>
</tr>
<tr>
<td>Increase (decrease) in other current assets</td>
<td>308</td>
<td>(346)</td>
<td>3,756</td>
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</tr>
<tr>
<td>Decrease in liability for retirement benefits</td>
<td>(31)</td>
<td>(511)</td>
<td>(44,402)</td>
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</tr>
<tr>
<td>Other - net</td>
<td>560</td>
<td>5</td>
<td>6,829</td>
<td></td>
</tr>
<tr>
<td><strong>Total adjustments</strong></td>
<td>(1,511)</td>
<td>(2,752)</td>
<td>(20,913)</td>
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</tr>
<tr>
<td><strong>Net cash provided by operating activities</strong></td>
<td>¥3,659</td>
<td>¥3,233</td>
<td>¥44,622</td>
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</tr>
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<td></td>
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<tr>
<td><strong>INVESTING ACTIVITIES:</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Proceeds from redemption of marketable securities</td>
<td>¥240</td>
<td>¥628</td>
<td>2,927</td>
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</tr>
<tr>
<td>Capital expenditures</td>
<td>(868)</td>
<td>(738)</td>
<td>(12,249)</td>
<td></td>
</tr>
<tr>
<td>Purchases of investment securities</td>
<td>(5)</td>
<td>(584)</td>
<td>(51)</td>
<td></td>
</tr>
<tr>
<td>Proceeds from redemption and sales of investment securities</td>
<td>172</td>
<td>127</td>
<td>2,099</td>
<td></td>
</tr>
<tr>
<td>Purchases of software</td>
<td>(249)</td>
<td>(239)</td>
<td>(1,573)</td>
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</tr>
<tr>
<td>Acquisition of license rights</td>
<td>(547)</td>
<td>(514)</td>
<td>(398)</td>
<td></td>
</tr>
<tr>
<td>Other - net</td>
<td>(46)</td>
<td>(88)</td>
<td>(398)</td>
<td></td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td>(705)</td>
<td>(2,644)</td>
<td>(22,256)</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>FINANCING ACTIVITIES:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash dividends paid</td>
<td>(1,281)</td>
<td>(1,281)</td>
<td>(15,422)</td>
<td></td>
</tr>
<tr>
<td>Increase of treasury stock</td>
<td>(17)</td>
<td>(41)</td>
<td>(297)</td>
<td></td>
</tr>
<tr>
<td>Other - net</td>
<td>(41)</td>
<td>(7)</td>
<td>(525)</td>
<td></td>
</tr>
<tr>
<td><strong>Net cash used in financing activities</strong></td>
<td>(1,341)</td>
<td>(1,293)</td>
<td>(16,354)</td>
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</tbody>
</table>

**FOREIGN CURRENCY TRANSLATION ADJUSTMENTS ON CASH AND CASH EQUIVALENTS**

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents, beginning of year</td>
<td>¥18,142</td>
<td>¥19,448</td>
<td>¥25,829</td>
<td></td>
</tr>
<tr>
<td><strong>Cash and cash equivalents, end of year</strong></td>
<td>¥19,666</td>
<td>¥18,142</td>
<td>$230,189</td>
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</tr>
</tbody>
</table>

See notes to consolidated financial statements.

---

# Notes to Consolidated Financial Statements

## 1. BASIS OF PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act, and its related accounting regulations, and in 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 2011 consolidated financial statements to conform to the classifications used in 2012.

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 ¥82 to $1, the approximate rate of exchange at March 31, 2012. 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, 2012 and 2011, include the accounts of the Company and its significant two domestic and one overseas subsidiaries (together, the “Companies”). Consolidation of the remaining subsidiary would not have a material effect on the accompanying consolidated financial statements.

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

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

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

### b. Cash Equivalents

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

### c. 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 determined by using the moving-average method to determine the cost of securities sold. Nonmarketable available-for-sale securities are stated at cost, cost being determined principally by the moving-average method.

Write-downs are recorded in earnings for securities with a significant decline in value that is considered to be other than temporary.

