

## Progressing with Global Expansion

Dainippon Sumitomo Pharma Co., Ltd. Annual Report 2012



## Progressing with Global Expansion

Since its formation in 2005 with the aim of becoming "an innovative pharmaceutical company with a strong market presence", Dainippon Sumitomo Pharma Co., Ltd. (DSP) has provided innovative and useful pharmaceuticals to people in Japan and around the world.

In 2007, we drew up our Mid-to-Long-term Vision under which we envisioned **"becoming an internationally competitive R&D-oriented pharmaceutical company"** and **"establishing two solid mainstreams of revenue, from domestic operations and from international operations"**, and began a full-scale advance into overseas markets.

With our acquisition of Sepracor Inc. (now Sunovion Pharmaceuticals Inc.) in 2009, we established our own sales and marketing infrastructure in the United States. In 2011, we substantially boosted the DSP Group's international presence by launching LATUDA®, a global strategic product. We are continuing our transformation toward our Vision with initiatives such as the April 2012 acquisition of U.S. company Boston Biomedical, Inc. to expand our presence in the area of oncology.

**Corporate Mission** 

To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide

#### Management Mission

- To contribute to healthcare and peoples well-being based upon the principles of patient-oriented management and innovative research
- To continuously strive to maximize corporate value through constant business development and to fulfill shareholder expectations
- To create an environment in which employees can fulfill their potential and increase their creativity
- To maintain the trust of society and to contribute to the realization of a better global environment

#### **Declaration of Conduct**

- 1. Help people to have "healthy bodies, healthy lives"
- 2. Pursue trustworthy corporate activities
- 3. Positively disclose information and properly manage information
- 4. Help employees reach their full potential
- 5. Respect human rights
- 6. Positively address global environmental issues
- 7. Build harmonious relationships with society









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#### Disclaimer Regarding Forward-Looking Statements

The forward-looking statements in this annual report are based on management's assumptions and beliefs in light of information available up to the date of publication, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document, being dependent on a number of factors. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

Note: This report is based on the financial results for fiscal 2011 (the year ended March 31, 2012). Some of the activities described were conducted in fiscal 2012.

# Progressing with Global

## Vision

DSP's vision for 2022 is to become an internationally competitive R&D-oriented pharmaceutical company with two solid mainstreams of revenue, from domestic operations and from international operations.

As a step toward this, by 2017 the Company aims to

- Establish a solid foundation for our domestic business
  - Expand our international business operation
  - Enrich our R&D product pipeline

2010

#### First Mid-term Business Plan (MTBP)

1st

#### (FY2007 - FY2009)

DSP worked to upgrade and strengthen its business platform for globalization. It submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) ahead of schedule for LATUDA<sup>®</sup>, an atypical antipsychotic. In addition, the Company progressed significantly in its globalization by establishing and expanding its business platform and R&D facilities in North America through the acquisition of Sepracor Inc. (now Sunovion Pharmaceuticals Inc.).

Sepracor Inc. acquired

NDA for LATUDA®

Five products newly launched in Japan



2005

# 2022

# Expansion

**3rd** Become an internationally competitive R&D-oriented pharmaceutical company

## 2015

# **2nc** Creation and transformation toward a new stage of globalization

### Second MTBP

#### (FY2010 - FY2014)

Based on the progress made in the first MTBP, the Company has set the theme of "Creation and transformation toward a new stage of globalization" for the second MTBP. The Company will strive to achieve the Vision and proceed to a new stage by

raising its creative capabilities and further transforming itself.



LATUDA® launched in the U.S.

**Boston Biomedical, Inc. acquired** 



#### Pharmaceuticals Business Sales Targets by Region



### **Highlights 2012**

#### May 2011

#### Launch of SUREPOST<sup>®</sup> in Japan



SUREPOST® is a rapid-acting insulin secretagogue that stimulates postprandial insulin secretion, thereby reducing postprandial blood glucose and drastically lowering HbA1c in type 2 diabetes patients. The launch of SUREPOST® has further enhanced DSP's product lineup in the diabetes area, which includes METGLUCO®, a biguanide oral hypoglycemic drug.

#### Favorable sales of LATUDA® December 2011



First-year sales of LATUDA®, an atypical antipsychotic that launched in the U.S. in February 2011, were \$86 million, the second highest among central nervous system (CNS) pharmaceuticals launched in the U.S. since 2007. Development of additional indications is progressing smoothly.

#### January 2012



The New Chemistry Research Building will consolidate the work of the Chemistry Research Laboratories of the Drug Research Division, and the Process Chemistry Research & Development Laboratories and Analytical Research & Development Laboratories of the Technology Research & Development Division. The aim of the new facility is to improve the efficiency of R&D operations from drug target discovery to applications for manufacturing and marketing approval. Completion of the New Chemistry Research Building is scheduled in March 2013 and operations are scheduled to start in July 2013. The total cost is expected to be about ¥8.7 billion.

#### April 2012

#### Acquisition of U.S. biotechnology company Boston Biomedical, Inc.

Start of construction of the New Chemistry Research Building



The acquisition of Boston Biomedical, Inc. (BBI) gives the DSP Group excellent drug discovery/development capabilities as well as an innovative pipeline in oncology. By putting BBI at the center of global oncology R&D for the DSP Group, DSP aims to make oncology one of its focus therapeutic areas next to CNS.

#### April 2012

#### Start of co-promotion of Paxil® CR Tablets in Japan with GlaxoSmithKline K.K.



CNS is one of DSP's focus marketing areas. The addition of antidepressant Paxil® CR Tablets to the product line will further enhance DSP's presence in this area. GlaxoSmithKline K.K. commenced sales in June 2012.

- Net sales decreased 7.7% year on year to ¥350.4 billion partly due to the impact of the strong yen and the absence of an upfront payment received in connection with a development and commercialization alliance.
- In the North America segment, sales increased year on year on a local currency basis, but decreased on a yen basis due to the impact of the strong yen. Sales increased in the China segment.
- Operating income decreased 34.1% year on year to ¥20.4 billion mainly due to the substantial impact of lower net sales, despite a decrease in licensing expenses and other research and development costs.
- Net income decreased 48.6% year on year to ¥8.6 billion due to other expenses, which included impairment losses on certain patent rights and business structure improvement costs associated with a revision of Sunovion's field force structure in the United States.



Overseas Sales/Overseas Sales as a Percentage of Total Net Sales







#### **Net Income**







#### **R&D** Costs



1. Earnings before interest, taxes, depreciation and amortization

2. ROE = Net income ÷ (Total net assets - Minority interests, average for the fiscal year)

3. ROA = Net income ÷ Total assets, average for the fiscal year

### **Interview with the President**

Fiscal 2011 was a productive year that positioned the Dainippon Sumitomo Pharma Group for the future as "an internationally competitive R&D-oriented pharmaceutical company".

Sales of the global strategic product LATUDA<sup>®</sup>, which was launched in February 2011, grew steadily, and we made progress in development for additional indications.

The highlight of the year was our acquisition of U.S. biotechnology company Boston Biomedical, Inc., which specializes in the area of oncology. With this acquisition, we made a full-scale start on global expansion to make oncology one of our focus therapeutic areas next to the central nervous system area.

Masayo Tada Representative Director, President and Chief Executive Officer

In fiscal 2011 we opened up new avenues. We will continue to expand steadily.

#### **Overview of Fiscal 2011**

# Q.1

What is your assessment of the Dainippon Sumitomo Pharma (DSP) Group's business activities during fiscal 2011?

# Overall, it was a productive year. While earnings results were less than favorable, our acquisition of Boston Biomedical, Inc., full-scale entry into the area of oncology, steady expansion of LATUDA<sup>®</sup> and other achievements positioned the DSP Group for the future.

In fiscal 2011, the second year of the five-year 2nd Mid-term Business Plan (2nd MTBP), net sales decreased 7.7% compared with the previous fiscal year to ¥350.4 billion. The decrease was largely due to the strong yen and the effect of special factors including the absence of an upfront payment received in connection with a development and commercialization agreement in the previous fiscal year. If we look at the real performance of our business excluding these special factors, sales were at or above the level of the previous fiscal year in both the domestic pharmaceuticals business and overseas business. The decrease in net sales had an impact on profits. Operating income was down 34.1% to ¥20.4 billion and net income declined 48.6% to ¥8.6 billion.

While results were disappointing in terms of earnings, there were several positive points that deserve mention. The most significant was our agreement with U.S. biotechnology company Boston Biomedical, Inc. (BBI) in February 2012 to acquire BBI\*. BBI specializes in the area of oncology and has two innovative compounds, BBI608 and BBI503, which are small molecular oral drugs aimed at causing an antitumor effect in cancer stem cells. BBI founder Dr. Chiang J. Li and his team have established an impressive track record of a number of research and development programs. We plan to build a global oncology R&D network with BBI at the center to develop oncology into one of our focus therapeutic areas next to the central nervous system (CNS) area.

We also made concentrated investments of resources to maximize earnings from our global strategic product LATUDA<sup>®</sup>, an atypical antipsychotic. Sales in fiscal 2011, the drug's first year on the market, were \$86 million. Clinical studies for new indications are also progressing smoothly.

In Japan, in the area of diabetes, high evaluations of METGLUCO<sup>®</sup>, a biguanide oral hypoglycemic drug launched in May 2010, helped to drive sales growth. In addition, SUREPOST<sup>®</sup>, a rapid-acting insulin secretagogue, was launched in May 2011. As a result, we successfully boosted our presence in the diabetes area.

One of our top priorities is to "expand the pipeline for continuous new drug creation". With the addition of the two BBI compounds and other oncology agents such as WT2725 and WT4869, which we are co-developing with Chugai Pharmaceutical Co., Ltd., and the addition of other in-house compounds to phase I clinical studies, we have significantly increased our pipeline.

My overall assessment is that in spite of our less than favorable results, fiscal 2011 was a sufficiently productive year from the standpoint of positioning the DSP Group for growth in the future.

\* The acquisition of BBI was completed in April 2012.

#### The DSP Group's Growth Strategy

Q.2

One of DSP's top priorities for fiscal 2012 is to "expand overseas operation and maximize earnings". What is the outlook for achieving those goals?

Changes in the status of major products, a delay in the launch of STEDESA<sup>TM</sup> and other factors led to a slight divergence from the initial targets of the 2nd MTBP. But sales of LATUDA<sup>®</sup> continue to expand, and we are making steady progress in developing additional indications, so the outlook is good.

First, in our North American operations, we will continue to focus on marketing LATUDA<sup>®</sup>, which is showing steady sales growth. We aim to more than double sales in fiscal 2012 compared with fiscal 2011. In the development of LATUDA<sup>®</sup>, an expansion of the daily dose was approved in April 2012, and positive results were obtained in clinical studies for the treatment of bipolar 1 depression. We aim to submit a supplemental New Drug Application (sNDA) for this new indication by September 2012. We also plan to resubmit an NDA for STEDESA<sup>™</sup>, an antiepileptic agent, by the end of September 2012.

In our Chinese operations, we continued to focus on expanding sales of MEPEM<sup>®</sup> (MEROPEN<sup>®</sup>), a carbapenem antibiotic, and will aim for sales growth in fiscal 2012 as well.

Fiscal 2012 is the midway point of the 2nd MTBP. The change in status of major products and the delay in launching STEDESA<sup>™</sup> in North America have resulted in a slight divergence from the initial targets of the 2nd MTBP, but we are making steady progress toward achieving our Mid- to Long-term Vision. In addition, the acquisition of BBI will further accelerate our global development in the oncology area.

#### Overseas Sales/Overseas Sales as a Percentage of Total Net Sales



# Q.3

Conditions remained challenging for the pharmaceutical business in Japan due to competition and drug price revisions. What are DSP's policies for the future and the current issues facing the company?

We will concentrate resources on strategic products and new products. Large-scale new products will be essential for further sales growth, so we will also focus on acquiring in-licensed products.

We think the National Health Insurance (NHI) drug price revisions in April 2012 will reduce sales for fiscal 2012 by over ¥10.0 billion. To offset the impact of the drug price revisions, we will seek to expand sales by concentrating resources on strategic products and new products.

We plan to increase sales by approximately ¥8.0 billion with four strategic products: AVAPRO<sup>®</sup>, a therapeutic agent for hypertension, LONASEN<sup>®</sup>, an atypical antipsychotic, PRORENAL<sup>®</sup>, a vasodilator, and TRERIEF<sup>®</sup>, a treatment for Parkinson's disease that we added to this category in fiscal 2012. As for new products, we added METGLUCO<sup>®</sup> and SUREPOST<sup>®</sup>, as well as Paxil<sup>®</sup> CR, an anti-depressant co-promoted with GlaxoSmithKline that we included in our portfolio in fiscal 2012. Moreover, we expect to obtain approval for DSP-8153, a combination product of irbesartan and amlodipine besilate for hypertension.

Our percentage of long-listed drugs for which patents have expired and generic versions are available currently stands at around 50%, but we want to lower that figure to about 30%. To do so, we will further enhance our lineup of new products by focusing on obtaining compounds through marketing alliances and in-licensing in addition to developing our own compounds.



What will be the "post-LATUDA<sup>®</sup>" growth drivers, and what is your strategy for expanding the development pipeline?

#### We are positioning oncology as a new focus therapeutic area next to CNS, and are setting up the R&D organization to make it a future growth driver. We will also continue to promote alliances and in-licensing to further enhance our pipeline.

Through the acquisition of BBI, the DSP Group gained outstanding R&D capabilities and two highly promising compounds in the area of oncology. BBI will lead our drive to make oncology another focus therapeutic area next to CNS, and is currently building a global oncology R&D base in the Boston area. A phase III clinical study of BBI608 is scheduled to begin in 2012, and we aim to launch it in 2015 at the earliest. BBI608 is the leading "post-LATUDA®" candidate compound.

Besides the two compounds from BBI, potential candidates in oncology at slightly different stages are WT2725, which we are co-developing with Chugai Pharmaceutical, and compounds in the preclinical stage. In the CNS area, our pipeline includes our own compounds for the treatment of Alzheimer's disease, depression, neuropathic pain and other conditions. Another candidate is SB623 (stroke recovery), for which we received an option-right from SanBio, Inc.

Looking at commercialization even further in the future, we will continue to strengthen research partnerships with domestic and overseas research institutions and in-licensing and alliance activities with other pharmaceutical companies to expand and enhance our pipeline.

#### The DSP Group's CSR Activities

Q.5

What specific measures did DSP take in fiscal 2011 to "promote CSR and continuous increases in management efficiency"?

#### The entire DSP Group worked to support reconstruction in the aftermath of the Great East Japan Earthquake. We also focused on strengthening risk management and diversity management.

In fiscal 2011, the entire DSP Group worked to support reconstruction in the aftermath of the Great East Japan Earthquake. Based on its business of medicine, which is closely related to human life, the DSP Group has a strong sense of mission to support the victims of such grievous disasters.

Immediately after the earthquake and tsunami, we made monetary donations, sent employee volunteers and supplied medicines to the affected areas. In May 2011, we established the Earthquake Disaster Reconstruction Support Office. This office investigated, planned and implemented DSP's activities for reconstruction and restoration. Since then, we have continued a wide range of activities including support for sports days of local elementary and junior high schools. (See page 37 for details on our support for reconstruction in the aftermath of the Great East Japan Earthquake.)

Using what we learned from that disaster, we also revised our business continuity plan. The Risk Management Committee led initiatives to improve supply chain management and maintain stockpiles at each site. In addition, we improved communication tools such as methods of ascertaining the whereabouts of employees.

DSP believes that energizing and training its employees is vital for developing its business. Since 2008, we have conducted a company-wide campaign to reform the attitude and behavior of employees under the mottos "Change for Challenge!" and "Seek Something New!"\* In addition, we have made progress in promoting female employees and in more active hiring of and exchanges with people from all countries. I believe these actions will further globalize and energize the DSP Group.

To improve management, we launched the "Overall Business Results Improvement Project" in fiscal 2009. In fiscal 2011, we implemented cost-cutting measures across the group, including overseas operations, for R&D, marketing, manufacturing and other expenses, based on streamlining and prioritization of work.

\* Implicit in these mottos are the meanings, "Transform ourselves to face difficult challenges", and "Accomplish things never done before".

#### **Increasing Corporate Value**

# Q.6

What is your policy for fiscal 2012? Also, please give a closing message to stakeholders.

## I see this as a year of progress for putting DSP on a growth track, and we will put our full effort into accomplishing that.

Fiscal 2011 was a productive year that positioned the DSP Group for the future. The expansion of sales of LATUDA<sup>®</sup> has put us on a growth track to "become an internationally competitive R&D-oriented pharmaceutical company".

I view fiscal 2012 as a year for taking a step toward further growth. We plan to conduct our business activities with a continued focus on three of our top priorities: "transform the earnings structure in Japan", "expand overseas operation and maximize earnings", and "expand the drug pipeline for future growth".

For our top-priority project, LATUDA<sup>®</sup>, we will put our full effort into sales and marketing in the U.S. and will continue to advance research and development globally.

With all employees fully committed to carrying out the basic strategies of the 2nd MTBP, we intend to further solidify our growth track.

Consistently delivering appropriate returns to shareholders is also one of our most important management priorities. In setting dividends, we emphasize appropriate allocation of profits while comprehensively considering management requirements such as investment for the company's future growth, enhancement of our business platform and improvement of our financial status, all oriented to further increase corporate value.

For fiscal 2011, we paid a year-end dividend of ¥9.00 per share. Combined with the ¥9.00 per share interim dividend, this brought total dividends for the year to ¥18.00 per share. We are planning to maintain total dividends at ¥18.00 per share in fiscal 2012 to continue delivering stable dividends to shareholders.

We will continue to focus on investor relations activities for our shareholders and other stakeholders, not only to disclose necessary management information but also to demonstrate the accountability of senior management. We welcome the candid feedback of our stakeholders, and ask for their continued support.

#### **Fiscal 2012 Targets**

(Billions of yen)	FY2011 (Actual)	FY2012 (Forecast)	YoY change	Percent change
Net sales	350.4	348.0	(2.4)	(0.7)%
Operating income	20.4	25.0	4.6	22.5%
Net income	8.6	12.0	3.4	39.1%

Foreign currency exchange rates FY2011: ¥79.8=U.S.\$1, ¥12.4=1 RMB FY2012 (forecast): ¥80=U.S.\$1, ¥12=1 RMB

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We are working to create a steady flow of new drugs from our global R&D organization. Moving to complement CNS with another core business area, the DSP Group began its full-scale entry into oncology in fiscal 2011.

#### **Basic Strategy**

DSP is determined to "become an internationally competitive R&D-oriented pharmaceutical company" and is working to "expand the pipeline for continuous new drug creation" as one of the basic strategies in the second Mid-term Business Plan (2nd MTBP).

#### **Drug Discovery Research Initiatives**

#### Focus Therapeutic Area and Challenge Therapeutic Areas

We are conducting R&D and concentrating resources in the following two core areas.

#### Focus Therapeutic Area: CNS Challenge Therapeutic Areas: Specialty areas

(oncology and immune-related diseases)

The CNS area has been our primary research area of focus in our drive to create global products. We have positioned it as our focus therapeutic area because it is an area with significant medical needs and an area in which DSP is highly competitive. In drug discovery research, we are focusing on diseases that have increasing medical needs within the current aging and high-stress society, such as schizophrenia, dementia and depression.

DSP has chosen specialty areas as its challenge therapeutic areas. Specialty areas are those that have significant unmet medical needs and that demand a high degree of specialization in research, development and marketing, such as oncology and immune-related diseases. In oncology, we are currently building a research and development base in the Boston area, centered on Boston Biomedical, Inc. (BBI), which we acquired in 2012.

We will accelerate the development of existing clinical-stage products to confirm Proof of Concept (POC)\*, to file new drug applications and to obtain approval as early as possible. For new research and development programs, we will concentrate on candidates in the focus therapeutic area and the challenge therapeutic areas to conduct speed- and efficiency-oriented research and development that ensures a high probability of success.

\* Proof of Concept: Confirmation in human subjects of estimated efficacy and safety characteristics

#### **Full-scale Participation in Oncology**

The DSP Group is enhancing its presence in oncology with the aim of making it a future core business area next to CNS. We established the Global Oncology Business Development Office in June 2011 to coordinate various functions and activities related to the area of oncology across multiple divisions and regions.

Since acquiring BBI in April 2012, as discussed earlier, the DSP Group has been building a global oncology research and development base with BBI at the center. We plan to open a 100-person facility in Cambridge, Boston in 2012. We are also building a network linking Japan, China and other areas to enhance collaboration among DSP Group companies.

#### **Global R&D Network**

The DSP Group has R&D bases in the four regions of Japan, the U.S., China and the U.K. that engage in collaborative activities.

The DSP Group established the Global Business Strategy Committee (GBSC) and the Global R&D Committee (GRDC) in April 2012 in order to more efficiently build a network for conducting global R&D. GBSC works to optimize the DSP Group's overall portfolio with a global perspective by discussing issues including global business strategy, licensing projects, and R&D strategy such as project prioritization and resource allocation. GRDC discusses the promotion of projects in initial development stages and other issues with a global perspective.

## Prioritize Investment in Obtaining POC of Next Strategic Candidates

To create novel strategic drug candidates to follow LATUDA®, an atypical antipsychotic, we will prioritize allocation of resources to compounds already in clinical-stage development to obtain POC as soon as possible. Our primary focus for "post-LATUDA®" candidates will be on areas in which the DSP Group has competitive advantages, such as CNS and oncology, and areas in which it can efficiently conduct R&D and marketing activities.

In the CNS area, the DSP Group is targeting inhouse products that are now under development in the U.S. for Alzheimer's disease, depression, neuropathic pain and other conditions. In addition, possible candidates include in-licensed products such as SB623 (stroke), for which DSP has obtained option rights in North America from SanBio, Inc. and compounds at the preclinical stage. In the oncology area, the acquisition of BBI added BBI608 and BBI503 to the development pipeline. Both of these compounds are expected to be leading "post-LATUDA<sup>®</sup>" candidates. Also, development of WT2725 has begun in North America.

We plan to select several promising candidates from the above, and will accelerate their development.

#### Promotion of Alliances and In-Licensing through Strategic Investment

From the standpoint of expanding our pipeline, the DSP Group will fully leverage its existing information network, knowledge and expertise as well as the resources of Sunovion and BBI as we actively promote alliances and in-licensing through strategic investment.

In Japan, we are aggressively promoting inlicensing with a focus on compounds for which we make use of our sales and marketing infrastructure. In fiscal 2011, DSP added antidepressant Paxil® CR Tablets to its product lineup by concluding a copromotion agreement with GlaxoSmithKline K.K. for this product in Japan.

In North America, we will place priority on inlicensing compounds in the CNS and respiratory areas where we can take advantage of Sunovion's sales network.





Sunovion Pharmaceuticals Inc. Executive Vice President, CMO Antony Loebel, M.D.

### CNS

The DSP Group launched the global strategic product LATUDA® in the U.S. in February 2011. Sales are expanding steadily, and development of additional indications is progressing. Antony Loebel, M.D., Executive Vice President and Chief Medical Officer of Sunovion Pharmaceuticals, leads the development of LATUDA®. In this interview, he discusses the current status of development.

#### Please explain the main points and implications of the LATUDA® (lurasidone HCl) PREVAIL studies.

PREVAIL is an acronym for **PR**ogram to **EV**aluate the **A**ntidepressant Impact of Lurasidone. On April 24, 2012, DSP announced results from two Phase III clinical trials, PREVAIL 1 and PREVAIL 2, designed to evaluate the efficacy and safety of LATUDA® as adjunctive therapy and monotherapy, respectively, in adult patients with bipolar 1 depression. Currently, there are very few medications approved in the U.S., or elsewhere, for the treatment of this relatively large patient population.

The results of these studies were encouraging. Lurasidone, as both monotherapy and adjunctive therapy, was found to be an effective treatment for bipolar 1 depression in these placebo-controlled trials. All primary and secondary efficacy endpoints were consistently met in both studies. Moreover, the overall safety profile for lurasidone in these studies was similar to that observed in previous studies of the product. In particular, the effects of lurasidone therapy on weight, lipids, glycemic control, and prolactin levels appeared to be low in these studies.

