







#### **Profile**

#### 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 people's 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

#### Corporate History

Sumitomo Dainippon Pharma Co., Ltd. was established in October 2005 through the merger of Dainippon Pharmaceutical Co., Ltd. and Sumitomo Pharmaceuticals Co., Ltd. with the aim of broadly contributing to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide.

Dainippon Pharmaceutical has its origins in Osaka Pharmaceuticals Co., Ltd., which was established in 1897 in Doshomachi, Osaka, by 21 prominent leaders in the pharmaceutical industry. In the following year, 1898, the company acquired Dainippon Pharmaceutical Company, which had been established under the supervision of the government in 1883 as Japan's first pharmaceutical manufacturer. The company inherited its new acquisition's name and trademark, becoming Dainippon Pharmaceutical Co., Ltd.

Sumitomo Pharmaceuticals was established in February 1984, from the Research, Development, and Manufacturing divisions of Sumitomo Chemical Co., Ltd.'s pharmaceuticals business, as well as the Pharmaceuticals Sales division of Inabata & Co., Ltd

The spirit of these two companies has been passed on to Sumitomo Dainippon Pharma. While striving to be a cutting-edge pharmaceutical company with a strong market presence, we will continue to provide innovative and useful pharmaceuticals to people not only in Japan, but also around the world.

described were conducted in fiscal 2015.
Organizational Scope: The report covers the 16 companies in the Sumitomo Dainippon Pharma Group (Sumitomo Dainippon
Pharma Co., Ltd., its 15 consolidated subsidiaries). However, environmental performance data in the report are totals for major

Reference guidelines regarding disclosure on non-financial information

- G4 Sustainability Reporting Guideline

**Disclaimer Regarding** Forward-Looking Statements

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

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We will contribute to the betterment of healthcare and fuller lives of people worldwide as a globally active R&D-based company.



# of Atypical Antipsychotic Agent LATUDA®

P15 Vision and Strategy

## **Sustained Growth**—Quest for Further Innovation

#### P16 Research & Development

Sumitomo Dainippon Pharma is actively investing its resources in new areas such as disease fields where no approved drugs exist and Regenerative Medicine & Cell Therapy as well as the focus therapeutic areas of psychiatry & neurology and oncology.



- Product Launch Plan / Seeking early approval of BBI608 and BBI503
- Drug Discovery / Intellectual Property / R&D Organization / Main Research Partners
- Development Pipeline

#### P25 Production

We provide a stable supply of products based on even more rigorous quality controls.

#### Marketing P27

In Japan, we are concentrating resources on growth products to expand sales. Globally we are focusing on maximizing the product value of LATUDA®.

- Pharmaceutical Business: Japanese Market
- Pharmaceutical Business: North American Market
- Pharmaceutical Business: Chinese Market
- **Related Business**

#### P35 **Corporate Governance**

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#### **CSR Management**

Human Rights / Labour Practices / Fair Operating Practices / Consumer Issues / Community Involvement and Development / Environment

#### **Financial Section**

Eleven-Year Summary of Selected Financial Data / Operating Results and Financial Condition / Business Risks / Consolidated Balance Sheets / Consolidated Statements of Income / Consolidated Statements of Comprehensive Income (Loss) / Consolidated Statements of Changes in Net Assets / Consolidated Statements of Cash Flows / Notes to Consolidated Financial Statements

#### **Shareholder Data**









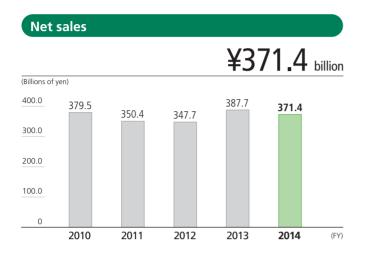


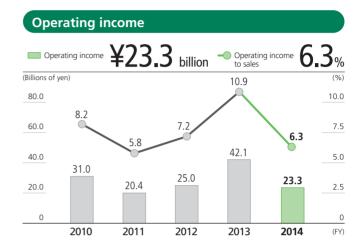


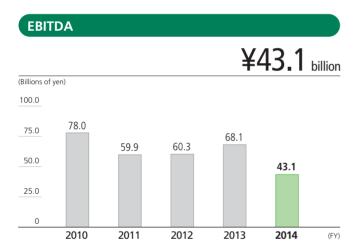
## Financial Highlights — Material Inputs and Outcomes

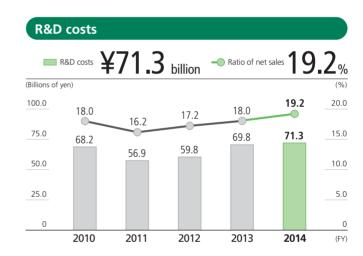
The Sumitomo Dainippon Pharma Group has been promoting the third Mid-Term Business Plan, which has Sustained Growth in the Quest for Further Innovation as its slogan. The plan sets targets of ¥450.0 billion in net sales (includes ¥400.0 billion in pharmaceutical sales), ¥80.0 billion in operating income and ¥110.0 billion in EBITDA\* in fiscal 2017.