### d. Inventories

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

### e. Property, Plant, and Equipment

Property, plant, and equipment are stated at cost. Depreciation is principally computed by the declining-balance method while the straight-line method is applied to buildings acquired after April 1, 1998. The range of useful lives is principally from 10 to 50 years for buildings and structures; from eight to ten years for machinery, equipment, and vehicles; and from four to six years for tools, furniture, and fixtures.
f. Long-lived Assets
The Companies review their long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset or asset group may not be recoverable. An impairment loss 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 years to receive postretirement benefits at their discretion. Consolidated domestic subsidiaries have unfunded retirement benefit plans.

h. Asset Retirement Obligations
In March 2007, the ASBJ issued ASBJ Statement No. 13, “Accounting Standard for Lease Transactions,” which revised the previous accounting standard for lease transactions issued in June 1993. The revised accounting standard for lease transactions was effective for fiscal years beginning on or after April 1, 2008. Under the previous accounting standard, finance leases that were deemed to transfer ownership of the leased property to the lessee were capitalized. However, other finance leases were permitted to be accounted for as operating lease transactions if certain “as if capitalized” information was disclosed in the notes to the lessee’s financial statements. The revised accounting standard requires that all finance lease transactions be capitalized by recognizing lease assets and lease obligations in the balance sheet. In addition, the accounting standard permits leases which existed at the transition date and do not transfer ownership of the leased property to the lessee to continue to be accounted for as operating lease transactions. The Company applied the revised accounting standard effective April 1, 2008. In addition, the Company continues to account for leases which existed at the transition date and did not transfer ownership of the leased property to the lessee as operating lease transactions. All other leases are accounted for as operating leases.

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

j. Leases
In March 2007, the ASBJ issued ASBJ Statement No. 13, “Accounting Standard for Lease Transactions,” which revised the previous accounting standard for lease transactions issued in June 1993. The revised accounting standard for lease transactions was effective for fiscal years beginning on or after April 1, 2008.

k. Bonuses to Directors and Corporate Auditors
Bonuses to directors and corporate auditors are accrued at the year-end to which such bonuses are attributable.

l. Income Taxes
The provision for income taxes is computed based on the pretax income included in the consolidated statement of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred taxes are measured by applying currently enacted tax laws to the temporary differences.

m. Foreign Currency Transactions
All short-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 statement of income to the extent that they are not hedged by forward exchange contracts.

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

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

p. Per Share Information
Basic net income per share (EPS) is computed by dividing net income available to common shareholders by the weighted-average number of common shares outstanding for the period. Cash dividends per share presented in the accompanying consolidated statement of income are dividends applicable to the respective years, including dividends to be paid after the end of the year.

q. Accounting Changes and Error Corrections
In December 2009, the ASBJ issued ASBJ Statement No. 24, “Accounting Standard for Accounting Changes and Error Corrections,” and ASBJ Guidance No. 24, “Guidance on Accounting Standard for Accounting Changes and Error Corrections.” Accounting treatments under this standard and guidance are as follows: (1) Changes in Accounting Policies - When a new accounting policy is applied with revision to current accounting standards, the new policy is applied retrospectively unless the revised accounting standards include specific transitional provisions. When the revised accounting standards include specific transitional provisions, an entity shall comply with the specific transitional provisions. (2) Changes in Presentations - When the presentation of financial statements is changed, prior-period financial statements are reclassified in accordance with the new presentation. (3) Changes in Accounting Estimates - A change in an accounting estimate is accounted for in the period of the change if the change affects that period only and is accounted for prospectively if the change affects both the period of the change and future periods. (4) Corrections of Prior-Period Errors - When an error in prior-period financial statements is discovered, those statements are restated. This accounting standard and the guidance are applicable to accounting changes and corrections of prior-period errors which are made from the beginning of the fiscal year that begins on or after April 1, 2011.
The Company expects to apply the revised accounting standard from the annual period beginning on April 1, 2013, and is in the process of measuring the effects of applying the revised accounting standard for the year ending March 31, 2014.

2. MARKETABLE AND INVESTMENT SECURITIES

 Marketable and investment securities as of March 31, 2012 and 2011, consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Millions of Yen</td>
<td>Thousands of U.S. Dollars</td>
</tr>
<tr>
<td>Current:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government and corporate bonds</td>
<td>¥ 6,844</td>
<td>$ 83,464</td>
</tr>
<tr>
<td>Other</td>
<td>¥ 1,391</td>
<td>$ 17,512</td>
</tr>
<tr>
<td>Total</td>
<td>¥ 8,235</td>
<td>$ 100,976</td>
</tr>
<tr>
<td>Non-current:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equity securities</td>
<td>¥ 11,170</td>
<td>$ 136,220</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>¥ 11,925</td>
<td>$ 145,427</td>
</tr>
</tbody>
</table>