With these results from two positive placebocontrolled trials, we plan to submit a bipolar 1 depression sNDA to the U.S. Food and Drug Administration (FDA) in the third quarter of 2012, seeking approval for use of lurasidone as monotherapy and adjunctive therapy. If approved by the U.S. FDA we believe lurasidone will be an important addition to available treatment options for patients with bipolar 1 depression. In fact, currently there are no approved medications for the adjunctive treatment of bipolar 1 depression (in combination with lithium or valproate), and only one medication (quetiapine, in IR and XR formulations) is approved as monotherapy for bipolar 1 depression in the U.S. Therefore, lurasidone may become the first atypical agent approved for adjunctive therapy use in combination with mood stabilizers. This is important as most patients with bipolar disorder receive treatment with mood stabilizing drugs such as lithium or valproate, as these are regarded as key for the treatment and prevention of manic episodes.

## Please explain the main points and implications of the LATUDA<sup>®</sup> switch study.

This study assessed methods of switching patients with schizophrenia from other atypicals to lurasidone. All patients were clinically stable, but experiencing some problems with their current treatment. Patients were randomized in open-label fashion to three different initial dose regimens of lurasidone (40mg/day or 80mg/day, or uptitrated from 40mg/day to 80mg/day).

Since the results of switching to LATUDA<sup>®</sup> were similar for the three initial dose groups, the choice of

#### PREVAIL 1: MADRS (MMRM) – primary endpoint



#### PREVAIL 2: MADRS (MMRM) – primary endpoint (ITT)



Study Design	Top Line Results
PREVAIL 1 (Adjunctive therapy)	First Positive Placebo-Controlled Study among Atypical
<ul> <li>6-week, placebo-controlled study</li> </ul>	Antipsychotics Added to Mood Stabilizers
<ul> <li>56 clinical sites worldwide</li> </ul>	LATUDA <sup>®</sup> experienced significant improvements in MADRS
<ul> <li>348 patients with bipolar 1 depression</li> </ul>	scores (primary endpoint) and CGI-BP-S scores (key secondary endpoint) compared to placebo
<ul> <li>LATUDA<sup>®</sup> 20mg/day-120mg/day</li> </ul>	
Lithium or valproate was administered on both LATUE	DA and Consistent Safety & Tolerability Profile
placebo arms	<ul> <li>In the study, LATUDA<sup>®</sup> was well tolerated with the same</li> </ul>
PREVAIL 2 (Monotherapy)	level of discontinuation rate as placebo
6-week, placebo-controlled study	<ul> <li>The most common adverse events reported for the lurasidone group (greater than 5% and twice the rate of</li> </ul>
<ul> <li>55 clinical sites worldwide</li> </ul>	placebo) were: nausea, headache, somnolence, tremor,
<ul> <li>505 patients with bipolar 1 depression</li> </ul>	akathisia, insomnia and sedation
<ul> <li>LATUDA<sup>®</sup> 20mg/day-60mg/day</li> </ul>	
LATUDA <sup>®</sup> 80mg/day-120mg/day	

#### **PREVAIL 1, 2 Top Line Results**

specific switch strategy may be based on individual need and clinical judgment. Our study results show that patients can be effectively switched to LATUDA® from other antipsychotic agents. This finding is important because it give psychiatrists increased flexibility and insights into how and why to change medications for patients being treated for schizophrenia.

#### How is the synergy between Sunovion Pharmaceuticals and DSP supporting LATUDA<sup>®</sup> and the drug development pipeline?

Together, Sunovion Pharmaceuticals and DSP have transformed R&D into a global function, with close integration between discovery activities and clinical development, allowing us to leverage our global resources and expertise. Management and governance synergies are helping to ensure that investments in commercial and R&D activities are coordinated globally and include timely and comprehensive information to support joint decision-making. The energetic exchange of scientific ideas and insights that has resulted from merging both companies' drug discovery knowledge and capabilities is helping us to discover new agents more efficiently.

Our global approach is also helping us to speed drugs to market worldwide. LATUDA® is now available in Canada. We intend to use Sunovion-sponsored study data to support schizophrenia and bipolar registration programs in Europe, China and elsewhere in Asia. All of these marketing applications will use the same fundamental set of studies, which we will then tailor with additional work to meet the needs of regulatory authorities in each country, as appropriate. The expected result is greater efficiency, lower cost and faster time to market. We believe that this is a good model for the future development of other investigational products.

## What is on the R&D horizon for Sunovion Pharmaceuticals and DSP?

We are committed to finding solutions for the unmet needs of patients around the world who are suffering from serious mental illnesses and other CNS disorders. As a clinician, scientist and chief medical officer at Sunovion Pharmaceuticals, I am proud to lead our mission of finding new and innovative treatments that can have a meaningful effect on the lives of patients.

LATUDA<sup>®</sup> is now approved for the treatment of schizophrenia in the United States and Canada. DSP has initiated a new Phase III study in patients with schizophrenia in Japan while working with co-development partner Takeda in Europe towards the objective of achieving regulatory submission and approval for LATUDA<sup>®</sup> for the treatment of patients with schizophrenia and, ultimately, bipolar disorder. As I mentioned, we also intend to submit a bipolar 1 depression sNDA to the U.S. FDA and Health Canada in 2012.

At the same time, we remain committed to the development of STEDESA<sup>™</sup> (eslicarbazepine acetate), a novel voltage-gated sodium channel blocker antiepileptic agent intended for the treatment of partial-onset epilepsy in adults and we plan to pursue several additional indications in the future. After receiving a Complete Response letter in April 2010 from the U.S. FDA, we plan to resubmit an NDA with new Phase III results by the end of September 2012.

In addition, Sunovion markets LUNESTA® (eszopiclone) for the treatment of insomnia. This is a unique and exciting CNS portfolio that covers the psychiatric, neurological and sleep disorder categories. Few companies have such breadth and depth in the CNS area, which we are further enhancing with clinical studies for compounds including SEP-228432 (neuropathic pain), DSP-8658 (Alzheimer's disease), DSP-1053 (major depressive disorder), DSP-0565 (epilepsy) and DSP-2230 (neuropathic pain). The DSP Group is also increasing its presence in other areas including oncology, which makes for a very exciting time to be part of this outstanding global R&D organization. In April 2012, the DSP Group obtained approval in the U.S. for an increase in the maximum daily dose of LATUDA<sup>®</sup>, an atypical antipsychotic, to 160mg. Targeting additional indications, we are moving forward with development for bipolar 1 depression and bipolar disorder maintenance and major depressive disorder (MDD) with mixed features. In Canada, LATUDA<sup>®</sup> was approved in June 2012 for adult acute schizophrenia. In Japan, a Phase III study is in progress, while in Europe the DSP Group is targeting an early NDA submission by co-developing LATUDA<sup>®</sup> with Takeda Pharmaceutical Company Limited.

In the U.S., we plan to resubmit the NDA for STEDESA<sup>TM</sup>, an antiepileptic agent, by the end of September 2012.

Compounds that moved into clinical development in fiscal 2011 are DSP-2230, for the treatment of neuropathic pain, and DSP-0565, an antiepileptic agent. In addition, the DSP Group's CNS pipeline includes DSP-8658, for the treatment of Alzheimer's disease, DSP-1053, for the treatment of major depressive disorder and SEP-228432, for the treatment of neuropathic pain and major depressive disorder. These three compounds are in Phase I clinical studies. In the U.S., SanBio, Inc. is currently conducting Phase I/II clinical studies for SB623, a therapy for stroke recovery for which DSP has obtained option rights in North America from SanBio. **STEDESA™:** A novel voltage-gated sodium channel blocker. In the U.S., the DSP Group aims to obtain approval as an adjunctive therapy for partial-onset epilepsy in adults. It is expected to be safe and tolerable, have clear dose-response correlation and marked and sustained seizure reduction. The DSP Group in-licensed STEDESA<sup>™</sup> from BIAL-Portela & C<sup>a</sup>, S.A.

**SB623:** A cell therapy for stroke recovery for which DSP has obtained the option agreement from SanBio, Inc. for North American rights. An innovative compound, SB623 is expected to be effective in treating various disabilities caused by stroke for which no effective therapies currently exist.

**DSP-2230:** A novel compound that selectively inhibits voltage-gated sodium channels Nav1.7 and Nav1.8. This drug is expected to be effective against peripheral neuropathic pain and highly safe because it does not produce CNS or cardiovascular side effects.



## Oncology

DSP began its full-scale entry into the oncology area in April 2012 with the acquisition of BBI. In this interview, BBI CEO Dr. Chiang J. Li gives an overview of the company and discusses the future of oncology at the DSP Group.



Boston Biomedical, Inc. President, CEO, CMO Chiang J. Li

#### Please provide an overview of Boston Biomedical, Inc.

Boston Biomedical (BBI) is a small biotech company, albeit with exceptional employees, a unique culture, and an exciting track record of outstanding accomplishments. Among our 30 employees, more than 80 percent have received a PhD and/or an MD education, with the majority of these having received training at Harvard University or MIT.

In less than 10 years, our R&D team has created two Phase III-stage, first-in-class, cancer drug programs and numerous Phase I/II-stage, first-inclass, innovative oncology drug programs. A key to this success is our exciting and unique startup culture which embodies innovation, challenge, diligence, teamwork, respect and caring. This distinctive culture has allowed BBI to recruit top talent in both the greater Boston area and throughout the U.S.

## How did BBI come to know and become part of the DSP Group?

I first met Dr. Hiroshi Noguchi (currently Member, Board of Directors, Executive Vice President, and Chief Strategic Officer of DSP) at Dana-Farber Cancer Institute/Harvard Medical School about 20 years ago. I also have enormous respect for DSP's long history of exemplary achievements in creating innovative products for patients, and the deep-rooted culture which focuses on long-term growth. I admire DSP's approach of "change for challenge" and "seek something new". Such compatibility between corporate cultures along with mutual understanding provides a strong foundation with which to leverage the value of the enormous synergy in science and technology between DSP and BBI.

The BBI team has established an outstanding track record in the creation of world-leading oncology therapeutic programs that owes largely to its strength in cutting-edge oncology science, deep clinical development capability, and talented people. However, BBI's growth has been hindered by its scarce resources, and its limited capabilities in pharmaceutical development, cGMP manufacture, commercialization, and support infrastructure. The DSP Group therefore complements BBI precisely in the areas that BBI is weak. This synergy will undoubtedly serve as a catalyst for the rapid growth and advancement of BBI's oncology product portfolio.

#### As a leader in the oncology area, what would you like to accomplish in the future?

The DSP-BBI oncology group is well positioned to solidify its leadership in creating innovative anti-cancer products targeting cancer stem cells, which are widely considered as a key frontier with the promise to deliver the next generation of breakthrough oncology therapeutics.

Humans have suffered from cancer for thousands of years, yet the first cancer chemotherapy drug was created only a little more than 50 years ago. However, as we all know, chemotherapy drugs are not particularly effective, and are quite toxic. The past decade has witnessed the exciting emergence of targeted cancer drugs. While we have seen improvement in toxicity profiles over the past 10 years with molecular target drugs, efficacy remains quite limited and transient for the vast majority of cancer patients. Based on the revolutionary understanding of cancer acquired during the past few decades, pharmaceutical manufacturers and research institutions are eagerly seeking new breakthroughs in order to make headway in cancer treatment.

One highly innovative frontier in cancer therapy is to target cancer stem cells. Cancer stem cells are considered to be the ultimate root of malignancy responsible for cancer metastasis, recurrence, and drug refractoriness. The DSP-BBI oncology group has a world-leading portfolio in the area of cancer stem cells drugs. BBI608, which is poised to enter Phase III trials for colorectal cancer in North America, has recently been selected as one of the "2012 Top Ten Promising Late Stage Cancer Drugs\*" in the world.

The BBI-DSP oncology group, therefore, has the rare opportunity and exciting prospect of creating and developing a leading innovative oncology product pipeline to fulfill our obligation to cancer patients. I am committed to this mission.

\* Selected by *Fierce Biotech* from its proprietary survey of top ten promising late stage cancer drugs in fiscal 2012

#### **DSP Cancer Institute**

In September 2012, DSP will establish a new organization called "The DSP Cancer Institute" that reports directly to the President of DSP to conduct faster and more flexible decision-making regarding research and development in the oncology area.

Chiang J. Li, Head of Global Oncology for the DSP Group, will direct the new laboratory.

The acquisition of BBI enhanced the DSP Group's oncology development pipeline with two innovative compounds, BBI608 and BBI503, which target cancer stem cells. In the U.S. and Canada, BBI608 is currently in preparation for Phase III clinical studies for patients with colorectal cancer (monotherapy) and BBI503 is undergoing Phase I clinical studies for patients with solid cancer (monotherapy).

Clinical studies are also under way for WT4869 in Japan and WT2725 in the U.S. in co-development with Chugai Pharmaceutical Co., Ltd. Both compounds are therapeutic cancer vaccine candidates using a peptide derived from Wilms' tumor gene 1 (WT1) protein.

In China, the DSP Group is conducting a Phase III clinical study of amrubicin hydrochloride (brand name in Japan: CALSED®) for the treatment of small cell lung cancer.

**BBI608, BBI503:** Orally administered, first-in-class, small molecular anti-cancer drugs created by BBI for an antitumor effect on cancer stem cells. Targeting cancer stem cells as well as other heterogeneous cancer cells, these compounds inhibit both growth of tumor cells and maintenance of cancer stem cells. BBI608 and BBI503 are expected to provide superior efficacy and safety as monotherapies or in combination with chemotherapeutic and other agents.

WT4869, WT2725: Therapeutic cancer vaccines targeting WT1, a protein expressed in cancer cells. DSP is co-developing these compounds with Chugai Pharmaceutical using the basic and clinical research of Professor Haruo Sugiyama of Osaka University. They are expected to demonstrate efficacy in the treatment of leukemia and various types of solid cancer by inducing WT1-specific cytotoxic T-lymphocytes that have the potential to attack cancer cells that express WT1.

#### Leveraging Our Proprietary Technologies

The DSP Group has a solid foundation of technologies and experience throughout its pharmaceutical research and development operations, and a particular competitive advantage in such cutting-edge technologies as genomics, proteomics and metabolomics. We aim to deploy these technologies in all phases of pharmaceutical research and development. In addition, we are conducting research on biopharmaceuticals, including antibody drugs and nucleic acid drugs.

#### Research Alliances with Outside Research Institutions

To ensure a continuous flow of new drug candidates, DSP works to create innovative therapeutic agents by promoting research alliances with universities and other research institutions.

A concrete example of joint research with outside research institutions is our established alliance in the CNS area with the Graduate School of Osaka University in the Neuropsychiatric Drug Discovery Consortium (NDDC). The NDDC is working to discover innovative mental/neural drugs that present characteristics not found in previous cures by addressing the mechanism of mental disease onsets at the genetic and molecular levels. NDDC transitioned to its second stage in October 2011. We have also launched the Laboratory for Malignancy Control Research (the DSK Project) with Kyoto University to discover innovative anti-cancer drugs based on controlling cancer malignancy. The DSK Project began full-scale operations in April 2011. In addition, we are conducting collaborative research with the Center for iPS Cell Research and Application (CiRA), Kyoto University to develop a treatment for a rare intractable disease, and with the University of Tokyo on an apoptosis inhibitor of macrophages (AIM).\*

Overseas, we are screening candidate molecules, primarily targeting Alzheimer's disease, at the Karolinska Institutet Sumitomo Pharmaceuticals Alzheimer Center (KASPAC), the DSP Group's research laboratory within Karolinska Institutet of Sweden. We are now in the third stage of joint research, which focuses on promising target molecules.

\* Apoptosis inhibitor of macrophages (AIM): Produced from a macrophage, AIM acts on fat cells and the macrophages itself. It was shown that AIM has a strong relation to metabolic syndrome.

#### Seek Various Measures to Expedite R&D

We are taking various measures to expedite R&D and raise operating efficiency.

Specifically, we are able to efficiently confirm POC in the shortest period with the fewest resources possible. We subsequently make the go/no go decision based on those study results and on an evaluation of the project. The Drug Research Division is in charge of the R&D process up until the implementation of POC studies to ensure a seamless transition from research to development. To expedite R&D, we utilize a screening cascade (evaluation steps and selection criteria for new drug candidates) in the drug discovery stage and proactively incorporate extemporaneous preparation, microdosing, and global clinical studies in the development stage.





#### **Cardiovascular & Diabetes**

DSP is conducting a domestic Phase III clinical study of ranirestat, a potential treatment for diabetic neuropathy with high market potential. Furthermore, we submitted an NDA in Japan for DSP-8153 in November 2011 for hypertension, a combination product of amlodipine besilate (AMLODIN<sup>®</sup> calcium channel blocker) and irbesartan (AVAPRO<sup>®</sup> angiotensin II receptor blocker), and expect to launch in fiscal 2012.

Moreover, in fiscal 2011 DSP-9599, a treatment for hypertension, entered clinical development.

Ranirestat: This compound is expected to alleviate diabetic neuropathy, a complication of diabetes, by inhibiting aldose reductase and thereby inhibiting the accumulation of intracellular sorbitol that causes diabetic neuropathy. The results of a Phase IIb clinical study in Japan showed that although a clear dose response relationship was not established, a significant increase in sensory-motor nerve conduction velocity, a primary endpoint, was seen in all ranirestat arms compared to before administration. We have granted the overseas development and commercialization rights for this compound to Eisai Co., Ltd., which is now conducting a Phase II/III clinical study in the U.S., Canada and Europe.

#### Respiratory

In the U.S., Sunovion received approval from the FDA for ZETONNA<sup>™</sup> Dry Nasal Aerosol Spray, a new dosage form of core product ciclesonide for the treatment of allergic rhinitis, and launched the product in July 2012. In Japan, DSP-3025, a potential treatment for bronchial asthma and allergic rhinitis, is at the Phase I stage.

**DSP-3025:** An immune response modifier with agonistic activity against Toll-like receptor 7 (TLR7). This compound is expected to become a therapeutic agent providing long-term disease remission in bronchial asthma and

allergic rhinitis. We have entered into a codevelopment and co-marketing agreement with AstraZeneca PLC under which we retain development and commercialization rights in Japan, China, Korea and Taiwan, and AstraZeneca retains development and commercialization rights worldwide excluding these four countries. AstraZeneca is conducting a Phase II study in Europe. (AstraZeneca's code name: AZD-8848)

#### Others

A Phase II clinical study for PRORENAL® for the treatment of carpal-tunnel syndrome as an additional indication in Japan is under way in co-development with Ono Pharmaceutical Co., Ltd. SMP-986, a potential treatment for overactive bladder syndrome, is at the Phase II stage in the U.S., Europe and Japan.

Compounds that entered clinical development in Japan in fiscal 2011 are DSP-6952 for the treatment of Irritable Bowel Syndrome (IBS) with constipation and chronic idiopathic constipation; DSP-1747 for the treatment of primary biliary cirrhosis (PBC) and nonalcoholic steatohepatitis (NASH), in-licensed from Intercept Pharmaceuticals Inc.; and DSP-5990 for treatment of MRSA infection, in-licensed from Takeda.

**DSP-1747:** In-licensed from Intercept Pharmaceuticals, DSP-1747 is a farnesoid X receptor (FXR) agonist whose ligand is the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. Intercept Pharmaceuticals is conducting development overseas. A Phase III study is underway for patients with PBC, and Phase II/III studies are underway for patients with NASH. DSP-1747 is expected to be the world's first drug approved for NASH.

## New Drugs in the R&D Pipeline

Droduct/	Conorio Nome	Formulation	Thoropoutio	Country/	Doucle	nmort	Ctore		Origin	Japan Overseas
Product/ Code Name	Generic Name	Formulation	Therapeutic Indications	Country/ Area	Develo Phase	Phase	Stage Phase III	NDA Submitted	Origin	Remarks
CNS										
LATUDA®	lurasidone	Oral	Schizophrenia	Canada						Approved in June 2012
(SM-13496)	hydrochloride			Japan						
			Schizophrenia Bipolar disorder	Europe					In-house	Co-development with Takeda Pharmaceutical Company Limited Takeda submitted an MAA in Switzerland in March 2012
			(New indication) Bipolar 1 depression	U.S. and Europe, etc.				•		
			(New indication) Bipolar maintenance	U.S. and Europe, etc.						
			(New indication) MDD with mixed features	U.S.						
STEDESA™	eslicarbazepine	Oral	Epilepsy adjunctive therapy	U.S.					BIAL-Portela & Ca, S.A.	
	acetate		Epilepsy monotherapy	U.S.						
DOPS <sup>®1</sup>	droxidopa	Oral	Neurogenic orthostatic hypotension	U.S.						
				Europe					In-house	Out-licensed to Chelsea Therapeutics
			Intradialytic hypotension	U.S.						International, Ltd.
			Fibromyalgia	U.K.				_		
LONASEN®	blonanserin	Oral	Schizophrenia	China					In-house	
			(Addition of pediatric usage) Schizophrenia	Japan					III-HOUSE	
		Transdermal patch	(New formulation – Transdermal patch) Schizophrenia	Japan					In-house	Co-development with Nitto Denko Corporation
DSP-8658	TBD	Oral	Alzheimer's disease	U.S.					In-house	
SEP-228432	TBD	Oral	Neuropathic pain Major depressive disorder	U.S.					In-house (Sunovion)	
DSP-1053	TBD	Oral	Major depressive disorder	U.S.					In-house	
DSP-0565	TBD	Oral	Epilepsy	U.S.					In-house	
DSP-2230	TBD	Oral	Neuropathic pain	U.K.					In-house	
Cancer										
CALSED®1	amrubicin	Injection Small cell lung cancer China								
	hydrochloride			U.S. and Europe					In-house	Out-licensed to Celgene Corporation
AG-7352	TBD	Injection	Cancer	U.S. and Canada					In-house	Out-licensed to Sunesis Pharmaceuticals, Inc
BBI608	TBD	Oral	Colorectal cancer (2nd/3rd line) Monotherapy	U.S. and Canada						
		1	Colorectal cancer (2nd/3rd line)	IIS and						

			Colorectal cancer (2nd/3rd line) Combination therapy	U.S. and Canada		In-house (BBI)	
			Solid cancer (2nd/3rd line) Combination therapy with paclitaxel	U.S. and Canada	2		
WT4869	TBD	Injection	Myelodysplastic syndromes	Japan	2	In-house/Chugai	Co-development with Chugai
			Solid cancer	Japan		 Pharmacutical Co., Ltd.	Pharmaceutical Co., Ltd.
WT2725	TBD	Injection	Solid cancer	U.S.		In-house/Chugai Pharmacutical Co., Ltd.	Co-development with Chugai Pharmaceutical Co., Ltd.
BBI503	TBD	Oral	Solid cancer monotherapy	U.S. and Canada		In-house (BBI)	

Product/ Code Name	Generic Name	Formulation	Therapeutic Indications	Country/ Area	Develo Phase	pment Phase II	Stage Phase III	NDA Submitted	Origin	Japan Overseas Remarks
Respirat	ory									
Ciclesonide Nasal Aerosol	ciclesonide	Collunarium	(HFA - New formulation) Allergic rhinitis	U.S.					Nycomed S.C.A., SICAR	Approved in Jan. 2012. Brand name: ZETONNA™
DSP-3025	TBD	Collunarium	Bronchial asthma, Allergic rhinitis	Europe					In-house	Out-licensed to AstraZeneca PLC
				Japan						
Cardiova	scular/Dia	betes								
DSP-8153	amlodipine besilate/ irbesartan	Oral	Hypertension	Japan					In-house	Submitted in Nov. 2011 Combination product
SUREPOST®	repaglinide	Oral	(New indication) Type 2 diabetes (Combination therapy with biguanide)	Japan					Novo Nordisk A/S	Submitted in Apr. 2012 Approved indication: The reduction of postprandial
			(New indication) Type 2 diabetes (Combination therapy with thiazolidine)	Japan						blood glucose in patients with type 2 diabetes Monotherapy Combination with α-Gl
			(New indication) Type 2 diabetes (All combination therapies including DPP4 inhibitors)	Japan					Novo Nordisk A/S	Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes Monotherapy Combination with α-Gl
METGLUCO®	metformin hydrochloride	Oral	(Addition of pediatric usage) Type 2 diabetes	Japan					Merck Santé	
AS-3201	ranirestat	Oral	Diabetic neuropathy	Japan U.S., Canada and Europe					In-house	Out-licensed to Eisai Co., Ltd.
DSP-8658	TBD	Oral	Type 2 diabetes	U.S.					In-house	
DSP-9599	TBD	Oral	Hypertension	Japan					In-house	
						_		_		
Others										
MEROPEN®	meropenem hydrate	Injection	(Change of maximum dose) Purulent meningitis: 6g daily	Japan					In-house	
SMP-986	afacifenacin fumarate	Oral	Overactive bladder syndrome	Japan					In-house	
				U.S. and Europe						
PRORENAL®	limaprost alfadex	Oral	(New indication) Carpal-tunnel syndrome	Japan					In-house/Ono Pharmaceutical Co., Ltd.	Co-development with Ono Pharmaceutical Co., Ltd. Approved indication: lumbar spinal canal stenosis, etc.
DSP-6952	TBD	Oral	IBS with constipation, Chronic idiopathic constipation	Japan					In-house	
DSP-1747	obeticholic acid	Oral	Primary biliary cirrhosis (PBC), Nonalcoholic steatohepatitis (NASH)	Japan					Intercept Pharmaceuticals, Inc.	
DSP-5990	ceftaroline fosamil	Injection	MRSA infection	Japan					Takeda Pharmaceutical Company Limited	

1. Product name in Japanese market (product name for overseas markets is to be decided) 2. Phase I stage of Phase I/II

Under preparation

(As of July 27, 2012)

### Manufacturing

## We provide a stable supply of products of the highest quality at the global level.

#### A Supply Chain That Supports Global Business

The Manufacturing Division takes the central role in the DSP Group's supply chain management to provide a stable supply of products to all customers through its manufacturing, logistics and shipping functions. To maintain an optimal product supply system, DSP runs four factories in Japan as its primary manufacturing bases, while also cooperating with domestic and overseas contract manufacturers.