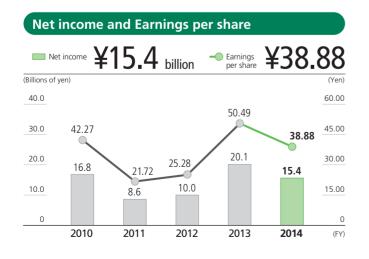
\* EBITDA: Earnings Before Interest, Taxes, Depreciation and Amortization, and Extraordinary income/loss

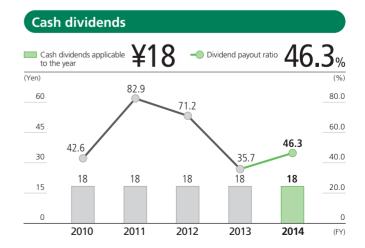




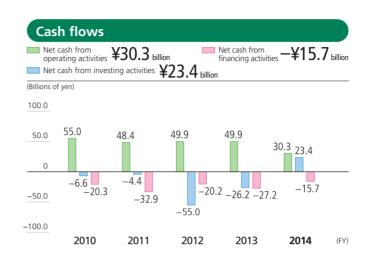


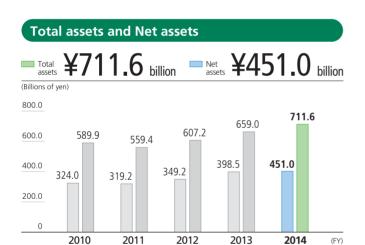


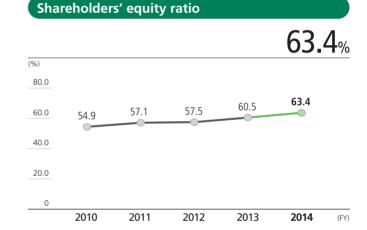


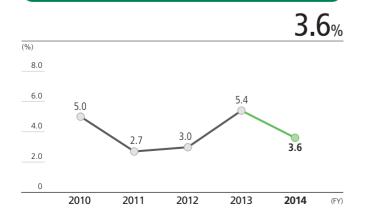


#### **Capital expenditures** (Acquisition cost of property, plant and equipment and intangible assets) ¥10.7 billion (Billions of yen) 30.0 23.4 22.5 15.0 12.4 10.7 8.7 8.7 7.5 0 2010 2012 2013 2014 2011 (FY)

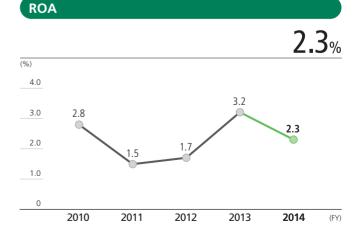








**ROE** 



## Non-Financial Capital Highlights — Key Inputs and Outcomes

We refer to the Integrated Reporting Framework of the International Integrated Reporting Council (IIRC)\* which defines not only financial capital, but also manufactured capital, intellectual capital, human capital, social and relationship capital, and natural capital as sources of value creation.

\* An international organization that has developed an integrated framework for reporting corporate financial and non-financial information.

#### Intellectual capital

## organizational, knowledge-based intangibles, including intellectual property, such as patents, copyrights, software, rights and licenses

## Once-Daily APTIOM® Launch in the U.S. Pharmacies

Sunovion Pharmaceuticals Inc. launched APTIOM®, a once-daily antiepileptic drug (AED) indicated for use as adjunctive treatment of partial onset seizures, in pharmacies across the U.S. on April 7, 2014.

The availability of APTIOM® not only marks Sunovion's entry into the epilepsy therapeutic area, but we believe that it can also make a significant contribution to improving the lives of people living with epilepsy in the U.S. as a new treatment option for epilepsy.

**→** Details on p.31

# LATUDA®, an Atypical Antipsychotic Launch in the U.K.

Sunovion Pharmaceuticals Europe Ltd. launched LATUDA®, a once-daily atypical antipsychotic for the treatment of schizophrenia in adults, in the U.K. on August 4, 2014.