The costs and aggregate fair values of marketable and investment securities at March 31, 2012 and 2011, were as follows:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Millions of Yen</td>
<td>Thousands of U.S. Dollars</td>
</tr>
<tr>
<td>Securities classified as:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Available-for-sale Equity securities</td>
<td>¥ 5,949</td>
<td>$ 72,605</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Securities classified as:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Available-for-sale Equity securities</td>
<td>¥ 6,134</td>
<td>$ 77,805</td>
</tr>
<tr>
<td>Held-to-maturity</td>
<td>¥ 2,000</td>
<td>$ 24,568</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Securities classified as:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Available-for-sale Equity securities</td>
<td>$ 72,549</td>
<td>$ 92,985</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Projects of Benefit obligations</td>
<td>¥ 26,147</td>
<td>$ 318,866</td>
</tr>
<tr>
<td>Fair value of plan assets</td>
<td>(12,990)</td>
<td>(156,415)</td>
</tr>
<tr>
<td>Unrecognized actuarial loss</td>
<td>(5,507)</td>
<td>(67,158)</td>
</tr>
<tr>
<td>Unrecognized prior service cost</td>
<td>(292)</td>
<td>(3,561)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net liability</td>
<td>¥ 7,358</td>
<td>$ 91,732</td>
</tr>
</tbody>
</table>

The components of net periodic benefit costs for the years ended March 31, 2012 and 2011, are as follows:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Millions of Yen</td>
<td>Thousands of U.S. Dollars</td>
</tr>
<tr>
<td>Service cost</td>
<td>¥ 857</td>
<td>$ 10,451</td>
</tr>
<tr>
<td>Interest cost</td>
<td>¥ 531</td>
<td>$ 6,476</td>
</tr>
<tr>
<td>Expected return on plan assets</td>
<td>(506)</td>
<td>(8,171)</td>
</tr>
<tr>
<td>Recognized actuarial loss</td>
<td>678</td>
<td>8,268</td>
</tr>
<tr>
<td>Amortization of prior service cost</td>
<td>45</td>
<td>549</td>
</tr>
<tr>
<td>Premiums for defined contribution pension plan and other</td>
<td>55</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net periodic benefit costs</td>
<td>¥ 1,660</td>
<td>$ 20,264</td>
</tr>
</tbody>
</table>

Assumptions used for the years ended March 31, 2012 and 2011, are set forth as follows:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discount rate</td>
<td>2.0%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Expected rate of return on plan assets</td>
<td>4.0%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Recognition period of actuarial gain/loss</td>
<td>15 years</td>
<td>15 years</td>
</tr>
<tr>
<td>Amortization period of prior service cost</td>
<td>15 years</td>
<td>15 years</td>
</tr>
</tbody>
</table>

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

(a) Dividends

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

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

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

The Companies Act requires that an amount equal to 10% of dividends must be appropriated as a legal reserve (a component of retained earnings) or as additional paid-in capital (a component of capital surplus) depending on the equity account charged upon the payment of such dividends until the aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock.

Under the Companies Act, the total amount of additional
Notes to Consolidated Financial Statements

9. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes, which, in the aggregate, resulted in a normal effective statutory tax rate of approximately 41% for the years ended March 31, 2012 and 2011. 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, 2012 and 2011, are as follows:

<table>
<thead>
<tr>
<th></th>
<th>Millions of Yen</th>
<th>Thousands of U.S. Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred tax assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retirement benefits</td>
<td>¥ 2,652</td>
<td>$ 32,341</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>¥ 1,096</td>
<td>$ 13,366</td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>¥ 69</td>
<td>$ 841</td>
</tr>
<tr>
<td>Other</td>
<td>¥ 1,175</td>
<td>$ 14,329</td>
</tr>
<tr>
<td>Net deferred tax assets</td>
<td>¥ 4,618</td>
<td>$ 56,517</td>
</tr>
<tr>
<td>Deferred tax liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealized gain on available-for-sale securities</td>
<td>¥ 1,518</td>
<td>$ 19,000</td>
</tr>
<tr>
<td>Deferred gains on sales of property</td>
<td>¥ 1,196</td>
<td>$ 14,585</td>
</tr>
<tr>
<td>Other</td>
<td>¥ 29</td>
<td>$ 354</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>¥ 2,783</td>
<td>$ 33,939</td>
</tr>
<tr>
<td>Net deferred tax assets</td>
<td>¥ 1,835</td>
<td>$ 22,378</td>
</tr>
</tbody>
</table>