Under the second Mid-term Business Plan, we are constructing a global supply network that includes overseas sourcing of raw materials and pharmaceutical intermediates and manufacturing at overseas factories. In upgrading our overseas manufacturing network, in addition to manufacturing at our own facilities, we are promoting contract manufacturing under technology alliances. This approach is exemplified by MIRIPLA<sup>®</sup>, a therapeutic agent for hepatocellular carcinoma, which is manufactured by Pierre Fabre in France.

The Great East Japan Earthquake of March 11, 2011 had no effect on DSP's manufacturing bases, and the impact on our distribution bases was also minor.

#### **Quality Assurance**

The production of pharmaceuticals requires a high level of quality assurance. Consequently, rigorous Good Manufacturing Practice (GMP) standards have been established in many countries.

The pharmaceuticals manufactured by the DSP Group are exported around the world after obtaining regulatory approvals from government institutions of importing nations, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and Australia's Therapeutic Goods Administration (TGA). Therefore, operating standards in the DSP Group are consistent with the GMP standards of Europe and the United States. Furthermore, we have established a high level of facility design and a quality assurance system to pass audits by overseas partner companies and meet strict quality standards at the global level, following the guidelines of the International Conference on Harmonisation (ICH), which deliberates the harmonization of EU, U.S. and Japanese pharmaceutical regulations.

Global standards for quality assurance are expected to become increasingly rigorous. The DSP Group is therefore making proactive investments in manufacturing

Dit Transfer But

facilities — including a new solid dosage form facility and a restricted access barrier system (RABS) that increases the level of sterility assurance — to meet future standards. Our manufacturing, quality assurance and other related divisions will work in concert to continue to provide pharmaceuticals of the highest quality.

#### A Trusted Pharmaceutical Company

DSP is striving for customer-oriented product development. For example, we have responded to requests from medical institutions and patients by improving package and label designs in an effort to help prevent medical errors.

We also continuously work to reduce production costs through automation of facilities and other laborsaving measures, optimization of production sites, and appropriate inventory control.

Moreover, as part of our commitment to eco-friendly production activities, we are thoroughly reducing waste and introducing co-generation systems.

#### **Japanese Plants**

DSP has four factories in Japan. The Suzuka Plant is our main factory serving global operations. It conducts integrated pharmaceutical manufacturing from production of active pharmaceutical ingredients to packaging. The Ibaraki Plant, which is also the main base of the Technology Research & Development Division, is a development-driven pharmaceutical plant able to accommodate a range of processes from commercial production to quality control in a flexible manner. The Ehime Plant is a manufacturing base for biopharmaceutical products. The Oita Plant is our core facility for the production of active pharmaceutical ingredients. Each of these factories manufactures pharmaceuticals while constantly ensuring the safety of the products based on GMP-compliant manufacturing equipment, processes and clinical study inspections.

#### **Overseas Plants**

The plant at Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. in China serves as our own production facility, and packages products for sale in the local market. The packaging process began after a merger with Kyowa Hakko Pharmaceuticals (Suzhou) Co., Ltd. in 2010. As the second phase, we are currently constructing a warehouse, which is scheduled to begin operating in October 2012. Fully integrated production, from formulation to packaging, is scheduled to start in 2014.

### Marketing

## In the Japanese market we are focusing on strategic and new products. In the North American market, we are focusing on quickly maximizing earnings from LATUDA<sup>®</sup>.

#### **Basic Strategy**

DSP has set "transform the earnings structure in Japan" and "expand overseas operation and maximize earnings" as the basic strategies of the Second Midterm Business Plan (2nd MTBP). Beyond that, we aim to fulfill our Vision for the future of establishing "two solid mainstreams of revenue, from domestic operations and from international operations".

In the Japanese pharmaceuticals business, in addition to development of compounds from DSP research, we are promoting alliances and in-licensing to increase the proportion of new drugs in our product portfolio. To maximize earnings, we have positioned central nervous system (CNS), cardiovascular/diabetes and cancer/infectious diseases as our focus marketing areas, and are concentrating sales resources on strategic products AVAPRO®, LONASEN®, PRORENAL® and TRERIEF®, and new products, MIRIPLA®, METGLUCO®, SUREPOST®, and Paxil® CR.

In the North American market, we aim to quickly maximize earnings from LATUDA®, a global strategic product, in addition to optimizing the field force structure for the existing products of Sunovion Pharmaceuticals Inc.

In the Chinese market, we are working to expand sales of existing products such as MEPEM<sup>®</sup> (MEROPEN<sup>®</sup>) and introduce new products.



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#### Domestic Pharmaceuticals Business

## Japanese Market

Net sales: ¥179.9 billion Number of MRs: 1,410 (Fiscal 2011)



#### **Key Measures**

- Focus on strategic and new products
- Promote alliances and in-licensing

#### **Focus Marketing Areas**

CNS, cardiovascular/diabetes, and cancer/infectious diseases

#### Key Products for Sales and Marketing

Strategic products	AVAPRO <sup>®</sup> (cardiovascular), LONASEN <sup>®</sup> (CNS), PRORENAL <sup>®</sup> (other), TRERIEF <sup>®</sup> (CNS) <sup>1</sup>
New products	MIRIPLA® (cancer), METGLUCO® (diabetes), SUREPOST® (diabetes), Paxil® CR (CNS) <sup>2</sup>

Changed from a new product to a strategic product in fiscal 2012.
 Launched by GlaxoSmithKline K.K. in June 2012. Co-promoted by DSP.

#### Summary of Fiscal 2011 results

In the domestic pharmaceuticals business, we worked to expand sales by concentrating resources on strategic products with a high market growth rate and new products. We minimized the impact of the decrease in sales of existing products caused by the influence of generic products. As a result, net sales decreased 1.6% year on year to ¥179.9 billion, and segment income was ¥66.4 billion. In addition, we established the CNS Sales & Marketing Department in April 2011 and focused on furthering market penetration of LONASEN<sup>®</sup>, an atypical antipsychotic, and TRERIEF<sup>®</sup>, a treatment for Parkinson's disease.

#### CNS

As a pharmaceutical company handling therapeutic agents for schizophrenia, Parkinson's disease, anxiety and epilepsy, DSP is promoting the expansion of sales with a focus on the strategic products LONASEN® and TRERIEF®.

We inaugurated the CNS Sales & Marketing Department in April 2011 to strengthen proposal and marketing functions. The department has been developing prescription proposal-based promotion activities covering all major CNS care facilities throughout Japan. In addition to further improving the quality of MRs through specialized CNS training, we increased the number of CNS MRs to 230 in October 2011 and concurrently assigned 13 Medical Science Liaisons (MSLs)<sup>3</sup>, including some with research and development experience. In April 2012 we increased the number of MSLs to 17 to further strengthen our

#### **Strategic Product Sales**



scientific support structure. Furthermore, we are using smartphones and tablet devices to strengthen our information-sharing capabilities.

For LONASEN®, we are conducting promotion activities from the perspective of evidence-based medicine (EBM)<sup>4</sup> using clinical data for Japan acquired over three years of sales and marketing. In addition to regular MR activities, we are actively using e-promotion such as provision of product information by MRs via the Internet, webcasts of lectures and e-mail magazines for healthcare practitioners.

For TRERIEF<sup>®</sup>, which we added to our strategic products category in fiscal 2012, we are providing information primarily to neurology specialists with the aim of establishing it as the first-line adjunctive treatment for Parkinson's disease.

We have been conducting co-promotion in Japan for Paxil<sup>®</sup> CR (paroxetine hydrochloride hydrate), an antidepressant launched by GlaxoSmithKline K.K. in June 2012. Paxil<sup>®</sup> CR is the controlled-release formulation of Paxil<sup>®</sup> tablets, a selective serotonin reuptake inhibitor (SSRI). With Paxil<sup>®</sup> CR tablets in our product line, we can conduct activities in the area of antidepressants, which will enable us to further increase our presence in the area of CNS.

In fiscal 2011, sales of LONASEN® increased 9.8% year on year to ¥9.8 billion, and sales of TRERIEF® increased 44% to ¥5.3 billion. In fiscal 2012, we are aiming for sales of ¥13.0 billion and ¥7.0 billion, respectively.

3. MSLs provide information on proper drug use and maximize product value from a medical and scientific perspective. The principle duties of the MSLs include collecting information to meet needs at the point of care and compile evidence; providing detailed information to physicians on the suitability of DSP's pharmaceuticals for their clinical studies and independent research; and checking academic conference presentations and other information from a medical perspective.

 The best treatment for a patient based on the most reliable evidence available

#### **Cardiovascular/Diabetes**

In the cardiovascular area, DSP strives to be a partner in hypertension treatment, handling a variety of antihypertensive products with a lineup consisting of an ARB, calcium blocker, diuretic, ACE inhibitor and alphabeta blocker.

While concentrating on expanding sales of our strategic product AVAPRO<sup>®</sup>, a therapeutic agent for hypertension, we are making prescription proposals that encompass this area as a whole, including AMLODIN<sup>®</sup>, a therapeutic agent for hypertension and angina pectoris. In fiscal 2011, sales of AVAPRO<sup>®</sup> increased 28.5% year on year to ¥10.7 billion. In fiscal 2012, we are aiming for sales of ¥14.3 billion.

In addition, in November 2011 we submitted an application for manufacturing and marketing approval of DSP-8153, a combination product of irbesartan (AVAPRO®) and amlodipine besilate (AMLODIN®), with approval expected in fiscal 2012. Clinical studies in Japan showed DSP-8153 to be effective for patients with essential hypertension uncontrolled by irbesartan or amlodipine besilate alone. Moreover, two doses are included in the application for this combination product, irbesartan 100mg/amlodipine 5mg and irbesartan 100mg/amlodipine 10mg. If approved, it will be the first combination product in Japan to include 10mg of amlodipine. Following approval, the product will be co-marketed as a single brand by DSP and Shionogi & Co., Ltd. in their respective channels, with both companies providing information on the product.

In the diabetes area, we are quickly maximizing sales of the new products METGLUCO<sup>®</sup>, a biguanide oral hypoglycemic drug launched in May 2010, and SUREPOST<sup>®</sup>, a rapid-acting insulin secretagogue launched in May 2011. Sales of METGLUCO<sup>®</sup> are



expected to grow substantially from ¥7.8 billion in fiscal 2011 to ¥11.9 billion in fiscal 2012. For SUREPOST<sup>®</sup>, we anticipate an increase in prescriptions following the lifting of the limit on the prescription period in April 2012. Moving forward, we aim to quickly maximize sales of SUREPOST<sup>®</sup> by adding indications for combination therapies with other diabetes drugs.

#### **Cancer/Infectious Diseases**

In the cancer area, we are focusing on expanding sales of MIRIPLA®, a therapeutic agent for hepatocellular carcinoma launched in January 2010. With this product, as well as the natural alpha interferon SUMIFERON®, we aim to contribute to the total care of liver diseases. In the area of infectious diseases, we work to contribute to medical treatment mainly by promoting appropriate use of MEROPEN<sup>®</sup>, a carbapenem antibiotic, while also highlighting the advantages of AmBisome<sup>®</sup>, a therapeutic agent for systemic fungal infection, and HIBITANE<sup>®</sup>, an antimicrobial agent for general antiseptic purposes.

#### **Other Areas**

In other therapeutic areas, we are focusing on our strategic product PRORENAL<sup>®</sup>, a vasodilator. Given the aging of society, we are working to expand the market for this product by educating patients about lumbar spinal canal stenosis. In fiscal 2011, sales increased 3.8% year on year to ¥15.5 billion. We expect sales of ¥15.2 billion in fiscal 2012.

#### **Strategic Products**



AVAPRO<sup>®</sup> (Therapeutic agent for hypertension) A long-acting ARB (angiotensin II receptor blocker) with a long half-life in blood and a 24-hour-lasting blood pressure-lowering effect, having high anti-hypertensive effect in mild to severe hypertension. Substantial evidence for efficacy and safety available from the U.S. and Europe where this drug is on the market under the brand name of AVAPRO® or APROVEL®.

#### PRORENAL® (Vasodilator)



This is the only drug indicated in Japan for lumbar spinal canal stenosis. PRORENAL® improves blood flow to nerve tissue compressed by changes in the vertebra associated with aging. It thus improves symptoms such as pain, numbness and intermittent claudication in the lower extremities, contributing to improvement of patients' quality of life. TRERIEF® (Therapeutic agent for Parkinson's disease) Improvement in movement ability and betterment in activities of daily living have been found when administered once daily in patients with Parkinson's disease who are not sufficiently cured by other anti-Parkinson's disease drugs

#### LONASEN® (Atypical antipsychotic)

This drug blocks dopamine-2 receptors and serotonin-2 receptors. In clinical studies, this drug showed efficacy on not only positive symptoms of schizophrenia (such as hallucinations or delusions), but also negative symptoms



(such as flat affect or hypobulia). The incidence of adverse reactions such as extrapyramidal symptoms or weight gain and hyperprolactinemia in the clinical studies was lower than the

incidence reported for other drugs in this therapeutic area.



Paxil<sup>®</sup> CR (antidepressant)\* Launched in June 2012

\* Marketed by GlaxoSmithKline K.K. Co-promoted by DSP.

#### Overseas Pharmaceuticals Business



#### **Summary of Fiscal 2011 Results**

We optimized the field force structure based on the strategy for each existing product and focused on quickly maximizing revenues from LATUDA®, which launched in February 2011. As a result, the decrease in the sales of LUNESTA® and XOPENEX® was offset by the launch of LATUDA® and the increase in sales of BROVANA®, etc.

#### CNS

At Sunovion Pharmaceuticals Inc. (Sunovion), we focused on quickly maximizing revenues from LATUDA®, an atypical antipsychotic launched in February 2011, as the primary key measure for fiscal 2011. Since the launch, the number of prescriptions has been steadily increasing, supported by initiatives to strengthen promotional activities. For example, we increased the team of MRs dedicated exclusively to LATUDA® to 360 people and enhanced the speakers program.\*

U.S. sales of LATUDA® for fiscal 2011 were \$86 million (¥6.9 billion), the second-highest first-year sales among CNS drugs launched in the U.S. since 2007. We forecast sales of \$190 million for fiscal 2012 based on continuing initiatives to strengthen promotional activities.

LUNESTA® is a non-narcotic sedative hypnotic indicated for insomnia. Since its launch in 2005, Sunovion has implemented effective promotional activities that position the drug as a highly safe and effective alternative to other sedative hypnotic medications. Over the years, Sunovion has used diverse advertising to build awareness of the benefits and features of LUNESTA® among patients with insomnia. Sales of LUNESTA® for fiscal 2011 were \$528 million (¥42.1 billion). Although Sunovion achieved its initial revenue target, sales decreased 14% year-on-year on a local currency basis due to the launch of generic competition. Sales of \$545 million are forecast for fiscal 2012, a slight increase from fiscal 2011.

\* A program of small-scale promotional meetings held in each region, with presentations by healthcare professionals, including physicians who have prescribed LATUDA<sup>®</sup>. The aim of the program is to effectively provide medical professionals with relevant information that has been approved internally for dissemination, including a review of the important safety information relating to LATUDA<sup>®</sup>.



#### Respiratory

XOPENEX® is a short-acting beta agonist for the treatment of constricted airways often experienced by patients with asthma. It is available in two different formulations: XOPENEX® Inhalation Solution, used with a nebulizer; and XOPENEX® HFA, which is delivered via a metered dose inhaler. Despite intensifying competition in the market, sales for fiscal 2011 were \$419 million (¥33.4 billion), essentially the same as in the previous fiscal year on a local currency basis. Generic versions of the XOPENEX<sup>®</sup> Inhalation Solution have entered the market upon the expiration of the exclusivity period in August 2012. Consequently, we forecast a significant decrease in sales for fiscal 2012. In order to optimize the sales structure in preparation for the imminent expiration of the exclusivity period, the XOPENEX® sales team was dissolved in December 2011.

BROVANA® is a long-acting beta agonist used as a maintenance treatment for chronic obstructive pulmonary disease. It continues to build sales volume as a result of Sunovion's ongoing promotional initiatives as well as efforts to ensure higher levels of patient access for the product. Sales for fiscal 2011 increased 21% year-on-year to \$127 million (¥10.2 billion).

OMNARIS<sup>®</sup> is an inhaled nasal corticosteroid used to treat the symptoms of allergic rhinitis. Sales for fiscal 2011 increased 19% year-on-year to \$64 million (¥5.1 billion). However, a substantial decrease in sales is expected in fiscal 2012 due to an interruption of supply from the manufacturer at the end of 2011. On the other hand, the allergic rhinitis therapeutic medication ZETONNA<sup>™</sup> was made commercially available in the U.S. in July 2012. As a new dosage form and delivery mechanism of ciclesonide, the same active ingredient as in OMNARIS<sup>®</sup>, ZETONNA<sup>™</sup> is the first non-aqueous dry nasal aerosol spray with once-daily, one spray per nostril dosing available in the U.S. We expect growth in total sales for the three products of the ciclesonide family, which includes OMNARIS<sup>®</sup> and the inhaled corticosteroid ALVESCO<sup>®</sup>.



#### **Major Products**



BROVANA® (Long-acting beta-agonist) An inhalation solution bronchodilator indicated for the maintenance treatment of COPD.



LUNESTA® (Sedative hypnotic) A non-narcotic sedative hypnotic indicated for sleep onset and sleep maintenance.



LATUDA<sup>®</sup> (Atypical antipsychotic) LATUDA<sup>®</sup> is an atypical antipsychotic agent with a proprietary chemical structure created originally by DSP. LATUDA is also in development for potential additional indications including bipolar 1 depression and major depressive disorder (with mixed features).

#### Overseas Pharmaceuticals Business



#### **Summary of Fiscal 2011 Results**

The rapid expansion of China's pharmaceutical market is expected to continue in the coming years, supported by the high economic growth rate. The DSP Group conducts marketing activities in China through its local subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. Operations in China generated sales of ¥6.5 billion in fiscal 2011.

Sumitomo Pharmaceuticals (Suzhou) currently sells four products in China: MEPEM® (MEROPEN®), a carbapenem antibiotic; ALMARL®, a therapeutic agent for hypertension, angina pectoris and arrhythmia; SEDIEL®, a serotonin-agonist antianxiety drug; and GASMOTIN®, a gastroprokinetic. In antibiotics, which formerly comprised a large segment of the pharmaceutical market, stronger moves by the authorities for proper use since 2011 have slowed growth in sales. Despite this situation, sales of MEPEM®, which has superior efficacy, safety and quality, remain solid.

In order to quickly capture a share of this large market, Sumitomo Pharmaceuticals (Suzhou) has reinforced and enhanced its sales structure, focused on departments that handle sales promotion and marketing. As of the end of March 2012, the company had 330 MRs conducting scientific promotion activities focused on the large-scale hospital market in 29 sectors (major urban, administrative and self-governing areas). It plans to increase the number of MRs to 380 by the end of 2012 to further enhance marketing activities.

For fiscal 2012, we are aiming for sales of ¥7.1 billion.

#### **Future Business Expansion**

The DSP Group goal for fiscal 2014 is sales of ¥10.0 billion. To meet this goal, Sumitomo Pharmaceuticals (Suzhou) is currently conducting development toward the introduction of CALSED<sup>®</sup>, a new small cell lung cancer treatment. China has a high rate of lung cancer and, considering its population of 1.3 billion, we believe that CALSED<sup>®</sup> will become a promising new product. We will maximize the scale of business and earnings by enhancing the marketing structure and continuously launching new products such as LONASEN<sup>®</sup>, an atypical antipsychotic we are developing.





### Non-pharmaceuticals Operations

## Developing business in a broad range of fields through cooperation with the pharmaceuticals business

## Food Ingredients, Food Additives and Chemical Product Materials

The food ingredients, food additives and chemical product materials business is handled by DSP subsidiary DSP Gokyo Food & Chemical Co., Ltd.

In the food ingredients and food additives business, the company develops and sells ingredients and additives for use in manufacturing safe, high-quality foods. Products include polysaccharides, primarily GLYLOID® (tamarind gum), the first product of its kind successfully produced on an industrial scale; seasonings such as soup bouillon; and sweeteners such as MIRASEE®, an easy-to-use preparation based on neotame, a high-intensity sweetener.

The chemical product materials business encompasses such products as cosmetic materials, active pharmaceutical ingredients, electronic chemicals and coating materials.

Leveraging DSP's technologies and know-how from the pharmaceuticals business, and through cooperation with domestic and overseas suppliers, we are expanding these business units as a company that integrates research, development and sales operations to continually create the value that customers require.

#### **Animal Health Products**

The animal health products business is conducted by DSP subsidiary DS Pharma Animal Health Co., Ltd., of which the major products are veterinary medicines for companion animals, primarily dogs and cats, as well as for farm animals such as cattle, swine, horses and cultured fish. The company produces and provides its own products to customers through development work, in close cooperation with the pharmaceuticals business.

In the companion animal market, its focus business segment, DS Pharma Animal Health sells various therapeutics, including VICTAS<sup>®</sup>, an antibacterial preparation, APINAC<sup>®</sup>, a treatment for chronic canine heart failure, PRONAMID<sup>®</sup>, a canine gastroprokinetic agent for the improvement of gastrointestinal motility, and STEROP<sup>®</sup>, the first anti-inflammatory steroid eye-drop



VICTAS®S MT Cream Antibacterial preparation for the treatment of bacterial and mycotic external otitis and skin infections in dogs and cats

approved for veterinary use in Japan. In addition to its veterinary medicines, the company provides a broad range of other products, including Prescription Diet<sup>®</sup>, a line of canine and feline therapeutic nutritional formulas, and Science Diet<sup>®</sup>, a pet food formulated for health maintenance, from Hill's Pet Nutrition, Inc.

In the livestock business, DS Pharma Animal Health sells URSO<sup>®</sup>, a medicine for cattle and swine, and EQVALAN<sup>®</sup>, a medicine for horses. In the fisheries business, the company sells vaccines, anesthetics and synthetic antibacterial drugs for fish and crustaceans, contributing to food security and safety. In addition to medicines, the company also deals in feed additives and mixed feed for maintaining the health of fish and improving productivity.

At DS Pharma Animal Health, several products for companion animals and livestock are currently under development, including medicines discovered by DSP.

#### **Diagnostics and Research Materials**

DSP subsidiary DS Pharma Biomedical Co., Ltd. conducts the diagnostics and research materials business. In the diagnostics business, to help ensure accurate and timely treatment, the company develops and supplies point-of-care testing (POCT) products such as diagnostics for infectious diseases such as influenza and *Streptococcus*, and for acute myocardial infarctions. It also develops and supplies in-vitro diagnostics for bone and calcium metabolism and central nervous system disorders.

In addition, DS Pharma Biomedical develops and supplies research materials that facilitate research related to medical care. It is focusing on creating new value by providing cells and culture media that can be applied in regenerative therapy using ES cells and iPS cells.