Sunovion Pharmaceuticals Europe is rolling out the sales strategy cultivated in the U.S. in the U.K., and aims to maximize LATUDA®, a global strategic product which is the first product launched by Sumitomo Dainippon Pharma Group in Europe.

Details on p.13

# **Establishment of External Innovation Development Office**

Sumitomo Dainippon Pharma established the External Innovation Development Office in December 2014 for the purpose of promoting and strengthening in-licensing, and cooperation for the future growth of our Company, in parallel with the drug discovery activities of our own.

The External Innovation Development Office will coordinate the Company's activities in the information gathering and evaluation of candidate pharmaceuticals and cutting-edge technologies and promote in-licensing and cooperation activities in the early stages of clinical studies. It has been conducting recruitment outside of the Company on several themes since July 2015.

Details on p.19







#### Manufactured capital

manufactured physical objects that are available to an organization for use in the production of products or the provision of services, including buildings, equipment, and infrastructure

#### **Kobe Regenerative & Cellular Medicine Center Commenced Operation**

In April 2014, Sumitomo Dainippon Pharma commenced operations at the Kobe Regenerative & Cellular Medicine Center, a research center established in the Kobe Biomedical Innovation Cluster\* located on Port Island in Kobe, Hyogo Prefecture as the main base for the two research groups under the Regenerative & Cellular Medicine Office.

The Kobe Regenerative & Cellular Medicine Center takes advantage of an environment that facilitates access to leading-edge information



on regenerative and cell therapy to promote research with aim of discovering new innovations using iPS cells among other techniques.

\* The Kobe Biomedical Innovation Cluster is a project being promoted by the City of Kobe. The aims are to establish a research and development site for leading-edge medical research, including RIKEN and others, as well as promoting partnerships linking industry, academia and government to develop practical and clinical applications for drugs, regenerative medicine and medical equipment through a biomedical industry complex.



#### **Reorganization of Production Sites**

Sumitomo Dainippon Pharma has decided to close Ehime Plant by fiscal 2018 and to integrate the productive functions of Ibaraki Plant and Suzuka Plant by fiscal 2020 with a view to establishing a robust business management structure to respond flexibly to the changes in the business environment.

**⇒** Details on p.25



#### Social and relationship capital

includes relationships with the community, stakeholders, and other networks, and brands, reputation, and shared norms established by the organization

# **Atypical Antipsychotic Lurasidone Cooperation in Four South American Countries and Three Asian Countries**

In May 2014, Sumitomo Dainippon Pharma entered into a license agreement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) for the commercialization of lurasidone hydrochloride ("lurasidone"), an atypical antipsychotic, in Brazil and Venezuela. Sumitomo Dainippon Pharma also announced that it had granted Daiichi Sankyo the option right for the commercialization of lurasidone in Argentina and Colombia.

Moreover, in January 2015, Sumitomo Dainippon Pharma concluded an agreement with DKSH (Thailand) Limited relating to marketing, sales and distribution of lurasidone in Thailand, Singapore, and Hong Kong.

For Sumitomo Dainippon Pharma, lurasidone is a product with global strategic importance. In parallel with an early maximization of the ongoing sales of lurasidone in the U.S., Canada, and the U.K., Sumitomo Dainippon Pharma seeks to expand its sales to Japan and China and aggressively expand the regions where it is sold through alliances. At present, applications for approval are underway in Taiwan, Venezuela, Thailand, Singapore, Hong Kong, Russia, and Turkey through our alliance partners. Our joint development and exclusive sales agreement with Takeda Pharmaceutical Company Limited in Europe has been cancelled, and we are examining all the options for future development, including an alliance with a new partner.

**⇒** Details on p.13

#### Conclusion of Joint Development and License Agreement for North America with respect to SB623, a Therapy for Stroke

In September 2014, Sumitomo Dainippon and SanBio, Inc. entered into a joint development and license agreement for exclusive marketing rights in the U.S. and Canada for SB623, a cell therapy for the treatment of chronic strokes discovered and currently under development by SanBio.

SB623 is the first cell therapy for stroke that has been approved by the U.S. FDA for human clinical trials. It is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. It is expected to have results in chronic stroke, for which no effective treatment yet exists, by encouraging the reproduction of central nervous system cells.

Addressing diseases where no approved drugs exist and offering regenerative therapies are important focuses of our research and development efforts. There are no drugs currently available to treat the frequently severe disability resulting from stroke; recovery from such disability represents a profound unmet medical need. We believe that SB623 has the potential to become the first effective therapy for stroke disability.