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, 2012 and 2011, is as follows:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal effective statutory tax rate</td>
<td>41.0%</td>
<td>41.0%</td>
<td>41.0%</td>
<td>41.0%</td>
</tr>
<tr>
<td>Expenses not deductible for income tax purposes</td>
<td>4.3</td>
<td>5.2</td>
<td>4.3</td>
<td>5.2</td>
</tr>
<tr>
<td>Income not taxable for income tax purposes</td>
<td>(1.4)</td>
<td>(2.1)</td>
<td>(1.4)</td>
<td>(2.1)</td>
</tr>
<tr>
<td>Increase in valuation allowance</td>
<td>(2.0)</td>
<td>(4.4)</td>
<td>(2.0)</td>
<td>(4.4)</td>
</tr>
<tr>
<td>Tax credits for research and development costs</td>
<td>(8.8)</td>
<td>(7.0)</td>
<td>(8.8)</td>
<td>(7.0)</td>
</tr>
<tr>
<td>Effect of tax rate reduction</td>
<td>6.0</td>
<td>6.0</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Other - net</td>
<td>0.6</td>
<td>0.3</td>
<td>0.6</td>
<td>0.3</td>
</tr>
<tr>
<td>Actual effective tax rate</td>
<td>39.7%</td>
<td>33.0%</td>
<td>39.7%</td>
<td>33.0%</td>
</tr>
</tbody>
</table>

On December 2, 2011, new tax reform laws were enacted in Japan, which changed the normal effective statutory tax rate from approximately 41% to 38% effective for the fiscal years beginning on or after April 1, 2012 through March 31, 2015, and to 36% afterwards. The effect of this change was to decrease deferred taxes in the consolidated balance sheet as of March 31, 2012, by ¥155 million ($1,890 thousand) and to increase income taxes - deferred in the consolidated statement of income for the year then ended by ¥171 million ($4,524 thousand).

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

(2) Nature and extent of risks arising from financial instruments
Receivables, such as trade notes and trade accounts, are exposed to customer credit risk. Marketable securities, mainly certificates of deposits, are exposed to little or no risk of market price fluctuations. Investment securities, mainly equity instruments, are exposed to the risk of market price fluctuations. Marketable and investment securities, mainly held-to-maturity securities of customers and suppliers of the Companies, are exposed to the issuer’s credit risk. Payment terms of payables, such as trade notes, trade accounts, other payables, and income taxes payable, are less than one year. Payables in foreign currencies are exposed to the risk of fluctuation in foreign currency exchange rates.

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

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

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

Market risk management
Foreign exchange risk and interest rate risk
Foreign currency trade payables are exposed to fluctuations in foreign currency exchange rates. Such foreign exchange risk is hedged principally by forward foreign currency contracts. The Companies have internal policies which restrict the use of

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derivatives only for the purpose of reducing market risks. Marketable and investment securities are managed by monitoring market values and the financial position of issuers on a regular basis.

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

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

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

(b) Financial instruments whose fair value cannot be reliably determined
Fair value information for derivatives is omitted from disclosure because fair values and unrealized gains were immaterial for the years ended March 31, 2012 and 2011.

(5) Maturity analysis of financial assets and securities with contractual maturities
The carrying values of notes and accounts receivables, other payables, and income taxes payable approximate fair value because of their short maturities.

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

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

Derivatives
Fair value information for derivatives is omitted from disclosure because fair values and unrealized gains were immaterial for the years ended March 31, 2012 and 2011.

(b) Financial instruments whose fair value cannot be reliably determined
Investments in equity instruments that do not have a quoted market price in an active market

11. COMPREHENSIVE INCOME
The components of other comprehensive income for the year ended March 31, 2012, were as follows:

12. NET INCOME PER SHARE
Net EPS for the years ended March 31, 2012 and 2011, was as follows:

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Notes to Consolidated Financial Statements

13. SUBSEQUENT EVENTS

At the general shareholders' meeting held on June 28, 2012, the Company's shareholders approved the following: Payment of a year-end cash dividend of ¥10 (¥0.12) per share to holders of record at March 31, 2012, for a total of ¥675 million ($8,231 thousand).

14. SEGMENT INFORMATION

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

1. Description of reportable segments

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

2. Methods of measurement for the amounts of sales, profit (loss), assets, and other items for each reportable segment

The accounting policies of each reportable segment are consistent with those disclosed in Note 2, "Summary of Significant Accounting Policies."