The company aims to contribute to drug discovery research through companion diagnostic biomarker developments and a new early-stage drug discovery assay system that applies cell culture techniques.



Point-of-care testing products and in-vitro diagnostic kit for bone metabolism

## **CSR** Activities

DSP is deepening its CSR activities to contribute more broadly to society through the creation, manufacture and provision of pharmaceuticals.

The mission of DSP for society is given in the company's Corporate Mission, and the aim of its operations, which are focused on its stakeholders, is given in the Management Mission. CSR for our company is the daily pursuit of our mission by each DSP executive and employee, never forgetting their position as a member of society. We have also established the Declaration of Conduct, which describes our basic stance for promoting CSR activities.

#### **Declaration of Conduct**

- 1. Help people to have "healthy bodies, healthy lives"
- 2. Pursue trustworthy corporate activities
- 3. Positively disclose information and properly manage information
- 4. Help employees reach their full potential
- 5. Respect human rights
- 6. Positively address global environmental issues
- 7. Build harmonious relationships with society

By boldly carrying out initiatives in accordance with our Declaration, we intend to help solve issues faced by society in a wide range of areas. These initiatives include providing even better pharmaceuticals, promoting compliance, respecting human rights, and addressing global environmental issues. In this way, we believe DSP will be better able to fulfill its responsibilities as a corporate citizen. Here, we describe some of the initiatives conducted in line with the Declaration.

#### More detailed information on our CSR activities is available on our website.

http://www.ds-pharma. com/csr/index.html

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### With Patients and Healthcare Practitioners

#### Contact for Inquiries: The Pharmaceuticals Information Center

DSP has established the Pharmaceuticals Information Center to respond to inquiries from patients, their families, and medical professionals. Many of the approximately 66,000 inquiries in fiscal 2011 concerned METGLUCO<sup>®</sup>, a biguanide oral hypoglycemic drug, and AMLODIN<sup>®</sup> tablets/OD tablets, a therapeutic agent for hypertension and angina pectoris.

The Pharmaceuticals Information Center uses in-house search systems such as DI-SaGaS, maintains a Center FAQ and provides a variety of other services to convey information promptly, precisely and courteously, which enhances customer trust. The Center also shares information on inquiries from medical professionals with our MRs.

Going forward, we will contribute to the health of patients by continuing to provide science-based information on the proper use of pharmaceuticals in a prompt, precise and courteous manner.

#### Inquiries during FY2011 (Approximately 66,000)



#### **Product Safety Measures**

At DSP, the safety of the patients who use our products is our top priority.

ALMARL<sup>®</sup> tablets 5mg/10mg (arotinolol hydrochloride) is a DSP therapeutic agent for hypertension, angina pectoris, arrhythmia and essential tremors. Incidents have occurred in which this product was mistaken for an oral hypoglycemic agent of another company. As a measure to prevent medical errors, we distributed notices drawing attention to this issue and changed the press-through package (PTP) design. We also renamed the product Arotinolol Hydrochloride tablets 5mg/10mg DSP.

Furthermore, to make our products more distinguishable and prevent errors when individual doses are separated from the PTP, we adopted special printing that positions the name and dosage over each dose for the following: METGLUCO<sup>®</sup> tablets 250mg, a biguanide oral hypoglycemic agent; AMLODIN<sup>®</sup> tablets 2.5mg/5mg

and AMLODIN® OD tablets 2.5mg/5mg/10mg, a therapeutic agent for hypertension and angina pectoris; and SUREPOST® tablets 0.25mg/0.5mg, a rapid-acting insulin secretagogue. DSP will continue to expand the use of this printing method as part of its efforts to ensure product safety.



#### Topic CSR Activities outside Japan: Sunovion Charitable Contributions

Sunovion Pharmaceuticals Inc. remains committed to supporting a variety of initiatives across the United States and Canada. Many of these initiatives focus on providing additional community support to patients impacted by central nervous system and respiratory diseases, and their advocates.

Currently, Sunovion supports ten International Center of Clubhouse Development (ICCD) "Clubhouses", which provide essential services to people affected by mental illness. Sunovion employees have also participated in over 30 walks for NAMI (National Alliance on Mental Illness) in local communities across the U.S. to help raise funds and awareness of mental illness.

In addition, Sunovion raised funds for Operation Homefront, a non-profit organization that provides financial assistance to the families of U.S. military personnel serving overseas.

Other areas of community focus and support include the National Epilepsy Foundation and the American Lung Association.



Sunovion employees attend a luncheon hosted by a member of the ICCD.
### With Employees

#### **Human Resource Development**

As part of its Management Mission, DSP seeks "to create an environment in which employees can fulfill their potential and increase their creativity". We are therefore fostering a corporate climate in which employees can independently develop their abilities, while actively supporting their growth by providing an environment that enables them to demonstrate their full potential.

Employees are primarily trained on the job, where they learn actual tasks and challenges. DSP also provides support measures and training sessions as supplemental off-the-job training and job rotation. In addition, DSP has clearly defined a human resource development program that integrates basic policies, goals and positioning. It divides responsibilities for company-wide and divisional measures to cultivate abilities efficiently and effectively.

DSP provides English training and subsidies for language school tuition to improve employees' language skills. We also provide a full range of opportunities for employees to acquire business skills tailored to individual needs, including free TOEIC tests, voluntary business seminars, distance learning and e-learning materials.

Moving forward, DSP will continue to focus on developing employees who can demonstrate leadership in the global arena.

#### **Comprehensive Consultation Service**

To quickly resolve issues inside and outside the workplace, DSP has a compliance hotline, sexual harassment consultation desk, and outside mental health consultation desk. In addition, we established the General Consultation Desk (the "Discuss Anything Desk") in January 2012.

The General Consultation Desk was set up in response to employee comments such as "I don't know where to turn when I have a problem or concern" and "I don't understand the consultation procedure". The Desk provides consultation for all DSP employees on a wide range of workplace-related issues and concerns that cannot be discussed with superiors or colleagues, as well as issues that remain unresolved after discussion, and questions related to work. By lowering barriers to consultation, communication and whistle-blowing, this service will help create a workplace environment in which employees can focus on their work with a sense of security.

#### **Occupational Health and Safety Initiatives**

DSP prepares company-wide shared priority subjects based on its Safety and Health Policy and the Mid-term Action Plan, which were established to promote the health and assure the safety of its employees. We develop an annual action plan containing concrete initiatives for each business site that reflect those subjects.

The priority subjects for fiscal 2011 were "complying with laws and regulations relating to occupational health and safety", "promoting health and safety risk management", "improving health and safety education and awareness-raising activities", and "promoting health management and mental health". Based on these subjects, we implemented internal audits, health and safety risk assessment, health and safety education, company-wide sharing of work-related injury information, and employee stress checkups.

Particularly in the internal audits for each business site, we confirm "the status of compliance with laws relating to occupational health and safety, chemical substances, and safety and disaster prevention", "the status of progress in health and safety activities", and "measures to minimize risk hazards", and provide appropriate guidance to further enhance health and safety management.

#### Topic CSR Activities outside Japan: Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.

As a social contribution activity befitting a pharmaceutical company, we are conducting support activities at Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. to ensure a healthy future for children. In May 2011, we donated a "Sumitomo Collection" to the Dafosi Orphanage School in Santai County, Sichuan Province, and in August we helped cover educational expenses at the Waka Orphanage School in Derong County, Sichuan Province. In October, we donated books, musical instruments and gymnastics equipment to the orphanage at the Lijiang Welfare Institute in Yunnan Province. We visited the schools that we supported to share time with the children. With our wholesale partners, we also met with children at orphanages in impoverished regions as part of our ongoing initiatives to draw attention to their education and psychological issues. The children sent us many letters of thanks during Chinese New Year, informing us of recent events.



Meeting with children at an orphanage school

# With Society

#### **Appropriate Information Disclosure**

DSP recognizes the importance of corporate transparency in earning the trust of society. We strive to disclose corporate information in a timely, appropriate and fair manner to a wide range of stakeholders.

In disclosing information, DSP gives due consideration to Japan's Financial Instruments and Exchange Law, stock exchange rules on timely disclosure, internal information management rules and compliance programs.

DSP promptly discloses its financial results and other information requiring timely disclosure through the timely disclosure systems of stock exchanges and on its corporate website.

We also actively disclose corporate, product and other information not requiring timely disclosure through news releases to media outlets and on our corporate website.

#### **Social Contribution Activities**

In its Declaration of Conduct, DSP states its intent to engage in social contribution activities and considers what it can do as a good corporate citizen. Based on this, we set the goal of identifying and resolving issues that a health care-related company should address, and decided to prioritize activities that help raise the quality of life for patients and their families. In addition, we are conducting disease awareness, education support and other initiatives based on our corporate slogan, "Healthy bodies, healthy lives".

DSP Group companies and their officers and employees contribute to organizations that share our commitment to promoting healthy bodies and healthy lives. In fiscal 2011 we donated funds to support the activities of the nonprofit organization Support Network for Chronic Sick Children of Japan ("Nanbyonet") and five clubhouses in Japan certified by the International Center for Clubhouse Development.

Employee volunteers have also continued to raise funds to support the reconstruction of the areas affected by the Great East Japan Earthquake.

#### The Japan Epilepsy Research Foundation

Funded by donations from DSP and other interested parties, the Japan Epilepsy Research Foundation conducts the following activities to promote research into the treatment of epilepsy and contribute to better health and medical care in Japan.

#### Monetary Support

- 1. Provides grants for basic and applied clinical research
- 2. Subsidizes the dispatch of Japanese researchers overseas
- 3. Provides fellowships to researchers from other Asian countries to study in Japan
- 4. Subsidizes the publication of the *Journal of the Japan Epilepsy Society*

#### Commendation

- Awards research prizes to researchers or research groups that achieve significant results through continuous research
- Awards research service prizes to researchers who have made a notable contribution and played a leading role in the progress of epileptology over many years

To publicize these support initiatives, the Foundation holds meetings to present research findings and publishes the *Research Annual Report*. DSP will continue to contribute to the improvement of medical care and welfare by supporting this foundation.

#### Elementary, Junior High and Senior High School Girls Tour the Suzuka Plant

In addition to company-wide activities such as fund-raising, DSP's plants and offices conduct social contribution and other activities that match the needs of the local community.

As an employer of many women with science degrees, the Suzuka Plant held a factory tour on August 29, 2011 to show its support for the Suzuka National College of Technology's "Budding Scientists: Draw the Blueprint for Your Future 2011" business plan, which the Japan Science and Technology Agency adopted for its program "Support for girl students to choose the science course". DSP plans to continue accommodating requests for community-focused tours such as this as part of its social contribution activities.



Fifty-one tour participants, including 33 elementary, junior high and senior high school girls intending to enter scientific fields, listen intently to a female engineer explain an experiment.

Topic

### Great East Japan Earthquake Reconstruction Support Activities

Among its social contribution activities, DSP has prioritized support for reconstruction in the aftermath of the March 2011 Great East Japan Earthquake, and has been carrying out support initiatives accordingly. On May 1, 2011, we established the Earthquake Disaster Reconstruction Support Office\* as a full-time organization to provide long-term support for reconstruction. The office has been involved in the investigation, planning and implementation of DSP's activities for reconstruction of the affected areas.

Below are a few examples of the reconstruction support activities that DSP has carried out to date. (Figures as of April 2012)

#### **Volunteer Pharmacists**

As a support activity that leverages our expertise in pharmaceuticals, 77 DSP employees with pharmacist qualifications participated in volunteer activities in the affected areas. They provided the Miyagi Prefecture Pharmaceutical Association with support for pharmaceutical services such as the sorting and transportation of medicine.

#### **Employee Volunteers**

General employees from the DSP Group have been going to Rikuzentakata City, Iwate Prefecture to carry out cleaning (mud and rubble removal) and other volunteer activities. To date, 150 employees have participated.

#### **Decontamination Volunteers**

Employees with experience handling radiation at DSP joined other decontamination volunteers recruited by Fukushima City. They engaged in ground refilling, grass cutting and removal of topsoil from private home gardens in areas where radiation levels had been reduced by decontamination work by specialists. Twenty employees have participated since October 2011.

#### Support at Children's Sports Day

DSP provided support at a sports day for children who had evacuated to another area within Fukushima Prefecture due to the impact of the nuclear accident. In addition to assisting in the preparation and administration of the event and providing material support such as tents and banners, our employees conveyed their feelings of solidarity with the local area by presenting a flag they had prepared containing messages of support.

#### **Healthy Projects**

Since December 2011, DSP has been conducting Healthy Projects in order to use our knowledge of medicines and health to achieve healthy lives for the people of the affected areas.

In the Oshima Healthy Project, we held lessons on medicine usage and hand-washing at the Oshima elementary and junior high schools on the island of Oshima, Kesennuma City. In the Miyagi Healthy Project and the Fukushima Healthy Project, we carried out support activities that leverage our specialties as a pharmaceutical company, such as presenting basic knowledge concerning medicines and health-related topics to life support counselors.

#### Local Produce Marché (markets) to Support the Affected Areas

As part of our efforts to support the areas affected by the Great East Japan Earthquake, since November 2011 we have held seven markets at our Headquarters, factories, laboratories and Tokyo Office to sell produce from the Tohoku region.



Children listen enthusiastically to a lesson on medicine

A sports day event

Working together to clear debris from a field

We will contribute to the earliest possible reconstruction of the affected areas through ongoing long-term reconstruction support activities that meet local needs.

\* The Earthquake Disaster Reconstruction Support Office was dissolved on April 1, 2012. DSP's reconstruction support activities are now coordinated by Corporate Communications.

## With the Environment

Recognizing its responsibility toward the environment, DSP is striving to reduce its environmental impact in all of its business activities. Established in fiscal 2005 and revised in fiscal 2008, our Basic Environmental Policies underpin all our environmental activities. They outline what the Company should aim to do with respect to the environment, and the points to follow toward those goals. Under the Basic Environmental Policies, we formulated a Mid-term Environmental Plan that specifies goals of special importance and objectives for the three years from fiscal 2011 to fiscal 2013. In addition, we draft an Annual Implementation Plan. In this way, we ensure that our environmental activities are systematic and effective.

#### **Basic Environmental Policies**

DSP understands that the global environment is entering a critical phase. As a company that aims to protect people's lives and their health, DSP makes all-out efforts to realize a world that is prosperous and nice to live in by proactively working for environmental protection and creating a recycling-oriented society through the company's business activities.



#### **Overview of Our Environmental Burden**

DSP's business activities affect the environment in various ways at every stage of research and development, manufacturing, logistics and marketing, as well as the use of its products by customers. All our employees are aware of this environmental impact and work to reduce our environmental burden.



Note: Totals include figures for workplaces in Japan only (plants, research laboratories, distribution centers, Headquarters, Tokyo Office, branches and business offices)

#### Mid-term Environmental Plan (Fiscal 2011 - Fiscal 2013)

DSP has formulated the Mid-term Environmental Plan to clearly define goals of special importance in environmental activities and to form an action plan for achieving and continuously improving on these goals. During fiscal 2011, we made steady progress in most areas, except for a few objectives. We will continue activities for further improvement.

Goals of Special Importance	Objectives	Progress in Fiscal 2011	Degree of Progress
1. To enhance the environmental preservation promotion system	(1) To implement a green procurement system	<ol> <li>Implementing guidelines for items including office supplies. Changed all copy paper throughout the company to eco-friendly products</li> </ol>	(1) ()
	(2) To implement a green logistics system	(2) Implementing guidelines. Conducted various initiatives at distribution centers, plants and other locations	(2) 🔘
	(3) To implement green product development	(3) Implementing in Manufacturing Division and Technology Research & Development Division	(3) 🔘
	(4) To implement a system for green equipment designing	(4) Implementing in Manufacturing Division, Drug Research Division and General Affairs Department	(4) 🔘
2. To reduce emissions of chemical substances	(1) To properly manage chemical substances, and to continually strive to reduce emissions of chemical substances (PRTR substances, etc.) into the environment	(1) Reduced atmospheric emissions of dichloromethane by 75% compared with FY2010. Also, reduced atmospheric emissions of 1,2-dichloroethane by approximately 13%	(1) ©
3. To promote energy saving and prevent global warming	<ul> <li>[1] Numerical targets:</li> <li>(1) To reduce CO<sub>2</sub> emissions for the whole company to the level of the base year (FY2006) by FY2012</li> </ul>	[1] Numerical targets: (1) CO <sub>2</sub> emissions for the whole company in FY2011 were 99.9% of the level in FY2006. The effect of measures to conserve electricity following the Great East Japan Earthquake helped the company to achieve the objective one year ahead of schedule	(1) 🔘
	(2) To improve the specific energy consumption and CO <sub>2</sub> emission rate for the whole company by 1% or more per year	(2) 98.2%	(2) 🔘
	<ul><li>[2] Activity targets:</li><li>(1) To promote greening of the company's work sites</li></ul>	<ul> <li>[2] Activity targets:</li> <li>(1) Considered various measures at each work site and in Environment &amp; Safety Department</li> </ul>	(1) 🛆
	(2) To promote the introduction of energy-efficient equipment and machinery at the company's work sites	(2) Conducted energy-saving capital investment, such as renewal of boiler at the Ibaraki Plant and application of thermal insulating coating on roofs of buildings at the Ehime Plant	(2) 🔘
	(3) To promote the use of renewable energy at the company's work sites	(3) Considered various measures at each work site and in Environment & Safety Department	<b>(3)</b> △
	(4) To promote efficiency in all types of business operations at the company's work sites	(4) Implemented across the whole company	(4) (5)
4. To reduce waste	<ul><li>(5) To promote visualization of energy use at work sites</li><li>(1) To maintain final landfill disposal by the whole</li></ul>	<ul><li>(5) Considered various measures at each work site</li><li>(1) Maintained at less than 1% (FY2011 result 0.2%)</li></ul>	(5) () (1) ()
10 Touloo wasto	company at less than 1% of waste generated		
	(2) Plants and research laboratories: To maintain final landfill disposal of industrial waste at less than 1% of amount generated	(2) Achieved zero emissions at DSP's four plants and two research laboratories	(2) 🔘
	<ul><li>(3) Other sites: To continue complete recycling of recyclable waste</li></ul>	(3) Other sites made progress in recycling recyclable waste	(3) 🔿
5. To promote communication with group companies	(1) To support environmental safety activities of group companies	(1) Conducted environmental safety audits at two group companies in Japan, and held meeting in March 2012 to exchange information on energy management of domestic group companies	(1) ()
6. To promote communication with local communities	<ol> <li>To understand environmental risks that corporate activities can present to the local community</li> </ol>	<ol> <li>Gained understanding of most risks, and are implementing countermeasures</li> </ol>	(1) 🔿
	(2) To disclose suitable information to the local community in an appropriate way	(2) Implementing appropriately	(2) 〇
	(3) To participate actively in local environmental activities	(3) Actively participating at each work site	(3) (3)
7. To support social contribution activities	<ol> <li>To support and collaborate with environment-related social contribution activities</li> </ol>	<ol> <li>Considered implementation within the framework for CSR activities of the whole company</li> </ol>	(1) △
8. To enhance environmental education	(1) To develop and implement educational programs	(1) Created and implemented a setup for education by job level, education of all employees, and support for education conducted by work sites	(1) 🔿
9. To train employees	(1) To train key persons in environmental management	(1) Training taking place at each work site	(1) 🔿

Degree of progress: 
© Goal achieved 
> Steady progress made toward objective 
> Progress somewhat behind schedule 
> Progress significantly behind schedule

# Efforts to Conserve Energy and Prevent Global Warming

Measures against global warming are one of the key issues facing society today. DSP has set an environmental target of reducing company-wide CO<sub>2</sub> emissions by fiscal 2012 to the level of the base year of fiscal 2006. We are actively using energy efficiently in all areas of our business as we work to reduce our greenhouse gas emissions.

In fiscal 2011, we took measures to conserve electricity following the Great East Japan Earthquake in addition to continuing to organize items produced, consolidate animal feeding rooms in research laboratories, introduce hybrid vehicles into our fleet, and introduce energy-saving equipment. As a result, we achieved our objective for CO<sub>2</sub> emissions\* a year ahead of schedule with a company-wide reduction in emissions of about 6.1% from the previous fiscal year. We will further reduce CO<sub>2</sub> emissions in fiscal 2012 through ongoing efforts to reduce greenhouse gas emissions in all of our business activities, and plan to discuss new reduction targets for fiscal 2013 and beyond.

In addition, the revised Law Concerning the Rational Use of Energy that went into effect in fiscal 2010 requires reporting of energy usage for each company. In fiscal 2011, we responded with measures including information exchange meetings for employees in charge of workplace energy management, and once again properly reported our results to the government.

\* CO<sub>2</sub> conversions presented in this report use the values prescribed within the company. Thus, the figures may differ from those reported in accordance with the Law Concerning the Promotion of Measures to Cope with Global Warming and other standards.

#### Waste Reduction

One objective of DSP's Mid-term Environmental Plan is to maintain the company-wide volume of final landfilled waste at less than 1% of waste generated. To that end, we actively employ the "3 Rs" (Reduce, Reuse, Recycle) for waste to make effective use of finite resources.

In fiscal 2011, the volume of waste generated decreased approximately 11% from the previous fiscal year, and the company-wide volume of final landfilled waste decreased approximately 60%, a significant reduction. Final landfilled waste was approximately 0.2% of waste generated, once again meeting our target of less than 1%.

At our plants and research laboratories, we are pursuing zero emissions, which we have defined as a volume of final landfilled industrial waste less than 1% of waste generated. In fiscal 2011, we achieved zero emissions at all our plants and research laboratories.

Throughout the company, we will continue to actively pursue thorough waste separation and consignment to waste recyclers, and strive to further reduce landfilled waste.



#### Waste Recycling



# Corporate Governance

#### **Basic Approach to Corporate Governance**

DSP works to enhance its corporate governance, recognizing that it is a key managerial responsibility for ensuring sustained augmentation of corporate value – one of the missions entrusted to management by shareholders and other stakeholders.

# Factors That Could Significantly Influence Corporate Governance

Sumitomo Chemical Co., Ltd. is the parent company of DSP with a 50.22% share of voting rights. Respect for autonomy is affirmed by the parent company and management independence is maintained, with no restraints on approvals or other matters by the parent company concerning DSP's business operations. Furthermore, no directors of Sumitomo Chemical sit on the DSP Board of Directors.

DSP accepts transferees from the parent company, but believes that this has no influence on its management or business operations because the decision to accept transferees is DSP's. Therefore, DSP believes that having a parent company does not undermine the interests of general shareholders.

#### Management Structure

DSP has chosen the company with a board of auditors structure, which provides the dual functions of supervision of operational execution by the Board of Directors and auditing of compliance and efficiency by the Board of Auditors. Moreover, the company has introduced an executive officer system to separate management oversight from operational execution in a way that promotes delegation of authority while clarifying operational responsibility, thereby realizing faster and more transparent decision-making.

The Board of Directors convenes at least once a month. In fiscal 2011, it met 18 times. Composed of several executive officers, the Management Committee serves as a consultative body to assist the President of DSP in decision-making. It convenes at least twice a month to deliberate on important business matters, guided by the basic strategies set by the Board of Directors. In fiscal 2011, it met 27 times. As an additional measure to ensure that top managers are fully aware of the operational status of the business and related important matters, DSP has instituted the Executive Committee, which consists of all the executive officers and convenes at least once a month. In fiscal 2011, the Executive Committee met 12 times.

#### **Audit System**

DSP has appointed five corporate auditors, three of whom are outside auditors. One of the outside auditors is

registered as an independent officer with Tokyo Stock Exchange, Inc. and the Osaka Securities Exchange. The outside auditors contribute statements from their respective professional viewpoints, thus enhancing the company's auditing system.

The Board of Auditors, composed of all the corporate auditors, convenes at least once a month to discuss and decide important audit-related matters and review the agenda for board meetings. In fiscal 2011, the Board of Auditors met 16 times. In line with the audit policy and task allocation determined by the Board of Auditors, each corporate auditor endeavors to communicate with directors, the employees belonging to the Internal Auditing Department and other relevant sections, and other parties, to gather information and maintain an environment conducive to the auditing process. Corporate auditors attend key business meetings including those of the Board of Directors. They receive reports from directors and employees on the status of task execution, requesting explanation as necessary and viewing significant approval forms and other documents. This enables the Corporate Auditors to take a proactive internal auditing stance, focusing in particular on legal compliance and the efficiency of business operations.