#### **Human capital**

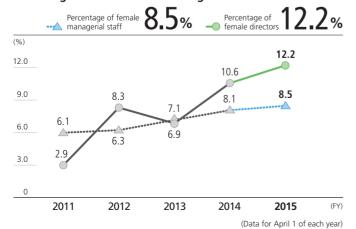
people's competencies, capabilities and experience, and their motivations to innovate

## Raising Corporate Value through the Utilization of Diverse Human Resources

Sumitomo Dainippon Pharma believes that it is important to create an environment in which every single employee can reach their full potential.

In recent years, we have been particularly active in striving to promote active participation by women as one of our human resource diversification initiatives. As of April 2015, women accounted for approximately 12% of directors positions and approximately 9% of managerial staff were women. We have established a target to double the percentage of female executives in 2020 by promoting a revolution in consciousness and corporate culture, increasing the number of female employees with continuous service and pursuing the enhancement of their careers.

#### Percentage of female senior managers and female executives



Natural capital

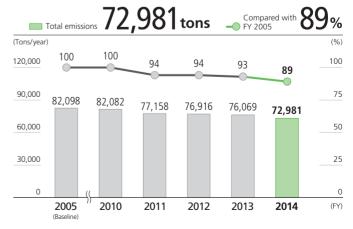
environmental resources and processes related to the organization's business

## Steadily Reducing Environmental Impact based on Mid-Term Environmental Plan

Sumitomo Dainippon Pharma formulates a Mid-Term Environmental Plan to clarify the key challenges in environmental activities and as an action plan for achievement and continuous improvement.

In particular, we strive to reduce greenhouse gases (CO2) by actively adopting new energy technologies with low CO2 emissions, such as renewable energy as well as making efforts to utilize energy efficiently in all our business activities.

#### CO<sub>2</sub> emissions



## **Message from the President**

We will contribute to the betterment of healthcare and fuller lives of people worldwide as a globally active R&D-based company.



# $Q_1$

# A

# Could you look back on fiscal 2014 (the year ended March 31, 2015) and tell us about the Group's business performance and the progress of R&D?

# Although sales and profit both declined due to the impact of NHI price revisions and generic drugs in Japan, we did achieve our initial projections thanks to the growth of LATUDA® in North America and other factors.

The Group has been promoting the third Mid-term Business Plan which covers the period from fiscal 2013 (the year ended March 31, 2014) to fiscal 2017 (the year ending March 31, 2018). In accordance with the plan, we have been actively extending our business activities in order to establish a strong domestic business foundation, strengthen profitability in North America and expansion into Europe and Asia, expand our global pipeline and develop leading-edge science fields. The consolidated financial results for fiscal 2014, the second year of the third Mid-term Business Plan, recorded ¥371.4 billion in net sales, down 4.2% year on year, ¥23.3 billion in operating income, down 44.8% year on year, and ¥15.4 billion in net income, down 23.0% year on year.

Overseas, sales in North America increased due to the growth in sales of the atypical antipsychotic LATUDA® as well as the effect of the weaker yen. In China, sales of MEROPEN®, a carbapenem antibiotic, also increased considerably. On the other hand, sales in Japan declined significantly amidst a challenging business environment that included the NHI price revisions implemented in April 2014 and the spread of government measures to encourage the use of generic drugs. This was the principal factor behind the decline in consolidated sales and profit. Nevertheless, sales, operating income and net income all achieved projections.

As for research and development, we promoted drug discovery research and clinical development with the aim of creating innovative drugs with Psychiatry & Neurology and Oncology as the focus areas. The enrollment of new participants in the global Phase III clinical study of BBI608 as a monotherapy for colorectal cancer was closed in May 2014. However, ongoing studies, including a global Phase III clinical study on BBI608 as combination therapy for gastric cancer and gastroesophageal junction adenocarcinoma, are proceeding in accordance with plans. In addition, we have commenced Phase I clinical studies for several cancers in the U.S., Canada and Japan. In the field of psychiatry & neurology and other fields, we have been moving ahead steadily with the aim of launching major products to follow LATUDA®, including the commencement of Phase III clinical studies for a number of compounds. Furthermore, we established Kobe Regenerative & Cellular Medicine Center in April 2014, and we are working on the discovery of world-first innovative drugs. This work includes the launch in May of joint research with The Center for iPS Cell Research and Application (CiRA), Kyoto University into the transplantation of iPS-cell derived dopaminergic neural progenitor cells for Parkinson's Disease.