3. Information about sales, profit (loss), assets, and other items as is follows.

<table>
<thead>
<tr>
<th>Million of Yen</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales to external customers</td>
<td>¥55,747</td>
<td>¥11,558</td>
</tr>
<tr>
<td>Intersegment sales or transfers</td>
<td>55,747</td>
<td>11,558</td>
</tr>
<tr>
<td>Total</td>
<td>55,747</td>
<td>11,558</td>
</tr>
<tr>
<td>Segment profit</td>
<td>5,571</td>
<td>442</td>
</tr>
<tr>
<td>Segment assets</td>
<td>66,299</td>
<td>8,068</td>
</tr>
<tr>
<td></td>
<td></td>
<td>31,938</td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td>2,758</td>
<td>156</td>
</tr>
<tr>
<td>Increase in property, plant and equipment and intangible assets</td>
<td>885</td>
<td>83</td>
</tr>
<tr>
<td>Increase in property, plant and equipment and intangible assets</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Million of Yen</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales to external customers</td>
<td>¥52,514</td>
<td>¥10,971</td>
</tr>
<tr>
<td>Intersegment sales or transfers</td>
<td>52,514</td>
<td>10,971</td>
</tr>
<tr>
<td>Total</td>
<td>52,514</td>
<td>10,971</td>
</tr>
<tr>
<td>Segment profit</td>
<td>4,733</td>
<td>446</td>
</tr>
<tr>
<td>Segment assets</td>
<td>64,131</td>
<td>7,557</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td>2,918</td>
<td>164</td>
</tr>
<tr>
<td>Increase in property, plant and equipment and intangible assets</td>
<td>1,085</td>
<td>102</td>
</tr>
</tbody>
</table>

Related Information

1. Information about products and services

Sales to external customers

<table>
<thead>
<tr>
<th>Name of Customers</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDICEO CORPORATION</td>
<td>¥13,048</td>
<td>$159,122</td>
</tr>
<tr>
<td>Alfresa Corporation</td>
<td>11,912</td>
<td>145,268</td>
</tr>
<tr>
<td>Suokem Co., Ltd</td>
<td>11,290</td>
<td>137,683</td>
</tr>
<tr>
<td>Toho Pharmaceutical Co., Ltd</td>
<td>6,888</td>
<td>84,000</td>
</tr>
</tbody>
</table>

2. Information about geographical areas

(a) Sales

Information about geographic area is omitted, as sales to external customers located in Japan accounted for more than 90% of net sales presented in the consolidated statement of income for the year ended March 31, 2012.

(b) Property, plant, and equipment

Information about geographic area is omitted, as property, plant, and equipment located in Japan accounted for more than 90% of property, plant, and equipment presented in the consolidated balance sheet as of March 31, 2012.
Corporate Data/Investor Information

As of March 31, 2012

Corporate Name: Nippon Shinyaku Co., Ltd.
Head Office: 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan
Phone: +81-75-321-1111
Fax: +81-75-321-0678
URL: http://www.nippon-shinyaku.co.jp/

Paid-in Capital: ¥5,174 million

Representative Director: Shigenobu Maekawa
President: Independent and Certified Public Accountants

Employees: 1,823

Issued and Outstanding Number of Shares: 78,251,494

Number of Shareholders: 5,281

Major Shareholders:
Meiji Yasuda Life Insurance Company
Japan Trustee Services Bank, Ltd. (Trust account)
The Master Trust Bank of Japan, Ltd. (Trust account)
The Bank of Tokyo-Mitsubishi UFJ, Ltd.
The Bank of Kyoto, Ltd.
Nippon Life Insurance Company
Pershing-Div. of DLJ Secs. Corp.
Tokio Marine & Nichido Fire Insurance Co., Ltd.
Mitsubishi Corporation
Japan Trustee Services Bank, Ltd. (Trust account 9)

Stock Price

Trading Volumes

Distribution of Shareholders

Securities Corporations: 32 (0.57%)
Domestic Corporations: 19,830 (33.33%)
Foreign Investors: 123 (0.38%)
Financial Institutions: 339,623 (56.67%)
Individuals and Others: 4,670 (0.81%)

Distribution of Shares Issued (Thousands of shares)

Financial Institutions: 34,275 (48.55%)
Securities Corporations: 11,195 (15.35%)
Domestic Corporations: 7,036 (11.33%)
Foreign Investors: 12,626 (17.97%)
Individuals and Others: 7,955 (11.33%)

Balance Sheet

Income Statement

Cash Flow Statement

Independent Auditors’ Report

Deloitte Touche Tohmatsu LLC

INDEPENDENT AUDITORS’ REPORT

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

We have audited the accompanying consolidated balance sheet of Nippon Shinyaku Co., Ltd. (the "Company") and consolidated subsidiaries as of March 31, 2012, and the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

Management’s Responsibility for the Consolidated Financial Statements

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

Auditor’s Responsibility

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

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

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

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and consolidated subsidiaries as of March 31, 2012, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

Convenience Translation

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

June 29, 2012

Member of Deloitte Touche Tohmatsu Limited