Accounting audits are handled by KPMG AZSA LLC, based on an audit agreement. Internal audits are carried out by the Internal Auditing Department, which reports directly to the President of DSP. The basic elements for achieving the objectives of internal control, including subsidiaries, are audited from a fair and independent standpoint.

Corporate auditors, accounting auditors and internal auditors meet periodically to exchange information and enhance cooperation.



#### **Corporate Governance Structure**

#### **Establishment of an Internal Control System**

The Board of Directors of DSP passed a resolution on the basic policies for the establishment of a system to ensure appropriate business operation. The status of implementation efforts pursuant to the basic policies for each year is reported at the Board of Directors meeting held in the last month of the fiscal year and the basic policies are revised as necessary to improve the system.

#### Internal Control over Financial Reporting

To ensure the reliability of financial reporting, DSP designs and operates a system in accordance with the company's basic framework for internal control over financial reporting, and conducts evaluations of internal control.

The scope of the evaluations is company-wide internal control at DSP and its major consolidated subsidiaries, as well as business processes with a significant impact on finances. DSP evaluates the effectiveness of the design and implementation of internal control by management.

#### **Executive Remuneration**

Remuneration for directors consists of basic remuneration and bonuses. Basic remuneration is set according to position, such as representative director, while bonuses are determined based on company and individual performance using methods approved by the Board of Directors, within the scope of total remuneration approved at the annual shareholders' meeting.

Remuneration for auditors consists of basic remuneration determined by the Board of Auditors, within the scope of total remuneration approved at the annual shareholders' meeting.

In fiscal 2011, total remuneration paid to directors and auditors was ¥301 million and ¥90 million, respectively. These amounts represent remuneration paid to directors and auditors holding office during fiscal 2011, and include director bonuses of ¥31 million for that year.

Auditors' remuneration includes ¥36 million paid to outside auditors.

#### Compliance

In the Declaration of Conduct, DSP stated both internally and publicly its commitment to "abide by laws and regulations, and conduct corporate activities in a transparent and fair manner with high ethical standards". To put this declaration into practice and ensure compliance, DSP has established the Compliance Standards for business activities.

The Compliance Committee, presided over by the

executive officer in charge of compliance, met three times in fiscal 2011. The committee ascertained the status of compliance efforts throughout DSP and issued reminders, recommendations, and advice as necessary to the parties concerned.

DSP has also set up a compliance hotline to provide consultation or accept reports internally or externally in the event that an employee has questions or has obtained information concerning violations related to compliance.

As an initiative in fiscal 2011, DSP conducted education and training for all employees on prevention of corruption and insider trading, the harmful effects of drugs, and the Compliance Standards.

#### **Risk Management**

To deal with risks that might affect its business activities, DSP has established in-house Risk Management Promotion Regulations and has organized a Risk Management Committee that is chaired by the president. In addition, a risk management program is established each fiscal year to enable all of the corporate departments to make systematic efforts to solve their respective issues. DSP has also established Emergency Response Rules to codify procedures in the event of an emergency.

In fiscal 2011, DSP investigated response measures for the predicted earthquake directly beneath the Tokyo metropolitan area and The Tokai, Tonankai and Nankai Earthquake. The main topics covered were revising the business continuity plan (BCP), strengthening the functions of the Disaster Countermeasures Headquarters, strengthening the safety administration system, improving the earthquake and tsunami resistance of plants and offices, improving IT infrastructure and network systems, and upgrading regulations and manuals for responding to a variety of risks. DSP is also improving its group-wide risk management system in cooperation with group companies in and outside Japan.

#### Supply Chain Management

DSP purchases raw materials from multiple business partners and takes other systematic and methodical measures to avoid supply cutoffs and ensure the stable and safe procurement of items including the raw materials used in its pharmaceuticals. To conduct fair, open and transparent transactions, DSP concludes basic agreements on transactions with business partners, complies with relevant laws and regulations including the Act against Delay in Payment of Subcontract Proceeds, Etc. to Subcontractors, and continuously evaluates business partners.

#### **Risk Management System**



In fiscal 2011, DSP cooperated with business partners in focused responses to raw material supply instability and pharmaceutical exports following the Great East Japan Earthquake and Fukushima Daiichi Nuclear Power Plant accident. As a result, DSP was able to nullify impacts on its pharmaceutical product supply chain. In addition, the company is systematically concluding memorandums of understanding with its business partners regarding the elimination of anti-social forces.

# Subsidiary Management Structure and Governance

Based on company rules for the operation and management of group companies, DSP has designated managing divisions for each group company and a division to govern them, and endeavors to monitor and administer the management and execution of duties at group companies. DSP also provides appropriate support for business execution. In addition, the DSP Group is implementing unified CSR management including the establishment of a global governance structure, enhancement of compliance, strengthening of risk management, and social contribution activities.

# Annual Shareholders' Meeting and Exercise of Voting Rights

DSP sends out a notice of convocation of the annual shareholders' meeting approximately three weeks before

the date of the meeting to facilitate the exercise of voting rights. For foreign shareholders, DSP posts an English translation of the convocation notice on the company's website together with the Japanese version on the day the convocation notices are sent. Methods of voting include electronic voting platforms and other digital methods (such as the Internet) in addition to conventional voting in writing.

DSP also uses video and narration to present business reports during the annual shareholders' meeting.

#### **IR Activities**

DSP regularly holds meetings for analysts and institutional investors worldwide. In Japan, meetings are held to coincide with financial results announcements at the end of the second and fourth quarters, while conference calls are carried out for announcements of financial results of the first and third quarters. For overseas investors, representatives of DSP visited investors in the U.S. and Europe in June and September 2011, respectively, and participated in a conference held by a securities firm in the U.S. in January 2012.

DSP presents financial information, presentation materials for investors, annual reports, and other materials on its website.

DSP Website (Investor Relations) http://www.ds-pharma.com/ir/

### Board of Directors and Executive Officers (As of June 22, 2012)



From left: Tetsuya Oida, Hiroshi Noguchi, Yoshihiro Okada, Masayo Tada, Masaru Ishidahara, Makoto Hara, Hiroshi Nomura

#### Directors

Masayo Tada Representative Director, President and Chief Executive Officer

Hiroshi Noguchi Representative Director, Senior Executive Vice President Business Development; Global R&D Office; Global Oncology Business Development Office

Makoto Hara Member, Board of Directors, Executive Vice President

Chief Financial Officer Global Corporate Management; Global Strategy; Legal Affairs; Finance & Accounting; Business Support Center; Global Sales and Marketing

Yoshihiro Okada Member, Board of Directors, Executive Officer

Executive Director, Manufacturing; Technology Research & Development Masaru Ishidahara Member, Board of Directors, Executive

Corporate Communications; Environment & Safety; Personnel; General Affairs; Procurement; Osaka Administration

Tetsuya Oida Member, Board of Directors (Representative Director, President, DSP Gokyo Food & Chemical Co., Ltd.)

Hiroshi Nomura Member, Board of Directors (Vice Chair, Executive Vice President, CFO, Sunovion Pharmaceuticals Inc.)

Corporate Auditors

Ikuo Hino Full-Time Corporate Auditor

Nobuo Takeda Full-Time Corporate Auditor

Masahiro Kondo Corporate Auditor

Harumichi Uchida Corporate Auditor

Hidehiko Sato Corporate Auditor **Executive Officers** 

Yasuji Furutani Senior Executive Officer Executive Director, Corporate Regulatory Compliance & Quality Assurance

Susumu Nakajima Senior Executive Officer Executive Director, Sales & Marketing

Masaharu Kanaoka Senior Executive Officer Executive Director, Drug Research; Intellectual Property; Information Systems Planning

Nobuhiko Tamura

Executive Director, Drug Development Yoshihiro Shinkawa

Executive Officer Deputy Executive Director, Sales & Marketing

Yoshinori Oh-e Executive Officer Director, Business Development

Yoshiharu Ikeda Executive Officer Executive Vice President, Sunovion Pharmaceuticals Inc. Mutsuo Taiji Executive Officer Deputy Executive Director, Drug Research; Director, Pharmacology Research Laboratories

Nobuyuki Hara

Executive Officer Deputy Executive Director, Corporate Regulatory Compliance & Quality Assurance; Director, Corporate Regulatory Compliance & Quality Assurance Management; Regulatory Affairs

Hitoshi Odagiri Executive Officer Director, Personnel; Career Development Support

Antony Loebel Executive Officer Executive Vice President, CMO, Sunovion Pharmaceuticals Inc.

Chiang J. Li Executive Officer President, CEO and CMO, Boston Biomedical, Inc.

# **Financial Section**

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# **Eleven-Year Summary of Selected Financial Data** Dainippon Sumitomo Pharma Co., Ltd. and Consolidated Subsidiaries Years ended March 31

	2012	2011	2010	2009	2008
RESULTS OF OPERATIONS:					
Net sales	¥350,396	¥379,513	¥296,262	¥264,037	¥263,993
Overseas sales revenue	130,243	152,226	53,015	22,051	24,521
Ratio of overseas sales revenue	37.2%	40.1%	17.9%	8.4%	9.3%
Cost of sales	98,857	110,030	112,263	103,741	99,385
Selling, general and administrative expenses	231,137	238,531	148,374	129,130	124,794
Operating income	20,402	30,952	35,625	31,166	39,814
Income before income taxes and minority interests	16,328	25,050	31,423	32,168	41,457
Net income	8,630	16,796	20,958	19,988	25,592
Comprehensive income (loss)	2,396	(12,066)	27,148	_	_
FINANCIAL POSITION:					
Current assets	334,251	333,000	287,555	263,540	251,063
Net property, plant and equipment	66,697	69,794	74,084	69,105	70,280
Total assets	559,410	589,868	626,743	391,295	399,791
Current liabilities	105,966	157,204	265,000	53,350	67,915
Long-term liabilities	134,217	108,681	18,260	13,449	13,598
Net assets	319,227	323,983	343,483	324,496	318,278
DTHER STATISTICS: R&D costs	56,891	68,160	51,371	52,819	47,266
R&D costs Capital expenditures	56,891 8,742	68,160 8,663	51,371 6,471	52,819 10,569	47,266 15,491
R&D costs Capital expenditures Depreciation and amortization	8,742 40,232	,		10,569 11,455	
R&D costs Capital expenditures	8,742	8,663	6,471	10,569	15,491
R&D costs Capital expenditures Depreciation and amortization	8,742 40,232	8,663 44,628	6,471 18,650	10,569 11,455	15,491 11,870
R&D costs Capital expenditures Depreciation and amortization EBITDA	8,742 40,232	8,663 44,628	6,471 18,650	10,569 11,455	15,491 11,870
R&D costs Capital expenditures Depreciation and amortization EBITDA	8,742 40,232	8,663 44,628	6,471 18,650	10,569 11,455	15,491 11,870
R&D costs Capital expenditures Depreciation and amortization EBITDA PER SHARE OF COMMON STOCK:	8,742 40,232 59,880	8,663 44,628 77,971	6,471 18,650 56,448	10,569 11,455 41,970	15,491 11,870 48,802
R&D costs         Capital expenditures         Depreciation and amortization         EBITDA	8,742 40,232 59,880 ¥ 21.72	8,663 44,628 77,971 ¥ 42.27	6,471 18,650 56,448 ¥ 52.75	10,569 11,455 41,970 ¥ 50.30	15,491 11,870 48,802 ¥ 64.39
R&D costs         Capital expenditures         Depreciation and amortization         EBITDA         PER SHARE OF COMMON STOCK:         Basic net income         Net assets	8,742 40,232 59,880 ¥ 21.72 803.47	8,663 44,628 77,971 ¥ 42.27 815.44	6,471 18,650 56,448 ¥ 52.75 864.51	10,569 11,455 41,970 ¥ 50.30 816.49	15,491 11,870 48,802 ¥ 64.39 800.63
R&D costs         Capital expenditures         Depreciation and amortization         EBITDA         PER SHARE OF COMMON STOCK:         Basic net income         Net assets	8,742 40,232 59,880 ¥ 21.72 803.47	8,663 44,628 77,971 ¥ 42.27 815.44	6,471 18,650 56,448 ¥ 52.75 864.51	10,569 11,455 41,970 ¥ 50.30 816.49	15,491 11,870 48,802 ¥ 64.39 800.63
R&D costs         Capital expenditures         Depreciation and amortization         EBITDA         PER SHARE OF COMMON STOCK:         Basic net income         Net assets         Cash dividends applicable to the year	8,742 40,232 59,880 ¥ 21.72 803.47	8,663 44,628 77,971 ¥ 42.27 815.44	6,471 18,650 56,448 ¥ 52.75 864.51	10,569 11,455 41,970 ¥ 50.30 816.49	15,491 11,870 48,802 ¥ 64.39 800.63
R&D costs         Capital expenditures         Depreciation and amortization         EBITDA         PER SHARE OF COMMON STOCK:         Basic net income         Net assets         Cash dividends applicable to the year	8,742 40,232 59,880 ¥ 21.72 803.47 18.00	8,663 44,628 77,971 ¥ 42.27 815.44 18.00	6,471 18,650 56,448 ¥ 52.75 864.51 18.00	10,569 11,455 41,970 ¥ 50.30 816.49 18.00	15,491 11,870 48,802 ¥ 64.39 800.63 18.00
R&D costs         Capital expenditures         Depreciation and amortization         EBITDA         PER SHARE OF COMMON STOCK:         Basic net income         Net assets         Cash dividends applicable to the year         FINANCIAL INDICATORS:         Operating margin	8,742 40,232 59,880 ¥ 21.72 803.47 18.00 5.8%	8,663 44,628 77,971 ¥ 42.27 815.44 18.00 8.2%	6,471 18,650 56,448 ¥ 52.75 864.51 18.00 12.0%	10,569 11,455 41,970 ¥ 50.30 816.49 18.00 11.8%	15,491 11,870 48,802 ¥ 64.39 800.63 18.00 15.1%

balance sheet from 2007. In accordance with the adoption of the new accounting standards, net assets in the financial position from 2002 to 2006 have been reclassified.

Ν	<i>I</i> illions of yen						Percent change	Thousands of U.S. dollars (Note 1)
	2007	2006	2005	2004	2003	2002	2012/2011	2012
¥	261,213	¥245,784	¥175,088	¥171,672	¥172,554	¥164,737	(7.7%)	\$4,273,122
	22,032	9,696	3,820	3,630	3,990	2,000	(14.4%)	1,588,329
	8.4%	3.9%	2.2%	2.1%	2.3%	1.2%		
	99,346	130,437	111,099	110,013	108,046	100,073	(10.2%)	1,205,573
	116,312	86,461	52,404	51,546	51,240	46,863	(3.1%)	2,818,744
	45,555	28,886	11,585	10,113	13,268	17,801	(34.1%)	248,805
	38,415	25,687	11,686	13,836	12,718	17,863	(34.8%)	199,122
	22,605	15,377	6,924	7,968	6,364	9,596	(48.6%)	105,244
	_	_	_	_	_	_	119.9%	29,220
	234,313	249,733	131,176	118,562	116,241	119,247	0.4%	4,076,232
	65,241	68,336	32,611	34,473	35,374	33,637	(4.4%)	813,378
	382,535	392,966	201,431	193,238	187,416	186,834	(5.2%)	6,822,073
	56,039	80,071	49,196	45,927	60,727	48,966	(32.6%)	1,292,268
	20,484	24,262	16,802	16,258	9,248	20,484	23.5%	1,636,793
	306,012	288,633	135,433	130,268	116,661	116,566	(1.5%)	3,893,012
	40,870	29,636	17,444	15,929	15,218	13,124	(16.5%)	693,793
	9,543	6,616	3,064	4,294	6,532	6,414	0.9%	106,610
	12,088	8,901	5,233	5,821	5,316	4,334	(9.8%)	490,634
	54,875	36,179	16,446	16,040	18,254	22,204	(23.2%)	
	Yen						Percent change	U.S. dollars
	¥ 56.86	¥ 54.57	¥ 41.76	¥ 48.05	¥ 38.02	¥ 57.06	(48.6%)	\$0.26
	767.52	723.63	815.76	784.24	702.09	689.79	(1.5%)	9.80
	14.00	12.00	10.00	10.00	10.00	10.00	0.0%	0.22
	17.4%	11.8%	6.6%	5.9%	7.7%	10.8%		
	7.6%	7.3%	5.2%	6.5%	5.5%	8.5%		
	5.8%	5.2%	3.5%	4.2%	3.4%	5.1%		
	79.8%	73.2%	66.8%	67.1%	61.9%	62.1%		

4: Dainippon Sumitomo Pharma Co., Ltd. acquired Sepracor Inc. (now Sunovion Pharmaceutical Inc.) in October 2009.

Consolidated results for 2010 include the results of this company for 2.5 months (October 15 - December 31, 2009).

5: Dainippon Sumitomo Pharma Co., Ltd. and its consolidated subsidiaries adopted the new accounting standard for presentation of comprehensive income and the revised accounting standard for consolidated financial statements. In accordance with the adoption of the new accounting standards, comprehensive income (loss) has been presented in the results of operations from 2010 to 2012.

6: EBITDA = income before income tax and minority interests + interest expense - interest income + depreciation and amortization + amortization of goodwill - extraordinary income (loss)

# Management's Discussion and Analysis

### Overview

During the fiscal year ended March 31, 2012 (fiscal 2011), uncertainty clouded the Japanese economy. While production showed signs of recovery compared to conditions immediately after the Great East Japan Earthquake that occurred in March 2011, protracted deflation and electricity supply problems accompanied severe employment conditions. Overseas, economic expansion continued despite the moderate pace of recovery in the U.S. economy and slower growth in China and other emerging countries. However, the outlook for the global economy is not optimistic because of the unresolved risk of a downturn caused by the financial problems in Europe.

The situation in the pharmaceutical industry remains challenging because of factors including the lack of breakthrough drug discovery, the rising cost of drug development, the increased rigor of the approval process, the ongoing drastic reform of healthcare systems worldwide, and the April 2012 drug price revision in Japan.

Under these conditions, the Dainippon Sumitomo Pharma Group ("the DSP Group") concentrated on "transforming the earnings structure in Japan," "expanding overseas operation and maximizing earnings," and "expanding the drug pipeline for future growth" during the second year of its Second Mid-term Business Plan.

In the domestic pharmaceuticals business, the DSP Group worked to expand sales by concentrating marketing resources on strategic products including AVAPRO<sup>®</sup>, a therapeutic agent for hypertension, and on new products including TRERIEF<sup>®</sup>, a Parkinson's disease drug. Moreover, in April 2011 we established the CNS Sales and Marketing Department to concentrate on further market penetration for LONASEN<sup>®</sup>, an atypical antipsychotic. We also strengthened our product lineup in the central nervous system area through marketing alliances and the launch of generic products.

In the U.S. pharmaceuticals business, the DSP Group launched LATUDA®, an atypical antipsychotic, in February 2011 and devoted all of its capabilities to achieving rapid market penetration and expanding sales. Also, in February 2012, the DSP Group enhanced its oncology development pipeline and expanded its R&D organization by agreeing with U.S. bio-venture company Boston Biomedical, Inc. ("BBI") on the acquisition of BBI. The DSP Group completed its acquisition of BBI in April 2012.

### **Results of Operations**

#### General Results Net Sales

Net sales for fiscal 2011 decreased ¥29.1 billion, or 7.7%, year on year to ¥350.4 billion. Factors included the impact of the strong yen, the absence of an upfront payment received in connection with a development and commercialization alliance in the previous fiscal year, and a change in the method for recognizing pet food sales.



#### Cost of Sales and Gross Profit

Cost of sales decreased ¥11.2 billion, or 10.2%, year on year to ¥98.9 billion because of the decrease in net sales, and the cost of sales ratio improved 0.8 percentage points to 28.2%. As a result, gross profit decreased ¥17.9 billion, or 6.6%, to ¥251.6 billion.

#### Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses decreased ¥7.4 billion, or 3.1%, year on year to ¥231.1 billion. Among these, research and development costs decreased ¥11.3 billion, or 16.5%, to ¥56.9 billion, largely because of the impact of the strong yen and lower licensing expenses. Excluding research and development costs, SG&A expenses decreased ¥9.8 billion because of the strong yen, but increased ¥3.9 billion, or 2.3%, overall to ¥174.2 billion due to factors such as increased advertising and personnel expenses in connection with the U.S. launch of LATUDA<sup>®</sup>.





#### **Operating Income**

As a result of the above factors, operating income decreased ¥10.5 billion, or 34.1%, year on year to ¥20.4 billion.



#### Other Income (Expenses) and Net Income

During fiscal 2011, other expenses exceeded other income by ¥4.1 billion. Other income included a ¥1.2 billion gain on sales of property, plant and equipment such as the land of the former Tokyo Northern Office. However, other expenses included impairment losses on certain patent rights of ¥2.3 billion and business structure improvement costs associated with a revision of our sales structure in the United States totaling ¥1.2 billion.

In addition, total income taxes increased for reasons including changes to the statutory tax rate in connection with the revision of the Corporation Tax Act. Consequently, net income for fiscal 2011 decreased ¥8.2 billion, or 48.6%, year on year to ¥8.6 billion.

#### **Results by Business Segment**

Effective fiscal 2011, the DSP Group changed its reportable segments to further strengthen the market-specific performance management of its pharmaceutical operations. Moreover, segment income is segment operating income before deduction of R&D costs because the DSP Group now manages research and development costs globally without allocating them to particular segments.



#### Japan

The DSP Group concentrated sales resources on strategic products AVAPRO<sup>®</sup>, LONASEN<sup>®</sup> and PRORENAL<sup>®</sup>, and on new products including TRERIEF<sup>®</sup>, MIRIPLA<sup>®</sup> and METGLUCO<sup>®</sup>. At the same time, the DSP Group focused on cost effectiveness and cost efficiency in emphasizing continuous improvement in operating efficiency to expand earnings. As a result, the DSP Group minimized negative factors including the impact of lower sales of existing

products. Sales in Japan decreased ¥3.0 billion, or 1.6%, year on year to ¥179.9 billion, and segment income decreased ¥1.7 billion, or 2.5%, to ¥66.4 billion.

#### North America

The DSP Group concentrated on rapidly expanding sales of LATUDA® and aggressively promoted existing products including the sedative hypnotic LUNESTA®. Sales increased slightly year on year on a local currency basis, but decreased ¥9.2 billion, or 7.8%, to ¥108.4 billion on a yen basis because of the strong yen. Segment loss was ¥0.3 billion, compared with segment income of ¥6.9 billion for fiscal 2010, because of increased expenses associated with LATUDA®. Excluding amortization of intangible assets associated with the acquisition of Sunovion Pharmaceuticals Inc., segment income would have been ¥27.4 billion for fiscal 2011.

#### China

Segment sales increased ¥0.9 billion, or 15.0%, year on year to ¥6.5 billion, primarily because of higher sales of MEPEM® (MEROPEN®). Segment income decreased ¥0.2 billion, or 19.3%, to ¥1.0 billion due to factors including higher selling expenses.

#### Other Regions

Segment sales decreased ¥13.2 billion, or 46.4 percent, year on year to ¥15.2 billion due to factors including lower upfront payments associated with development and marketing alliances. Segment income decreased ¥13.1 billion, or 65.1%, to ¥7.0 billion.

#### Other Business

In addition to the reportable segments above, businesses such as food ingredients, food additives, chemical product materials, veterinary drugs and diagnostics are included in Other Business. Segment sales decreased ¥4.6 billion, or 10.2%, year on year to ¥40.3 billion. Segment income increased ¥0.4 billion, or 15.6%, to ¥3.2 billion.

#### Sales of Major Pharmaceutical Products

In the domestic pharmaceuticals business, sales of DSP's three strategic products AVAPRO®, LONASEN® and PRORENAL® totaled ¥36.0 billion, an increase of ¥3.8 billion, or 11.9%, year on year. Sales of new products,

including TRERIEF®, MIRIPLA® and METGLUCO® (including MELBIN®), totaled ¥15.2 billion, an increase of ¥5.3 billion, or 54.0%, year on year.

Sales of AMLODIN<sup>®</sup> and MEROPEN<sup>®</sup> decreased by ¥5.4 billion and ¥0.5 billion, respectively, compared with the previous fiscal year. However, these decreases were less than forecast.

In North America, sales of the new product LATUDA® totaled ¥6.9 billion. On the other hand, sales of LUNESTA® decreased ¥11.8 billion year on year to ¥42.1 billion and sales of XOPENEX® decreased ¥5.0 billion to ¥33.4 billion. The strong yen affected sales of all products in North America, and a surge in shipments at the end of the previous fiscal year affected the year-on-year comparison for LUNESTA® sales.

### **Domestic Sales of Major Pharmaceutical Products**

(Before deduction of rebates; Billions of yen)

Brand name	Therapeutic indication	FY2011	FY2010
AMLODIN®	Therapeutic agent for hypertension and angina		
	pectoris	36.0	41.4
<b>GASMOTIN®</b>	Gastroprokinetic	21.2	21.0
PRORENAL®	Vasodilator	15.5	14.9
MEROPEN®	Carbapenem antibiotic	12.2	12.6
AVAPRO®	Therapeutic agent for hypertension	10.7	8.3
LONASEN®	Atypical antipsychotic	9.8	9.0
REPLAGAL®	Anderson-Fabry disease drug	9.1	6.2
METGLUCO <sup>®</sup> and MELBIN <sup>®</sup>	Biguanide oral hypoglycemic	8.5	4.7
EBASTEL <sup>®</sup>	Antiallergic	6.6	8.6
TRERIEF®	Parkinson's disease drug	5.3	3.7
AmBisome®	Therapeutic agent for systemic fungal infection	4.5	4.6
SUMIFERON®	Natural alpha interferon	3.6	5.1
EXCEGRAN <sup>®</sup>	Antiepileptic	3.3	3.5
DOPS®	Neural function ameliorant	3.2	3.3
MIRIPLA®	Therapeutic agent for hepatocellular carcinoma	1.3	1.5

#### Major Exported Pharmaceuticals (Billions of yen)

Brand name	Therapeutic indication	FY2011	FY2010
<b>MEROPEN®</b>	Carbapenem antibiotic	11.9	14.5
<b>EXCEGRAN®</b>	Antiepileptic	1.2	1.5
<b>GASMOTIN®</b>	Gastroprokinetic	0.8	1.0
Note: For external	customers		

#### U.S. Subsidiaries Sales (Billions of yen)

Brand name	Therapeutic indication	FY2011	FY2010
LUNESTA®	Sedative hypnotic	42.1	53.9
XOPENEX®	Short-acting beta-agonist	33.4	38.4
BROVANA®	Long-acting beta-agonist	10.2	9.3
LATUDA®	Atypical antipsychotic	6.9	_
<b>OMNARIS®</b>	Corticosteroid nasal spray	5.1	4.8
ALVESCO®	Inhaled corticosteroid	2.8	2.5

#### China Subsidiaries Sales (Billions of yen)

Brand name	Therapeutic indication	FY2011	FY2010
<b>MEROPEN®</b>	Carbapenem antibiotic	5.5	5.0

### Financial Position

#### Assets, Liabilities and Net Assets Total Assets

Total assets as of March 31, 2012 amounted to ¥559.4 billion, a decrease of ¥30.5 billion from the end of the previous fiscal year. A primary factor was a decrease in intangible assets including goodwill and patent rights.

Current assets increased ¥1.3 billion from a year earlier to ¥334.3 billion. Factors included a decrease in notes and accounts receivable, and an increase in marketable securities and inventories.

Noncurrent assets decreased ¥31.7 billion from a year earlier to ¥225.2 billion, primarily reflecting a decrease in intangible assets due to amortization of goodwill and patent rights.



#### **Total Liabilities**

Total liabilities as of March 31, 2012 were ¥240.2 billion, a decrease of ¥25.7 billion from a year earlier. The principal factor was a decrease in interest-bearing debt reflecting the repayment of loans.

#### **Net Assets**

Net assets as of March 31, 2012 were ¥319.2 billion, a decrease of ¥4.8 billion from a year earlier. While retained earnings and unrealized gains on available-for-sale securities, net of tax increased, foreign currency translation adjustments reduced net assets due to the strong yen.



#### Cash Flows Net Cash Provided by Operating Activities

Net cash provided by operating activities was ¥48.4 billion, compared with ¥55.0 billion for fiscal 2010, and primarily consisted of income before income taxes and minority interests along with adjustments for depreciation and amortization and other items, partially offset by factors including increase in inventories and income taxes paid.

#### Net Cash Used in Investing Activities

Net cash used in investing activities was ¥4.4 billion, compared with ¥6.6 billion for fiscal 2010. The primary factor was purchases of property, plant and equipment.

#### Free Cash Flow

Free cash flow, defined as the total of net cash provided by operating activities and net cash used in investing activities, was ¥44.0 billion, compared with ¥48.5 billion for fiscal 2010.

#### Net Cash Used in Financing Activities

Net cash used in financing activities was ¥32.9 billion, compared with ¥20.3 billion for fiscal 2010. While proceeds from issuance of bonds provided cash, an increase in repayment of long-term debt used cash.

#### **Cash and Cash Equivalents**

As a result of the above, cash and cash equivalents as of March 31, 2012 increased ¥9.3 billion from a year earlier to ¥92.2 billion.



#### Major Cash Flow Indicators

#### FY2006 FY2007 FY2008 FY2009 FY2010 FY2011 Equity ratio 79.8% 79.6% 82.9% 54.8% 54.9% 57.1% Equity ratio on fair value basis 130.8% 90.6% 83.1% 54.3% 52.2% 62.3% Ratio of interest-bearing debt to cash flows 18.1% 17.5% 8.5% 431.2% 218.4% 205.4% Interest coverage ratio (times) 42.7 37.4 57.9 960.4 748.5 648.1

#### **Dividend Policy and Dividends**

The Company views the regular and consistent return of profits to shareholders as one of its most important management policies.

The Company's basic policy is to pay dividends from retained earnings twice a year, first as an interim dividend and second as a year-end dividend. The Board of Directors and the general meeting of shareholders determine the interim and year-end dividends, respectively.

We believe that it is important to allocate profits to our shareholders in a way that accurately reflects our business performance. When determining the amount of dividends to be distributed, we take a comprehensive view that includes consideration for the importance of raising corporate value through aggressive investment in future growth, solidifying our operating base and enhancing our financial position. We also take into consideration the importance of paying stable dividends.

Based on this policy, the Company paid cash dividends applicable to fiscal 2011 of ¥18.00 per share, consisting of an interim dividend and a year-end dividend of ¥9.00 per share each.

The Company plans to use internal reserves primarily for investments in R&D and business development in Japan and overseas, for capital investments to improve the efficiency of business activities, and to strengthen its financial position through repayment of borrowings and other means.



#### Number of Employees

The DSP Group had 7,601 employees as of March 31, 2012, down 145 from a year earlier. The number of employees decreased by 11 to 4,449 in the Japan (Pharmaceuticals) segment; decreased by 203 to 2,216 in the North America segment; increased by 66 to 626 in the China segment; and increased by 3 to 310 in the Other Business segment.



### Outlook for Fiscal 2012

In fiscal 2012, the DSP Group will continue to concentrate on "transforming the earnings structure in Japan," "expanding overseas operation and maximizing earnings," and "expanding the drug pipeline for future growth" during the third year of the five-year Second Mid-term Business Plan, under the slogan "Creation and transformation toward a new stage of globalization."

In the domestic pharmaceuticals business, the DSP Group forecasts that sales will be on par with fiscal 2011 because concentrated efforts to expand sales of strategic and new products will compensate for the impact of drug price revisions and generic drugs. In the North American pharmaceuticals business, the DSP Group forecasts that sales will increase slightly because of increased sales of LATUDA<sup>®</sup> and other products. However, the DSP Group forecasts that net sales will decrease ¥2.4 billion year on year to ¥348.0 billion due to factors including reduced exports of MEROPEN<sup>®</sup> because of the impact of generic products.

The DSP Group expects sales volume to increase, but net sales to decrease overall because of the impact of factors including drug price revisions. Gross profit is expected to decrease as a result. In addition, the acquisition of BBI and other factors is forecast to increase research and development costs, but the entire DSP Group will focus on efforts to raise operating efficiency. The DSP Group therefore forecasts that operating income will increase ¥4.6 billion year on year to ¥25.0 billion, and that net income will increase ¥3.4 billion to ¥12.0 billion. The DSP Group also forecasts that earnings before income taxes, depreciation and amortization will increase ¥1.0 billion to ¥60.0 billion.

These forecasts reflect management's judgments based on currently available information. Actual results may differ from these forecasts due to various risks and uncertainties.

\* Foreign currency exchange rates used for forecasts: \$80 = U.S.\$1.00, \$12 = 1 RMB

### **Business Risks**

Below is a discussion of the most significant risks that could negatively impact the operating results and financial position of the DSP Group.

Forward-looking statements in the discussion of risks discussed below reflect the judgment of the Group as of March 31, 2012.

#### (i) Risk relating to research and development of new products

The Group works to research and develop highly original and globally viable products. The Group strives to maintain an extensive product pipeline and to bring products to market as early as possible. Nevertheless, the Group can envision scenarios in which not all products under development will progress smoothly to eventual sale, as well as instances in which the development of certain products must be halted. Depending on the nature of the product under development, such cases could have a significant and negative impact on the Group's operating results and financial position.

#### (ii) Problems concerning adverse events

The Group conducts rigorous safety testing of its pharmaceutical products at different stages of development, with products receiving approval only after rigorous screening by the competent authorities in all the countries. These efforts notwithstanding, previously unreported adverse events are sometimes discovered only after a drug has already been marketed. The appearance of such unexpected adverse events once a product has been sold could have a significant and negative impact on the Group's operating results and financial position.

#### (iii) Healthcare system reforms

The precipitous decline in Japan's birthrate and the rapid rise in the country's elderly population are the prime factors causing the financial state of Japan's healthcare insurance system to deteriorate. In this climate, measures continue to emerge aimed at curbing healthcare costs, and how to best reform the country's healthcare system continues to be debated. The direction that any healthcare system reforms might take, including mandated NHI price revisions, could ultimately have a significant and negative impact on the Group's operating results and financial position. In addition, pharmaceutical products are subject to various kinds of regulations in foreign countries and, therefore, have a possibility that they might be significantly affected depending on the way administrative measures are implemented.

#### (iv) Risk relating to the sale of products

The Group can envision scenarios in which sales of its pharmaceutical products are threatened to decrease due to a competition with the products of the same area of other manufacturers or a launching of generic products following the expiration of a patent period or otherwise. Such cases could have a significant and negative impact on the Group's financial position and operating results.

#### (v) Risk relating to intellectual property rights

The Group utilizes a wide range of intellectual property during the course of its R&D activities, including both property owned by the Group and property that the Group lawfully uses with the authorization of the property's owner. Nevertheless, the Group recognizes the possibility, no matter how slight, that some use might be deemed an infringement of a third party's intellectual property rights. Consequently, legal disputes pertaining to intellectual property rights could arise and have a significant and negative impact on the Group's operating results and financial position.

#### (vi) Termination of partnerships

The Group enters into a variety of partnerships with other companies for the sale of purchased goods, the establishment of joint ventures, co-promotion, and the licensing in and out of products under development, as well as for collaborative research and other purposes. The termination, for whatever reason, of such partnerships could have a significant and negative impact on the Group's operating results and financial position.

#### (vii) Prerequisites for primary business activities

The Group's core business is the ethical pharmaceutical products business. Accordingly, the Group requires licenses and other certifications to engage in R&D and the manufacture and sale of drugs pursuant to Japan's Pharmaceutical Affairs Law and other laws and regulations related to pharmaceuticals. The Company has obtained licenses and other certifications, including Type 1 and Type 2 Pharmaceuticals Manufacturing and Sales Business licenses (both valid for five years). In addition, in order to engage in the ethical pharmaceutical products business in overseas

countries, the Group also has obtained licenses as needed under laws and regulations related to pharmaceuticals of those countries. These licenses and other certifications will cease to be valid unless gone through procedures as stipulated by the applicable laws and regulations. These laws and regulations also stipulate that these licenses and certifications may be revoked and/or that the Group may be ordered to suspend part of or all of its operations for a fixed period of time or be subject to other measures in the event that the Group violates these laws and regulations. The Group currently has no knowledge of any facts that would warrant the revocation of its licenses or other certifications.

However, an order to revoke the Group's licenses or other certifications could have a significant and negative impact on the Group's operating results and financial position.

#### (viii) Risk relating to litigation

There is a possibility that a suit may be brought to court in terms of an adverse effect of a pharmaceutical product, product liability, labor issues, fair trade, etc., relating to the business activities of the Group. Depending on the development thereof, such cases could have a significant and negative impact on the Group's operating results and financial position.

#### (ix) Closedown or shutdown of a plant

The Group can envision scenarios in which the Group's plant is closed down or shut down due to technical problems, stoppage of supply of raw materials, fire, earthquake, or any other disaster where the supply of products is delayed or halted. Such cases could have a significant and negative impact on the Group's operating results and financial position.

# (x) Impact of financial market situation and foreign exchange fluctuations

A sluggish equity market will give rise to a loss on valuation or sale of shares held, and the interest rate trend may increase interest expenses on borrowings etc., and the deterioration of financial market situation will cause the retirement benefit obligations to increase. All these factors could have a significant and negative impact on the Group's operating results and financial position. Furthermore, foreign exchange fluctuations may have a material impact on importing and exporting transactions and the conversion of operating results of consolidated subsidiaries into yen.

#### (xi) Impact of impairment of fixed assets

The Group owns various types of tangible and intangible fixed assets, such as business assets and goodwill. In the future, in the event of substantial deterioration of operating results or reduction in values, the need to treat the impairment will arise, which could have a significant and negative impact on the Group's operating results and financial position.

#### (xii) Transactions with the parent company

The Company and its parent company, Sumitomo Chemical Co., Ltd., have concluded agreements for the leasing of land for the Osaka Research Laboratories, Ehime Plant and Oita Plant, as well as for the purchase of raw materials used in the production of active pharmaceutical ingredients at these sites and other locations. These agreements involve prices that are determined based on discussions between the two parties with reference to general market prices. These agreements are customarily renewed every year. The Company also accepts employees on loan from the parent company.

Furthermore, during the year we also made short-term loans to our parent company to raise capital efficiency.

The Company's policy is to continue these transactions and other ties with the parent company.

However, changes in these agreements, including changes in the transaction terms specified therein, could have a significant and negative impact on the Group's operating results and financial position.

#### (xiii) Risk relating to overseas operations

The Group conducts global business activity mainly in regions North America and China. The risks such as change of local restrictions, worsening of diplomatic relations and political uncertainties are inherent in these activities. In the event the Group faces such risks, it could have a significant and negative impact on the Group's operating results and financial position.

The Group also faces risks other than those discussed above.

# **Consolidated Balance Sheets**

Dainippon Sumitomo Pharma Co., Ltd. and Consolidated Subsidiaries March 31, 2012 and 2011

	Millions	s of yen	Thousands of U.S. dollars (Note 1)
ASSETS	2012	2011	2012
CURRENT ASSETS:			
Cash and time deposits (Note 3)	¥ 12,953	¥ 14,939	\$ 157,963
Marketable securities (Notes 3 and 6)	99,118	90,921	1,208,756
Receivables:			
Trade notes	2,971	2,811	36,232
Trade accounts	99,653	106,437	1,215,280
Due from parent company, unconsolidated subsidiaries			
and affiliates (Note 13)	25,050	25,101	305,488
Allowance for doubtful receivables	(110)	(123)	(1,341)
Total	127,564	134,226	1,555,659
Inventories (Note 4)	58,118	55,972	708,756
Deferred tax assets (Note 9)	31,783	33,489	387,598
Other current assets	4,715	3,453	57,500
Total current assets	334,251	333,000	4,076,232

#### **PROPERTY, PLANT AND EQUIPMENT:**

	10.040	10.000	404.070
Land	10,248	10,292	124,976
Buildings and structures	91,116	91,227	1,111,171
Machinery and equipment	104,959	104,619	1,279,987
Construction in progress	2,121	942	25,866
Total	208,444	207,080	2,542,000
Accumulated depreciation	(141,747)	(137,286)	(1,728,622)
Net property, plant and equipment	66,697	69,794	813,378

#### **INVESTMENTS AND OTHER ASSETS:**

TOTAL	¥ 559,410	¥ 589,868	\$ 6,822,073
Total investments and other assets	158,462	187,074	1,932,463
Other assets (Note 10)	9,075	8,660	110,671
Deferred tax assets (Note 9)	11,625	7,024	141,768
Intangible assets	43,395	72,897	529,207
Goodwill	64,311	70,370	784,280
Investment securities (Note 6)	29,083	27,150	354,671
Investment in unconsolidated subsidiaries and affiliates	973	973	11,866

	Million	s of yen	Thousands of U.S. dollars (Note 1)	
IABILITIES AND NET ASSETS	2012	2011	2012	
URRENT LIABILITIES:				
Short-term bank loans (Note 8)	¥ —	¥ 50,000	\$ -	
Current portion of long-term debt (Note 8)	10,000	10,600	121,951	
Payables:				
Trade notes	151	193	1,841	
Trade accounts (Notes 6 and 7)	42,488	45,047	518,147	
Due to parent company, unconsolidated subsidiaries				
and affiliates (Note 13)	2,280	2,309	27,805	
Total	44,919	47,549	547,793	
Income taxes payable	5,437	7,678	66,305	
Accrued expenses	40,163	34,312	489,793	
Other current liabilities	5,447	7,065	66,426	
Total current liabilities	105,966	157,204	1,292,268	
ONG-TERM LIABILITIES:				
Long-term debt (Note 8)	118,000	93,000	1,439,025	
Liability for retirement benefits (Note 10)	10,790	10,274	131,585	
Other liabilities (Notes 8 and 9)	5,427	5,407	66,183	
Total long-term liabilities	134,217	108,681	1,636,793	

#### NET ASSETS:

Shareholders' equity (Note 11)			
Common stock: authorized — 1,500,000,000 shares in the years ended March 31, 2012 and 2011; issued — 397,900,154 shares in the		00.400	
years ended March 31, 2012 and 2011	22,400	22,400	273,171
Capital surplus	15,860	15,860	193,415
Retained earnings	305,664	304,186	3,727,609
Treasury stock, at cost: 588,699 shares in the year ended			
March 31, 2012 and 587,168 shares in the year ended March 31, 2011	(649)	(649)	(7,915
Total shareholders' equity	343,275	341,797	4,186,280
Accumulated other comprehensive income (loss)			
Unrealized gains on available-for-sale securities, net of tax	8,016	5,414	97,756
Foreign currency translation adjustment	(32,064)	(23,228)	(391,024
Total accumulated other comprehensive income (loss)	(24,048)	(17,814)	(293,268
Total net assets	319,227	323,983	3,893,012
TOTAL	¥559,410	¥589,868	\$6,822,073

# **Consolidated Statements of Income**

Dainippon Sumitomo Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2012 and 2011

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2012	2011	2012
NET SALES (Notes 12 and 13)	¥ 350,396	¥379,513	\$4,273,122
COST OF SALES (Notes 12 and 13)	98,857	110,030	1,205,573
Gross profit	251,539	269,483	3,067,549
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Note 13)	231,137	238,531	2,818,744
Operating income	20,402	30,952	248,805
OTHER INCOME (EXPENSES):			
Interest and dividend income (Note 13)	1,025	1,248	12,500
Interest expense	(1,123)	(1,919)	(13,695)
Impairment loss (Note 2 (i))	(2,338)	(3,246)	(28,512)
Loss on valuation of investment securities (Note 6)	(224)	(320)	(2,732)
Gain on sales of property, plant and equipment	1,241	—	15,134
Restructuring (Note 16)	(1,224)	—	(14,927)
Other — net	(1,431)	(1,665)	(17,451)
Other income (expenses) — net	(4,074)	(5,902)	(49,683)
INCOME BEFORE INCOME TAXES	16,328	25,050	199,122
INCOME TAXES (Note 9):			
Current	12,291	13,989	149,890
Deferred	(4,593)	(5,735)	(56,012)
Total income taxes	7,698	8,254	93,878
NET INCOME	¥ 8,630	¥ 16,796	\$ 105,244
	Y	/en	U.S. dollars (Note 1)
PER SHARE OF COMMON STOCK:			
Basic net income	¥ 21.72	¥ 42.27	\$0.26
Cash dividends applicable to the year	18.00	18.00	0.22

See Notes to Consolidated Financial Statements.

# **Consolidated Statements of Comprehensive Income (Loss)**

Dainippon Sumitomo Pharma Co., Ltd. and Consolidated Subsidiaries		Thousands of	
Years Ended March 31, 2012 and 2011	Millions	U.S. dollars (Note 1)	
	2012	2011	2012
Net Income	¥ 8,630	¥ 16,796	\$ 105,244
Other comprehensive income (loss)			
Unrealized gains (losses) on available-for-sale securities, net of tax (Note 17)	2,602	(2,532)	31,732
Foreign currency translation adjustment (Note 17)	(8,836)	(26,330)	(107,756)
Total other comprehensive income (loss) (Note 17)	(6,234)	(28,862)	(76,024)
Comprehensive income (loss)	2,396	(12,066)	29,220
Comprehensive income (loss) attributable to			
Comprehensive income (loss) attributable to owners of the parent	2,396	(12,066)	29,220
Comprehensive income (loss) attributable to minority interests	_	_	_

# **Consolidated Statements of Changes in Net Assets** Dainippon Sumitomo Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2012 and 2011

	Thousands	s of shares					Millions of ye	en			
-		_		S	nareholders' eq	uity			cumulated o		
	lssued number of shares of common stock	Number of treasury stocks	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	Unrealized gains (losses) on available-for-sale securities	Foreign currency translation adjustments	Total accumulated other comprehensive income (loss)	e Total net assets
BALANCE, APRIL 1, 2010	397,900	(585)	¥22,400	¥15,860	¥294,702	¥(647)	¥332,315	¥7,945	¥ 3,223	¥ 11,168	¥343,483
Cash dividends, ¥18.00 per share					(7,152)		(7,152)				(7,152)
Net income					16,796		16,796				16,796
Purchases of treasury stock		(2)				(2)	(2)				(2)
Sales of treasury stock		0			(0)	0	0				0
Change in scope of consolidation	1				(160)		(160)		(120)	(120)	(280)
Net change in items other than shareholders' equity								(2,531)	(26,331)	(28,862)	(28,862)
BALANCE, APRIL 1, 2011	397,900	(587)	¥22,400	¥15,860	¥304,186	¥(649)	¥341,797	¥ 5,414	¥(23,228)	¥(17,814)	¥323,983
Cash dividends, ¥18.00 per share					(7,152)		(7,152)				(7,152)
Net income					8,630		8,630				8,630
Purchases of treasury stock		(2)				(0)	(0)				(0)
Sales of treasury stock		0			(0)	0	0				0
Net change in items other than shareholders' equity								2,602	(8,836)	(6,234)	(6,234)
BALANCE, MARCH 31, 2012	397,900	(589)	¥22,400	¥15,860	¥305,664	¥(649)	¥343,275	¥ 8,016	¥(32,064)	¥(24,048)	¥319,227

		Thousands of U.S. dollars (Note 1)							
		Shareholders' equity				Accumulated other comprehensive income (loss)			
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	Unrealized gains (losses) on available-for-sale securities	Foreign currency translation adjustments	Total accumulated other comprehensive income (loss)	e Total net
BALANCE, APRIL 1, 2011	\$273,171	\$193,415	\$3,709,585	\$(7,915)	\$4,168,256	\$66,024	\$(283,268)	\$(217,244)	\$3,951,012
Cash dividends, U.S.\$0.22 per share			(87,220)		(87,220)				(87,220)
Net income			105,244		105,244				105,244
Purchases of treasury stock				(0)	(0)				(0)
Sales of treasury stock			(0)	0	0				0
Net change in items other than shareholders' equity						31,732	(107,756)	(76,024)	(76,024)
BALANCE, MARCH 31, 2012	\$273,171	\$193,415	\$3,727,609	\$(7,915)	\$4,186,280	\$97,756	\$(391,024)	\$(293,268)	\$3.893.012

# **Consolidated Statements of Cash Flows**

Dainippon Sumitomo Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2012 and 2011

	Million	ns of yen	Thousands of U.S. dollars (Note -
	2012	2011	2012
DPERATING ACTIVITIES:			
Income before income taxes	¥ 16,328	¥ 25,050	\$ 199,122
Adjustments for:			
Depreciation and amortization	36,468	40,591	444,732
Impairment loss	2,338	3,246	28,512
Amortization of goodwill	3,764	4,037	45,902
Provision for liability for retirement benefits, less payments	(130)	369	(1,585)
Interest and dividend income	(1,025)	(1,248)	(12,500)
Interest expense	1,123	1,919	13,695
Loss on valuation of investment securities	224	320	2,732
Restructuring	1,224	—	14,927
Changes in assets and liabilities:			
Increase (decrease) in receivables	5,824	(15,175)	71,024
Decrease (increase) in inventories	(2,585)	8,161	(31,524)
Increase (decrease) in payables	(2,490)	2,296	(30,366)
Other — net	1,570	766	19,146
Subtotal	62,633	70,332	763,817
Interest and dividend received	1,349	1,578	16,451
Interest paid	(1,106)	(1,925)	(13,488)
Income taxes paid	(14,493)	(14,943)	(176,743)
Net cash provided by operating activities	48,383	55,042	590,037
NVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(6,715)	(7,134)	(81,890)
Purchases of intangible assets	(2,136)	(2,012)	(26,049)
Proceeds from sales of property, plant and equipment	1,945		23,720
Proceeds from sales of intangible assets	_	1,097	
Net decrease in marketable securities	5,348	(714)	65,220
Proceeds from sales of investment securities	363	3,581	4,427
Purchases of investment securities	(3,203)	(2,524)	(39,061)
Proceeds from redemption of investment securities	47	1,624	573
Other – net	(22)	(486)	(269)
Net cash used in investing activities	(4,373)	(6,568)	(53,329)
INANCING ACTIVITIES:			
Net decrease in short-term bank loans	(50,000)	(115,500)	(609,756)
Proceeds from issuance of bonds	19,895	49,763	242,622
Redemption of bonds	_	(74)	_
Proceeds from long-term debt	15,000	58,000	182,927
Repayment of long-term debt	(10,600)	(5,300)	(129,268)
Increase in treasury stock	(1)	(2)	(12)
Dividends paid	(7,149)	(7,149)	(87,183)
Other – net	(68)	(73)	(830)
Net cash used in financing activities	(32,923)	(20,335)	(401,500)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(1,776)	(3,797)	(21,659)
NET DECREASE IN CASH AND CASH EQUIVALENTS	9,311	24,342	113,549
NCREASE IN CASH AND CASH EQUIVALENTS RELATED	0,011		110,049
TO CHANGE IN SCOPE OF CONSOLIDATION		386	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	82,868	58,140	1,010,585
CASH AND CASH EQUIVALENTS, END OF YEAR	¥ 92,179	¥ 82,868	\$1,124,134

# **Notes to Consolidated Financial Statements**

Dainippon Sumitomo Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2012 and 2011

#### 1. BASIS OF PRESENTING CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Financial Instruments and Exchange Law and its related accounting regulations and in conformity with accounting principles generally accepted in Japan, which are different in certain respects as to application and disclosure requirements from International Financial Reporting Standards.

The accounts of consolidated subsidiaries in U.S. are prepared in accordance with U.S. generally accepted accounting principles, with adjustments for the specified five items as applicable according to Practical Issues Task Force No. 18 "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements".

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

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Dainippon Sumitomo Pharma 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 translated at the rate of ¥82 to U.S.\$1.00, the approximate rate of exchange at March 31, 2012. These 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.

The Company and its consolidated subsidiaries (together, the "Group") have made certain reclassifications in the 2011 consolidated financial statements to conform to the classifications applied in 2012. These reclassifications have had no effect on the previously reported net income or retained earnings.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### a. Consolidation

The consolidated financial statements include the accounts of the Company and its 13 significant subsidiaries. Under the control or influence concept, those companies in which the Company directly or indirectly is able to exercise control over operations are consolidated, and those companies over which the Group has the ability to exercise significant influence are accounted for by the equity method.

Investments in the unconsolidated subsidiaries and all affiliates are stated at cost. If the equity method of accounting had been applied to the investments in these companies, the effect on the accompanying consolidated financial statements would not have been material.

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

There are 10 consolidated overseas subsidiaries. The fiscal year ends of all 10 companies are December 31. The Company uses the consolidated subsidiaries' financial statements as of December 31 to prepare the consolidated financial statements. For significant transactions which have occurred during the period between December 31 and March 31, necessary adjustments have been made to the consolidated financial statements.

#### b. Cash Equivalents

Cash equivalents are short-term investments that are readily convertible into cash and have no significant risk of change in value. Cash equivalents include time deposits, certificates of deposit, commercial paper and bond funds, all of which mature 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 are expected to be held to maturity with 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 either trading securities or held-to-maturity debt securities, are reported at fair value with unrealized gains and losses net of applicable taxes reported in a separate component of net assets. Non marketable available-for-sale securities are stated at cost, determined by the moving average method. If the fair value of investment securities declines to below cost and the decline is material and other than temporary, the carrying value is reduced to net realizable value by a charge to income.

#### d. Inventories

Inventories are stated at the lower of weighted-average cost or net realizable value. Certain overseas consolidated subsidiaries use the FIFO (first-in, first-out) costing method. Book values have been calculated using the lower of cost or net realizable value.

#### e. Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation of buildings is computed by the straight-line method over the estimated useful life of the asset. Depreciation of machinery and equipment is computed by the declining balance method over the estimated useful life of the asset. At the overseas consolidated subsidiaries, depreciation of all tangible fixed assets is computed by the straight-line method. Ranges of useful lives used in the computation of depreciation are as follows:

Buildings and structures 3–60 years Machinery and equipment 2–17 years

#### f. Intangible Assets

Intangible assets are stated at cost less accumulated amortization, which is computed by the straight-line method. Ranges of useful lives used in the computation of depreciation are as follows:

Patent rights: 1 to 10 years

#### g. Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net assets of businesses acquired and is amortized using the straight-line method over 20 years.

#### h. Leases

Finance leases are to be capitalized, except for finance leases that commenced prior to April 1, 2008 and do not transfer the ownership of the leased property to the lessee.

Capitalized finance leases are depreciated by the straight-line method in which the lease period is taken as the useful life and the residual value is zero.

#### i. Long-Lived Assets

Long-lived assets presented as property, plant and equipment, and intangible assets on the consolidated balance sheets are carried at cost less depreciation and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount 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 is measured as the result from the continued use and eventual disposition of the asset or the net selling price at disposition. The impairment loss that the Group recognized and charged to income for the year ended March 31, 2012 was ¥2,338 million for intangible assets, and for the year ended March 31, 2011 was ¥1,067 million for property, plant and equipment and ¥2,179 million for intangible assets.

#### j. Retirement and Severance Benefits

Upon retirement or termination of employment, employees are normally entitled to lump-sum and/or annuity payments based on their rate of payment at the time of retirement or termination and length of service.

The Group has a lump-sum plan, a defined benefit pension plan and a defined contribution plan for employees. The liability for retirement benefit is provided based on projected benefit obligations and the fair value of plan assets at the balance sheet date.

#### k. Research and Development Costs

Research and development costs are charged to income as incurred. Research and development costs included in selling, general and administrative expenses for the years ended March 31, 2012 and 2011 were ¥56,891 million (\$693,793 thousand) and ¥68,160 million, respectively.

#### I. Income Taxes

The provision for income taxes is computed based on the pre-tax income included in the consolidated statements of income. The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred tax assets and liabilities are measured by using currently enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

#### m. Foreign Currency Items

All short-term and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates prevailing at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the statements of income.

Financial statements of overseas subsidiaries are translated into Japanese yen at the year-end rate for all assets and liabilities and at weighted average rates for income and expense accounts. Differences arising from such translation are shown as "Foreign currency translation adjustments" in a component of net assets.

#### n. Derivative Financial Instruments

Foreign exchange contracts are utilized to hedge the exposure risk arising from fluctuations in foreign exchange rates. Derivative instruments are stated at fair value and accounted for using deferred hedge accounting. Recognition of gain or loss resulting from a change in fair value of a derivative financial instrument is deferred until the related loss or gain on the hedged item is recognized if the derivative financial instrument is used as a hedge and meets certain hedging criteria. Foreign exchange contracts that meet certain hedging criteria are accounted for under the allocation method. The allocation method requires recognized foreign currency receivables and payables to be translated using the corresponding foreign exchange contract rates. The Group has established a hedging policy which includes policies and procedures for risk assessment and for the approval, reporting and monitoring of derivatives transactions. The Group does not hold or issue derivative financial instruments for speculative trading purposes.

The Group is exposed to certain market risk arising from its forward foreign exchange contracts. The Group is also exposed to the risk of credit loss in the event of non-performance by the counterparties to its currency contracts. However, the Group does not anticipate non-performance by any of these counterparties as all are financial institutions with high credit ratings.

#### o. Per Share Information

Basic net income per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding for the period, retroactively adjusted for stock splits. The number of shares used in the calculation of net income per share was 397,312 thousand and 397,314 thousand for the years ended March 31, 2012 and 2011, respectively.

Cash dividends per share presented in the accompanying consolidated statements of income are dividends applicable to the respective years including dividends to be paid after the end of the year.

#### p. Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in Japan requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

#### q. Additional Information

#### Adoption of "Accounting Standard for Accounting Changes and Error Corrections"

The Company and its consolidated domestic subsidiaries adopted the "Accounting Standard for Accounting Changes and Error Corrections" (Accounting Standards Board of Japan ("ASBJ") Statement No. 24 issued on December 4, 2009) and the "Guidance on Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Guidance No. 24, issued on December 4, 2009) for accounting changes and corrections of prior period errors which are made from the fiscal year beginning on April 1, 2011.

#### 3. CASH AND CASH EQUIVALENTS

Cash and cash equivalents at March 31, 2012 and 2011 for purposes of the consolidated statements of cash flows consisted of the following:

	Million	s of yen	Thousands of U.S. dollars
	2012	2011	2012
Cash and time deposits	¥12,953	¥14,939	\$ 157,963
Marketable securities with a maturity of three months or			
less when purchased	79,226	67,929	966,171
Cash and cash equivalents	¥92,179	¥82,868	\$1,124,134

#### 4. INVENTORIES

Inventories at March 31, 2012 and 2011 consisted of the following:

	Millior	is of yen	Thousands of U.S. dollars
	2012	2011	2012
Finished goods and semi-finished goods	¥42,481	¥38,443	\$518,061
Work-in-process	2,591	2,388	31,597
Raw materials and supplies	13,046	15,141	159,098
Total	¥58,118	¥55,972	\$708,756

#### 5. FINANCIAL INSTRUMENTS

#### 1) Policies for using financial instruments

The Group procures funds through bank loans and the issuance of corporate bonds that are required for investment plans and other purposes in order to carry out business inside and outside of Japan. Temporary surplus funds are to be invested only in safe financial instruments for which there is a low probability of losses of invested capital. Derivative transactions are used only to avoid the risks described below, and speculative transactions are not undertaken.

#### 2) Details of financial instruments and risks, policies and systems for risk management

In order to reduce the credit risks of notes and accounts receivable associated with customers, due dates and amounts outstanding are managed for each customer in accordance with the standards pertaining to the management of loans as determined by each Group Company. In addition, a system to regularly obtain and review the credit standing of major clients has been adopted.

Marketable securities and investment securities consist primarily of negotiable certificates for deposit, bonds held to maturity and stocks. Among them, bonds held to maturity and stocks are exposed to risks associated with changes in market prices. The market values of the securities and the financial standing of the issuers of these investments are regularly monitored. The shareholding status is also reviewed continuously, and relationships with the client companies are taken into account. In addition, bonds held to maturity consist of only highly rated bonds, pursuant to the Group regulations for the management of funds to minimize credit risks.

Payables such as trade notes and trade accounts payable are all due within one year. As some of these payables consist of notes and accounts payable that are denominated in foreign currencies due to the import of raw materials, they are exposed to risks of fluctuations in exchange rates. When significant, these risks are hedged using foreign exchange forward contracts.

Almost all income taxes payable are due within two months.

Trade accounts payable, loans payable and bonds are exposed to liquidity risks. The risks are managed within the Group by producing cash flow plans on a monthly basis.

Derivative financial instruments of the Group include forward exchange contracts for the purpose of hedging risks of fluctuations in exchange rates of receivables and payables denominated in foreign currencies. With respect to forward exchange contracts, the Finance & Accounting Division formulates an implementation plan for hedging foreign currency risks every half year pursuant to the regulations for management of foreign currency risks and upon reporting to the Board of Directors, executes transactions and posts the applicable entries. The results of derivative transactions are also reported to the Board of Directors. See "Derivative Financial Instruments" as stated in the above "Summary of Significant Accounting Policies" for information on hedging instruments, hedged items, hedging policy, and the method by which the effectiveness of hedging is evaluated, as they relate to hedge accounting.

#### 3) Supplemental information on market values

In addition to value based on quoted market prices, the market value of financial instruments includes fair value which is determined by using valuation techniques. Since certain assumptions are considered in the calculation of such amounts, the adoption of different assumptions may cause prices to vary.

Book values and market values of the financial instruments on the consolidated balance sheet at March 31, 2012 and 2011 were as follows:

	Millions of yen			
	2012			
	Book values	Market values	Difference	
(1) Cash and time deposits	¥ 12,953	¥ 12,953	¥ —	
(2) Trade notes	2,971	2,971	_	
(3) Trade accounts	99,653	99,653	_	
(4) Due from parent company, unconsolidated subsidiaries and affiliates	25,050	25,050	-	
(5) Marketable securities and investment securities	125,872	125,872	-	
Total assets	¥266,499	¥266,499	¥ —	
(1) Short-term bank loans	_	-	-	
(2) Trade notes	151	151	_	
(3) Trade accounts	42,488	42,488	_	
(4) Due to parent company, unconsolidated subsidiaries and affiliates	2,280	2,280	_	
(5) Income taxes payable	5,437	5,437	_	
(6) Bonds payable	70,000	70,791	791	
(7) Long-term debt (*)	58,000	58,032	32	
Total liabilities	¥178,356	¥179,179	¥ 823	
Derivative transactions	¥ –	¥ —	¥ —	

(\*) Long-term debt includes the amount of current portion of long-term debt.

	Millions of yen			
	Book values	Market values	Difference	
(1) Cash and time deposits	¥ 14,939	¥ 14,939	¥ —	
(2) Trade notes	2,811	2,811	_	
(3) Trade accounts	106,437	106,437	_	
(4) Due from parent company, unconsolidated subsidiaries and affiliates	25,101	25,101	_	
(5) Marketable securities and investment securities	115,609	115,616	7	
Total assets	¥264,897	¥264,904	¥ 7	
(1) Short-term bank loans	50,000	50,000	—	
(2) Trade notes	193	193	_	
(3) Trade accounts	45,047	45,047	_	
(4) Due to parent company, unconsolidated subsidiaries and affiliates	2,309	2,309	_	
(5) Income taxes payable	7,678	7,678	_	
(6) Bonds payable	50,000	50,002	2	
(7) Long-term debt (*)	53,600	53,422	(178)	
Total liabilities	¥208,827	¥208,651	¥(176)	
Derivative transactions	¥ —	¥ —	¥ —	

(\*) Long-term debt includes the amount of current portion of long-term debt.

	Thousands of U.S. dollars			
	2012			
	Book values	Market values	Difference	
(1) Cash and time deposits	\$ 157,963	\$ 157,963	\$ -	
(2) Trade notes	36,232	36,232	_	
(3) Trade accounts	1,215,280	1,215,280	_	
(4) Due from parent company, unconsolidated subsidiaries and affiliates	305,488	305,488	_	
(5) Marketable securities and investment securities	1,535,025	1,535,025	_	
Total assets	\$3,249,988	\$3,249,988	\$ —	
(1) Short-term bank loans	_	_	-	
(2) Trade notes	1,841	1,841	_	
(3) Trade accounts	518,147	518,147	_	
(4) Due to parent company, unconsolidated subsidiaries and affiliates	27,805	27,805	_	
(5) Income taxes payable	66,305	66,305	_	
(6) Bonds payable	853,659	863,305	9,646	
(7) Long-term debt (*)	707,317	707,707	390	
Total liabilities	\$2,175,074	\$2,185,110	\$10,036	
Derivative transactions	\$ —	\$ —	\$ —	

(\*) Long-term debt includes the amount of current portion of long-term debt.

(Note 1) Basis of determining fair value of financial instruments, and matters pertaining to securities and derivative transactions

Assets

(1) Cash and time deposits

As all time deposits are short-term deposits, fair value is approximately equal to book value and is calculated according to the applicable book value. (2) Trade notes, (3) Trade accounts, (4) Due from parent company, unconsolidated subsidiaries and affiliates

As these assets are settled on a short-term basis, fair value is approximately equal to book value and is calculated according to the applicable book value. (5) Marketable securities and investment securities

The fair value of these assets is calculated according to the guoted market price for shares and the price indicated by the applicable financial trading institution for bonds. As negotiable certificates of deposit are settled on a short-term basis, fair value is approximately equal to book value and is calculated according to the applicable book value. See Note 2 (c), "Summary of Significant Accounting Policies — Marketable and Investment Securities" for notes pertaining to securities according to the purpose for which they are held.

Liabilities

(1) Short-term bank loans, (2) Trade notes, (3) Trade accounts, (4) Due to parent company, unconsolidated subsidiaries and affiliates, (5) Income taxes payable As these liabilities are settled on a short-term basis, fair value is approximately equal to book value and is calculated according to the applicable book value. (6) Bonds payable

The fair value of corporate bonds is calculated according to market price.

(7) Long-term debt

The fair value of long-term debt is calculated as the present value of the total sum of principal and interest discounted by an assumed rate that would have been applicable had a new identical loan been undertaken. Derivative transactions

See notes on "Derivative Transactions".

(Note 2) Financial instruments for which the ascertainment of a fair value is deemed to be exceedingly difficult and are not included in "(5) Marketable and investment securities" are as follows:

	A	mount on consolidated ba	alance sheet
	N	fillions of yen	Thousands of U.S. dollars
	2012	2011	2012
Unlisted shares	¥ 479	¥ 486	\$ 5,841
Investment in unconsolidated subsidiaries and affiliates	973	973	11,866
Investment in limited partnership	1,850	1,977	22,561

The fair value of unlisted shares and investment in unconsolidated subsidiaries and affiliates is not disclosed given the unavailability of quoted market prices because they are deemed to be exceedingly difficult to ascertain.

The fair value of investment in limited partnerships is not disclosed as their assets consist of those deemed to be exceedingly difficult to ascertain, such as unlisted shares.

(Note 3) Scheduled redemption amounts after March 31, 2012 for monetary claims and securities with period of maturity

	Millions of yen					
	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years		
Cash and time deposits	¥ 12,953	¥ —	¥—	¥ —		
Trade notes	2,971	_	_	_		
Trade accounts	99,653	_	_	_		
Due from parent company, unconsolidated subsidiaries and affiliates	25,050	_	_	_		
Marketable securities and investment securities:						
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)	45,900	_	_	_		
Available-for-sale securities with terms of maturity (Bonds)	19,892	81	_	40		
Total	¥206,419	¥81	¥—	¥40		
	Thousands of U.S. dollars					
	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years		
Cash and time deposits	\$ 157,963	\$ -	\$ -	\$ -		
Trade notes	36,232	_	_	_		
Trade accounts	1,215,280	_	_	_		
Due from parent company, unconsolidated subsidiaries and affiliates	305,488	_	_	_		
Marketable securities and investment securities:						
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)	559,756	_	_	_		
Available-for-sale securities with terms of maturity (Bonds)	242,585	988	_	488		
Total	\$2,517,304	\$988	\$-	\$488		

#### 6. MARKETABLE SECURITIES AND INVESTMENT SECURITIES

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

	Millions of yen		Thousands of U.S. dollars	
	2012	2011	2012	
Current:				
Government / local government bonds	¥ 2,721	¥ 2,173	\$ 33,183	
Corporate bonds	17,171	15,158	209,402	
Negotiable certificates of deposits	45,900	40,500	559,756	
MMF	33,326	27,430	406,415	
Trust fund investments and other	-	5,660	_	
Total	¥99,118	¥90,921	\$1,208,756	
Noncurrent:				
Equity securities	¥26,633	¥23,815	\$ 324,793	
Government and corporate bonds	81	821	988	
Trust fund investments and other	2,369	2,514	28,890	
Total	¥29,083	¥27,150	\$ 354,671	

The carrying amount and aggregate fair value of marketable securities and investment securities at March 31, 2012 and 2011 were as follows:

		Millions of yen					
	Cost	Unrealized gains	Unrealized losses	Fair value			
Securities classified as:							
Available-for-sale:							
Equity securities	¥14,402	¥12,349	¥(118)	¥26,633			
Bonds and debentures	20,133	3	(163)	19,973			
Other securities	26	14	(0)	40			
Held-to-maturity	-	-	-	_			
		Millions of yen					
			)11	Faircrahas			
	Cost	Unrealized gains	Unrealized losses	Fair value			
Securities classified as:							
Available-for-sale:							
Equity securities	¥14,783	¥9,732	¥(700)	¥23,815			
Bonds and debentures	16,397	10	(251)	16,156			
Other securities	5,594	118	(O)	5,712			
Held-to-maturity	1,997	8	(1)	2,004			
		Thousands of U.S. dollars					
	Cost	2012 Cost Unrealized gains Unrealized losses Fair value					
Securities classified as:	COSI	Unrealized gains	Unrealized losses	Fail Value			
Available-for-sale:							
Equity securities	\$175,634	\$150,599	\$(1,439)	\$324,793			
Bonds and debentures	245,524	37	(1,988)	243,573			
Other securities	317	171	(0)	488			
Held-to-maturity	_	_	_	_			

The Company recognized ¥224 million (\$2,732 thousand) and ¥320 million as impairment losses of equity securities in available-for-sale securities with determinable market value in the years ended at March 31, 2012 and 2011 respectively.

Proceeds from sales of available-for-sale securities were ¥39,812 million (\$485,512 thousand) and ¥11,401 million for the years ended March 31, 2012 and 2011 respectively. On those sales, gross realized gains and losses computed on a moving average cost basis were ¥118 million (\$1,439 thousand) and ¥1 million (\$12 thousand) respectively for the year ended March 31, 2012, and ¥32 million and ¥12 million respectively for the year ended March 31, 2011.

At March 31, 2012, investment securities of ¥51 million (\$622 thousand) were pledged as collateral for accounts payable of ¥206 million (\$2,512 thousand). At March 31, 2011, investment securities of ¥60 million were pledged as collateral for accounts payable of ¥168 million.

#### 7. DERIVATIVE TRANSACTIONS

Derivative transactions as of March 31, 2012 and 2011 were as follows:

Currency related

2012								
Hedge accounting method	Transaction type	Main hedged items	Cont	ract amount	Portio	n over 1 year	Ma	arket value
Appropriation of	Foreign exchange		Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars
foreign exchange forward contracts	contracts Sell contracts USD Buy contracts	Trade accounts receivable Trade accounts	¥13	\$158	-	_	(*)	(*)
USD EUR	ÚSD	SD payable	¥66 47	\$805 573	Ξ	Ξ	(*) (*)	(*) (*)
2011								
Hedge accounting method	Transaction type	Main hedged items	Cont	ract amount	Portio	n over 1 year	Ma	arket value
Appropriation of foreign exchange	Foreign exchange contracts	-	Milli	ons of yen	Milli	ons of yen	Mill	ions of yen
forward contracts	Buy contracts USD EUR	Trade accounts payable		¥116 37		_		(*) (*)
	GBP			4		—		(*)

(\*) As forward exchange contracts subject to appropriation are processed in an integrated manner together with the hedged trade accounts receivable and payable, the fair value of the forward exchange contract is included in the fair value of the applicable trade accounts payable items and stated accordingly.

#### 8. SHORT-TERM BANK LOANS AND LONG-TERM DEBT

Short-term bank loans consisted of unsecured loans from banks bearing interest at a rate of 0.75% at March 31, 2011. Other liabilities include deposits received from customers in the amount of ¥3,348 million (\$40,829 thousand) as of March 31, 2012, bearing interest at a rate of 1.52%, and ¥3,296 million as of March 31, 2011, bearing interest at a rate of 1.52%.

Long-term debt at March 31, 2012 and 2011 was as follows:

Long-term debt at March 31, 2012 and 2011 was as follows:	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Unsecured loans from banks and financial institutions, due 2012 to 2018 with average interest rate of 0.69%	¥ 58,000	¥ 53,600	\$ 707,318
Unsecured bonds due 2014 with average interest rate of 0.53%	10,000	10,000	121,951
Unsecured bonds due 2016 with average interest rate of 0.78%	30,000	30,000	365,854
Unsecured bonds due 2016 with average interest rate of 0.54%	10,000	_	121,951
Unsecured bonds due 2018 with average interest rate of 1.11%	10,000	10,000	121,951
Unsecured bonds due 2018 with average interest rate of 0.82%	10,000	_	121,951
Total	¥128,000	¥103,600	\$1,560,976
Less current portion	(10,000)	(10,600)	(121,951)
Long-term debt, less current portion	¥118,000	¥ 93,000	\$1,439,025

The aggregate annual maturities of long-term debt were as follows:

Year ending March 31	Millions of yen	Thousands of U.S. dollars
2013	¥ 10,000	\$ 121,951
2014	20,000	243,903
2015	10,000	121,951
2016	35,000	426,829
2017 and thereafter	53,000	646,342
Total	¥128,000	\$1,560,976
#### 9. INCOME TAXES

The Group is subject to Japanese national and local income taxes which, in the aggregate, resulted in a normal effective statutory tax rate of approximately 40.6% for the years ended March 31, 2012 and 2011.

Significant components of deferred tax assets and liabilities as of March 31, 2012 and 2011 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Deferred tax assets:			
Liability for retirement benefits	¥ 2,592	¥ 3,015	\$ 31,610
Accrued enterprise taxes	516	782	6,293
Accrued bonuses to employees	2,821	2,974	34,402
Reserve for sales rebates	7,200	5,881	87,805
Loss on devaluation of investment securities	601	595	7,329
Research and development costs	10,380	11,093	126,585
Inventories	2,163	2,660	26,378
Net operating loss carried forward	8,830	13,252	107,683
Amortization of intangible assets	9,543	10,909	116,378
Tax credit for R&D expenses of overseas subsidiaries	10,113	7,968	123,329
Other	11,404	14,438	139,074
Gross deferred tax assets	66,163	73,567	806,866
Valuation allowance	(4,005)	(4,307)	(48,842)
Total deferred tax assets	¥ 62,158	¥69,260	\$ 758,024
Deferred tax liabilities:			
Unrealized gains on available-for-sale securities	¥ (4,236)	¥ (3,588)	\$ (51,659)
Deferred gain on sales of fixed assets	(883)	(632)	(10,768)
Tax effect of intangible assets related to business combination	(13,962)	(24,923)	(170,268)
Total deferred tax liabilities	¥(19,081)	¥(29,143)	\$(232,695)
Net deferred tax assets	¥ 43,077	¥ 40,117	\$ 525,329

A reconciliation between the normal statutory tax rates and the effective tax rates reflected in the accompanying consolidated statements of income for the years ended March 31, 2012 and 2011 was as follows:

2012	2011
40.6%	40.6%
11.4	6.5
(2.6)	(0.8)
(23.2)	(17.5)
9.4	6.6
(0.1)	(2.6)
10.9	_
0.7	0.2
47.1%	33.0%
	40.6% 11.4 (2.6) (23.2) 9.4 (0.1) 10.9 0.7

On December 2, 2011, amendments to the Japanese tax regulations were enacted into law. As a result of these amendments, the statutory income tax rate for the Company will be reduced to 38.0% for years beginning on or after April 1, 2012 and 35.9% for years beginning on or after April 1, 2015. Based on the amendments, the statutory income tax rates utilized for the measurement of deferred tax assets and liabilities expected to be settled or realized from April 1, 2012 to March 31, 2015 and on or after April 1, 2015 are 38.0% and 35.9% respectively as of March 31, 2012. Due to these changes in statutory income tax rates, net deferred tax assets decreased by ¥1,181 million and unrealized gains on available-for-sale securities increased by ¥601 million as of March 31, 2012 and deferred income tax expense recognized for the year ended March 31, 2012 increased by ¥1,783 million.

#### **10. RETIREMENT AND SEVERANCE BENEFITS**

The liability (asset) for employees' retirement benefits at March 31, 2012 and 2011 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Projected benefit obligation	¥ 81,097	¥ 80,179	\$ 988,988
Fair value of plan assets	(67,106)	(65,379)	(818,366)
Unrecognized prior service benefit	757	976	9,232
Unrecognized actuarial gain (loss)	(7,471)	(8,369)	(91,110)
Prepaid pension cost	3,513	2,860	42,841
Liability for employees' retirement benefits	¥ 10,790	¥ 10,267	\$ 131,585

Certain consolidated subsidiaries have adopted a simplified calculation method for projected benefit obligation allowed for small business entities in Japan. The components of net periodic retirement benefit costs were as follows:

	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Service cost	¥ 3,108	¥ 3,210	\$ 37,902
Interest cost	1,596	1,628	19,463
Expected return on plan assets	(1,232)	(1,235)	(15,024)
Amortization of prior service cost	(218)	(222)	(2,658)
Recognized actuarial loss	893	946	10,890
Net periodic benefit costs	¥ 4,147	¥ 4,327	\$ 50,573
Contribution payments to a defined contribution pension plan	2,199	2,604	26,817
Total	¥ 6,346	¥ 6,931	\$ 77,390

The Company has a lump-sum payment plan, a non-contributory defined benefit pension plan and a defined contribution pension plan.

The liability for retirement benefits for directors and corporate auditors in the consolidated subsidiaries as of March 31, 2011 was ¥7 million.

Assumptions used for the years ended March 31, 2012 and 2011 were as follows:

	2012	2011
Method of attributing benefits to periods of service	straight-line basis	straight-line basis
Discount rate	2.0%	2.0%
Expected rate of return on plan assets	2.0%	2.0%
Amortization period for prior service cost	15 years	15 years
Recognition period for actuarial gain/loss	15 years	15 years

#### **11. SHAREHOLDERS' EQUITY**

Under The Japanese Corporate Law ("the Law") and regulations, the entire amount paid for new shares is required to be designated as common stock. However, a company may, by a resolution of the Board of Directors, designate an amount not exceeding one half of the price of the new shares as additional paid-in capital, which is included in capital surplus.

Under the Law, in cases where a dividend distribution of surplus is made, the smaller of an amount equal to 10% of the dividend or the excess, if any, of 25% of common stock over the total of additional paid-in capital and legal reserve must be set aside as additional paid-in capital or legal reserve. Legal reserve is included in retained earnings in the accompanying consolidated balance sheets.

Under the Japanese Commercial Code, legal reserve and additional paid-in capital could be used to eliminate or reduce a deficit by a resolution of the shareholders' meeting or could be capitalized by a resolution of the Board of Directors. Under the Law, both of these appropriations generally require a resolution of the shareholders' meeting.

Additional paid-in capital and legal reserve may not be distributed as dividends, but may be transferred to other capital surplus and retained earnings respectively which are potentially available for dividends.

The maximum amount that the Company can distribute as dividends is calculated based on the unconsolidated financial statements of the Company in accordance with Japanese laws and regulations.

At the annual shareholders' meeting held on June 22, 2012, the shareholders approved year end cash dividends of ¥9.00 (\$0.11) per share, amounting to ¥3,576 million (\$43,610 thousand). These appropriations have not been accrued in the consolidated financial statements as of March 31, 2012. Such appropriations are recognized in the period in which they are approved by the shareholders.

#### 12. TRANSACTIONS WITH PARENT COMPANY, UNCONSOLIDATED SUBSIDIARIES AND AFFILIATES

Transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., unconsolidated subsidiaries and affiliates for the years ended March 31, 2012 and 2011 were as follows:

	Milli	ons of yen	Thousands of U.S. dollars
	2012	2011	2012
Sales	¥ 149	¥ 205	\$ 1,817
Purchases	8,485	8,104	103,476

#### **13. RELATED PARTY TRANSACTIONS**

Major transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., for the years ended March 31, 2012 and 2011 were as follows:

				Thou	sands of
	Milli	Millions of yen			
	2012		2011		012
Sales of products	¥ 8	¥	8	\$	98
Purchases of products	4,971	<b>4,971</b> 4,		60,622	
Payment of other expenses	1,195	1	1,244		4,573
Sales of other assets	1		2		12
Loan	25,000	25	,000	30	4,878
Interest income	85		96		1,037

The balances due to or from the parent company, Sumitomo Chemical Co., Ltd., at March 31, 2012 and 2011 were as follows:

		Millions of yen			Thousands of U.S. dollars	
	201:	2012		2011		012
Trade receivable accounts	¥	6	¥	3	\$	73
Other current assets	25,0	00	25,000		30	4,878
Trade payable accounts	1,5	06	1	,662	1	8,366

#### 14. LEASES

The Group leases certain machinery, computer equipment, office space and other assets. Total rental expenses for the years ended March 31, 2012 and 2011 were ¥7,358 million (\$89,732 thousand) and ¥7,592 million respectively including ¥63 million (\$768 thousand) and ¥265 million of lease payments under finance leases.

Pro forma information for leased property including acquisition cost, accumulated depreciation, obligations under finance leases and depreciation expense for finance leases that do not transfer ownership of the leased property to the lessee on an "as if capitalized" basis for the years ended March 31, 2012 and 2011 was as follows:

	Millions of ven		Thousands of U.S. dollars
	2012	2011	2012
Machinery and equipment:			
Acquisition cost	¥ 239	¥ 597	\$ 2,915
Accumulated depreciation	(210)	(505)	(2,561)
Net leased property	¥ 29	¥ 92	\$ 354
			Thousands of
	Millions	of yen	U.S. dollars
	2012	2011	2012
Obligations under finance leases:			
Due within one year	¥27	¥63	\$329
Due after one year	2	29	25
Total	¥29	¥92	\$354

#### **15. SEGMENT INFORMATION**

#### 1) Outline of reportable segments

The Group's reportable segments are the components of the Group whose operating results are regularly reviewed by the board of directors to make decisions about resources to be allocated to the segment and assess their performance, and for which discrete financial information is available.

The Group assesses our pharmaceutical business performance by markets such as Japan, North America, China, and the like. The reportable segments of the Group consist of the following four segments: Japan, North America, China, Other regions.

From this consolidated fiscal year, in order to strengthen the market-specific performance management, such as Japan, North America, China, the classification of profit management within the Group has changed from the previous three [Japan (Pharmaceuticals), U.S., China] to four reportable segments [Japan, North America, China, Other Regions]. Because of this, results from overseas dealings that were included in the previous Japan (Pharmaceuticals) segment are now included in the North America, China and Other Regions segments. In addition, the businesses such as food ingredients, food additives, chemical product materials, veterinary drugs, diagnostics, and other products, are included in "Other Business".

Moreover, from this consolidated fiscal year, in order to manage R&D costs globally, they are not included in each segment. As a result, segment income is changed to the operating income before R&D costs from the past operating income.

#### 2) Method of calculating sales and income/loss, assets, liabilities and other items by reportable segments

Accounting method for business segment reporting is the same as presentation on "Significant Basic Items for Preparing Consolidated Financial Statements". Income by reportable segments is calculated based on operating income before R&D costs. Intersegment sales and transfers are calculated based on current market prices.

Assets and liabilities by reportable segment are not shown because they are not supplied to make decisions about resources to be allocated to the segment and assess their performance.

#### 3) Information on sales, income/loss, assets, liabilities and other items by reportable segment

Segment information for the Group for the years ended March 31, 2012 and 2011 was as follows:

	Millions of yen							
				2012				
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total	
Net sales								
Sales to customers	¥179,880	¥108,432	¥6,542	¥15,209	¥310,063	¥40,333	¥350,396	
Intersegment sales and transfers	201	_	_	_	201	84	285	
Total	180,081	108,432	6,542	15,209	310,264	40,417	350,681	
Income (loss) of segment	66,446	(324)	965	7,010	74,097	3,162	77,259	
Others								
Depreciation and amortization	6,029	25,324	362	698	32,413	153	32,566	
Amortization of goodwill		3,764	_	_	3,764		3,764	
Impairment loss	-	2,338	-	-	2,338		2,338	
Balance of goodwill	_	64,311	_	_	64,311	_	64,311	

Note: The "Other Business" category incorporates operations not included in reportable segments, including food ingredients, food additives, chemical product materials, veterinary drugs, diagnostics and other products.

				Millions of yer	I		
				2011			
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Net sales							
Sales to customers	¥182,860	¥117,647	¥5,688	¥28,392	¥334,587	¥44,926	¥379,513
Intersegment sales and transfers	188	_	_		188	57	245
Total	183,048	117,647	5,688	28,392	334,775	44,983	379,758
Income (loss) of segment	68,181	6,905	1,197	20,067	96,350	2,735	99,085
Others							
Depreciation and amortization	6,462	28,698	356	748	36,264	187	36,451
Amortization of goodwill	_	4,037	_		4,037	_	4,037
Impairment loss	1,067	2,179	_	_	3,246	_	3,246
Balance of goodwill	_	70,370	_	_	70,370	_	70,370

		Thousands of U.S. dollars							
				2012					
	Japan	North America	China	Other Regions	Subtotal	Other Business	s Total		
Net sales									
Sales to customers	\$2,193,659	\$1,322,341	\$79,780	\$185,476	\$3,781,256	\$491,866	\$4,273,122		
Intersegment sales and transfers	2,451	-	_	-	2,451	1,024	3,475		
Total	2,196,110	1,322,341	79,780	185,476	3,783,707	492,890	4,276,597		
Income (loss) of segment	810,317	(3,951)	11,768	85,488	903,622	38,561	942,183		
Others									
Depreciation and amortization	73,524	308,829	4,415	8,512	395,280	1,866	397,146		
Amortization of goodwill	-	45,902	-	-	45,902	-	45,902		
Impairment loss	-	28,512	-	-	28,152	-	28,152		
Balance of goodwill	-	784,280	_	-	784,280	_	784,280		

# 4) Reconciliation of differences between total of reportable segments and the amount on consolidated financial statements

Net sales	Million	is of yen	Thousands of U.S. dollars
	2012	2011	2012
Reportable segments total	¥310,264	¥334,775	\$3,783,707
Net sales of "Other Business" category	40,417	44,983	492,890
Elimination of intersegment transactions	(285)	(245)	(3,475)
Net sales on consolidated statements of income	¥350,396	¥379,513	\$4,273,122

Income	Millions of yen		Thousands of U.S. dollars
	2012	2011	2012
Reportable segments total	¥ 74,097	¥ 96,350	\$ 903,622
Income of "Other Business" category	3,162	2,735	38,561
Research and development costs	(56,891)	(68,159)	(693,792)
Elimination of intersegment transactions	34	26	414
Operating income on consolidated statements of income	¥ 20,402	¥ 30,952	\$ 248,805

#### 5) Relative information

Sales information by product or service for the Group for the years ended March 31, 2012 and 2011 was as follows:

Sales to customers	Millio	Millions of yen		
	2012	2011	2012	
Pharmaceuticals	¥310,063	¥334,587	\$3,781,256	
Other products	40,333	44,926	491,866	
Total	¥350,396	¥379,513	\$4,273,122	

Geographical segment information for the Group for the years ended March 31, 2012 and 2011 was as follows:

Net sales	Millior	Thousands of U.S. dollars	
	2012	2011	2012
Japan	¥220,153	¥227,287	\$2,684,793
U.S.	107,010	115,404	1,305,000
Other regions	23,233	36,822	283,329
Total	¥350,396	¥379,513	\$4,273,122

Property, plant and equipment	Millio	Millions of yen		
	2012	2011	2012	
Japan	¥59,293	¥62,132	\$723,085	
Other regions	7,404	7,662	90,293	
Total	¥66,697	¥69,794	\$813,378	

Sales information by major customer for the Group for the years ended March 31, 2012 and 2011 was as follows:

Net sales	Million	s of yen	Thousands of U.S. dollars
Name of major customer and related segment	2012	2011	2012
McKesson Corporation / North America	¥43,808	¥44,188	\$534,244
Alfresa Corporation / Japan	37,934	38,192	462,610
Mediceo Corporation / Japan	37,814	38,983	461,146

#### **16. RESTRUCTURING**

Restructuring was attributable to the review of the business structure in Sunovion.

#### **17. COMPREHENSIVE INCOME**

Amount of recycling and amount of income tax effect associated with other comprehensive income (loss) for the year ended March 31, 2012 was as follows:

		Thousands of
	Millions of yen	U.S. dollars
Unrealized gains on available-for-sale securities		
Amount recognized in the period under review	¥ 2,950	\$ 35,976
Amount of recycling	354	4,317
Before income tax effect adjustment	3,304	40,293
Amount of income tax effect	(702)	(8,561)
Unrealized gains on available-for-sale securities, net of tax	¥ 2,602	\$ 31,732
Foreign currency translation adjustment		
Amount recognized in the period under review	¥(8,836)	\$(107,756)
Foreign currency translation adjustment	(8,836)	(107,756)
Total other comprehensive income (loss)	¥(6,234)	\$ (76,024)

#### **18. CONTINGENT LIABILITIES**

Contingent liabilities for guarantees of indebtedness of an affiliate, and employees' housing loans guaranteed at March 31, 2012 were as follows:

		Thousands of
	Millions of yen	U.S. dollars
Guarantees of indebtedness	¥281	\$3,427
Loans guaranteed	167	2,037

#### **19. LITIGATION**

In April 2007, Dey, L.P. and Dey, Inc. (together, "Dey") filed a lawsuit in the U.S. District Court for the Southern District of New York against Sunovion, alleging that the manufacture and sale of BROVANA<sup>®</sup> Inhalation Solution infringes or will induce infringement of a single United States patent owned by Dey. Sunovion has been litigating this matter however, and in May 2012 reached agreements to settle this litigation.

#### 20. SUBSEQUENT EVENTS

#### Acquisition of a company by way of the acquisition of shares

On February 29, 2012, we reached an agreement with Boston Biomedical, Inc. of the United States (hereinafter referred to as "BBI") on our acquisition of BBI. Pursuant to said agreement, we acquired the relevant shares on April 24, 2012 (U.S. time), whereupon BBI became a fully owned subsidiary of our company.

#### • Purpose of acquisition

BBI is a biotechnology company focusing on the oncology area and possesses two highly promising products in their pipeline called BBI608 and BBI503, which are small molecular oral drugs created by BBI with the aim to cause an antitumor effect in cancer stem cells. Anticancer drugs targeting cancer stem cells are considered to be effective against refractory, recurrent and metastatic cases, which are the main challenges in current cancer treatment, and BBI608 and BBI503 are likely to become the first anticancer drugs in the world targeting cancer stem cells.

After execution of the option agreement with BBI, DSP recognized BBI's innovative development pipeline and its excellent ability of drug discovery & development, which led to DSP's decision to acquire BBI.

The acquisition of BBI is not only an acquisition of an innovative pipeline in the oncology area, it also represents obtaining an excellent drug discovery & development platform with the capabilities of BBI, enabling us to continuously create candidate compounds likely to advance into later development stages. Subsequently we intend to establish our R&D base in the US to expand our presence in cancer treatment globally. We are aiming to make the oncology area one of our future focus therapeutic areas next to the CNS area.

- Name of the parties from whom shares were acquired Shareholders of BBI and BBI itself
- Name of acquired company and the description and size of operations undertaken thereby Name: Boston Biomedical, Inc.
   Description of business: Biotechnology company focusing on R&D in the cancer stem cell area Size: Amount of net assets: US\$11 million
   Amount of total assets: US\$4 million (As of March 31, 2012)
- Date on which shares were acquired April 24, 2012 (U.S. time)
- Acquisition price and equity ratio after acquisition
  Consideration for acquisition: US\$200 million (excluding incidental costs)
  Equity ratio after acquisition: 100%
- Contents of the condition clause for the acquisition cost under an acquisition agreement and its accounting method hereafter

DSP will make an upfront payment of US\$200 million on closing of the acquisition of its shares, and thereafter it will make development milestone payments up to US\$540 million related to the compounds (BBI608 and BBI503) currently being developed by BBI. Furthermore, after the launch, DSP will also make milestone payments up to US\$1,890 million based on the achievement of various net sales targets with the last milestone being paid upon net sales of greater than US\$4 billion in any fiscal year. If additional payment for the acquisition cost occurs as mentioned above, the acquisition cost is revised assuming that the additional payment had been made at the time of acquisition and the Company revises the amount of goodwill and the amortization of goodwill.

 Method by which funds for payment were procured Own funds

### **Independent Auditor's Report**

To the Board of Directors of Dainippon Sumitomo Pharma Co., Ltd.:

We have audited the accompanying consolidated financial statements of Dainippon Sumitomo Pharma Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at March 31, 2012 and 2011, and the consolidated income statements, statements of comprehensive income, statements of changes in net assets and statements of cash flows for the years then ended, and a summary of significant accounting policies and other explanatory information.

#### Management's Responsibility for the Consolidated Financial Statements

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

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we comply with ethical requirements and 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 our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider 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, while the objective of the financial statement audit is not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

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

#### Opinion

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Dainippon Sumitomo Pharma Co., Ltd. and its consolidated subsidiaries as at March 31, 2012 and 2011, and their financial performance and cash flows for the years then ended in accordance with accounting principles generally accepted in Japan.

#### Emphasis of Matter

As described in significant subsequent event of notes to consolidated financial statement, on April 24, 2012, the Company acquired Boston Biomedical, Inc. and made it a wholly-owned subsidiary of the Company. Our opinion is not qualified in respect of this matter.

#### **Convenience Translation**

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2012 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 1 to the consolidated financial statements.

KPMG AZSA LLC

July 27, 2012 Osaka, Japan

## Corporate Data (As of March 31, 2012)

Name	Dainippon Sumitomo Pharma Co., Ltd.
Establishment	May 14, 1897
Date of Merger	October 1, 2005
Headquarters	6-8 Doshomachi 2-chome, Chuo-ku, Osaka 541-0045, Japan TEL: +81-6-6203-5321 FAX: +81-6-6202-6028
Capital	¥22.4 billion
Employees	7,601 (consolidated), 4,449 (non-consolidated)
Total Number of Shares Issued	397,900,154
Total Number of Shareholders	18,350
Stock Exchange Listings	First Sections of Tokyo and Osaka
Securities Code	4506
Independent Public Accountants	KPMG AZSA LLC
Fiscal Year-end	March 31
Ordinary General Meeting of Shareholders	June

Administrator of Shareholders' Register	Sumitomo Mitsui Trust & Bank, Ltd.*
Lead Managers	(Main) Daiwa Securities Capital Markets Co., Ltd. (Sub) SMBC Nikko Securities Inc., Nomura Securities Co., Ltd.
Main Banks	Sumitomo Mitsui Banking Corporation; The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Key Facilities (As of June 30, 2012)	Headquarters (Osaka), Tokyo Office (Tokyo), Osaka Center (Osaka), 22 Branches, 4 Plants (Mie, Osaka, Ehime, Oita), 2 Research Laboratories (Osaka), 2 Distribution Centers (Saitama, Hyogo)
Major Consolidated Subsidiaries (As of June 30, 2012)	DSP Gokyo Food & Chemical Co., Ltd. DS Pharma Animal Health Co., Ltd. DS Pharma Biomedical Co., Ltd. Sunovion Pharmaceuticals Inc. (U.S.) Boston Biomedical, Inc. (U.S.) Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (China)

\* As of April 1, 2012, The Sumitomo Trust & Banking Co., Ltd. changed its name.

#### **Principal Shareholders**

	No. of Shares Held (Thousands of Shares)	Percentage of Shareholding
Sumitomo Chemical Co., Ltd.	199,434	50.20
Inabata & Co., Ltd.	27,282	6.87
The Master Trust Bank of Japan, Ltd. (Trust Account)	14,829	3.73
Nippon Life Insurance Company	10,530	2.65
Japan Trustee Services Bank, Ltd. (Trust Account)	8,724	2.20
Japan Trustee Services Bank, Ltd. (Trust Account for Sumitomo Mitsui Banking Corporation's retirement benefi	its) 7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa General Insurance Co., Ltd.	4,928	1.24
Dainippon Sumitomo Pharma Employee Shareholding Associ	iation 4,327	1.09
JPMorgan Securities Japan Co., Ltd.	2,850	0.72

Composition of Shareholders



Note: Percentage of shareholding is calculated excluding treasury stock (588,699 shares).

#### Share Price Range and Trading Volume





### Dainippon Sumitomo Pharma Co., Ltd.

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