#### Vision and the Third Mid-term Business Plan

	First Phase FY2007 to FY2009	Second Phase FY2010 to FY2012	Third Mid-term Business Plan FY2013 to FY2017	n	Vision
	Solid Fundamentals Strengthening and maintaining our business foundation towards globalization		Sustained growth  Quest for Further Innovation		
Japan	Focus resources on four strategic products Early maximization of new products	Transform domestic business foundation	Establish strong domestic business foundation	>	Aspire to be a globally active R&D-based
Over- seas	Establish U.S. marketing organization Expand U.S./EU clinical development organization Start-up U.S. business in our own sales organization	Expand North American business through our own sales organization	Strengthen profitability in North America Expansion into Europe and Asia	>	Contribute to medical care through leading-
R&D	Strengthen new drug discovery activities and in-licensing activities	Expand new product pipeline	Expand global pipeline Develop leading-edge science fields	$\rangle$	edge technologies

### Message from the President

 $Q_2$ 

 $A_2$ 

Please explain the future growth strategy for further expansion of the North American business, which has become a pillar of earnings.

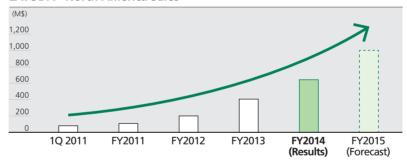
# In fiscal 2015, we will invest marketing resources effectively with the aim of turning LATUDA® into a blockbuster drug.

Sales of LATUDA®, which is the growth driver of the North American business, have increased significantly since it gained a new indication for treatment of bipolar depression in June 2013. North American sales in fiscal 2014 reached US\$752 million. In order to further strengthen the business foundation in North America, we will continue to implement activities to provide information using approximately 400 MRs and the broadcast of television advertisements for increasing brand recognition with the aim of turning LATUDA® into a blockbuster drug with North American sales of US\$1.0 billion in fiscal 2015. Television advertisements cost approximately US\$100 million in fiscal 2014, and this represents the peak as we will continue to advertise effectively.

In the first half of fiscal 2015, we plan to obtain approval for an additional indication for epilepsy (monotherapy) for APTIOM®, the antiepileptic agent which was launched in the U.S. in April 2014. Going forward, we will work toward a target of around ¥50.0 billion in peak sales, including the additional indication.

Furthermore, we will speed up development of large-scale new drugs ahead of the expiry of the exclusivity period for LATUDA® in 2019.

#### **LATUDA® North America Sales**



 $\mathbf{Q}_3$ 

Д3

In light of the results of Phase III clinical study in Japan for schizophrenia and the termination of the joint development and exclusive commercialization agreement in Europe, what is your policy on how to expand sales of LATUDA® in the future?

We are considering our business strategy from a variety of angles, including examining the development plan for schizophrenia in Japan and alliances with new partners in Europe, and we will continue striving to expand the sales region.

As a global strategic product, our goal is to launch and expand sales of LATUDA® not only in North America but in the world's leading markets. We have already been marketing it in the U.K. since 2014, and we plan to submit an application in China during 2015. In addition, the application process is underway in South America and Southeast Asia through our overseas alliance partners.

While improvement was demonstrated in the lurasidone group compared to the placebo group under the Phase III clinical study (PASTEL study) aimed at obtaining approval in Japan for schizophrenia, it was not statistically significant. Therefore, we determined that it would be difficult to submit an

application for approval of manufacturing and marketing based on the study. The plan for future development in Japan is currently under consideration. Meanwhile, a Phase III clinical study related to bipolar disorder is proceeding according to plan, and we intend to submit an application in fiscal 2017.

The termination of the joint development and exclusivity agreement with Takeda Pharmaceutical Company Limited in Europe is a decision made accompanying a review of Takeda's market and business considerations rather than resulting from any new knowledge concerning the safety and efficacy of LATUDA®. We are considering all the options for expansion in the Europe region, including an alliance with a new partner. We will aim for a prompt business transfer with regards to the regions where Takeda Pharmaceutical's European subsidiary is currently marketing LATUDA®.

 $Q_4$ 

 $A_4$ 



While the Japan domestic business environment continues to become harsher with the impact from NHI price revisions and the increased usage of generic drugs, what is the progress status of the company's efforts towards "establishing a strong domestic business foundation"?

We are concentrating our resources on strategic products and new products, and we are working to stabilize and expand domestic sales, as well as improve profitability.

In Japan, we are aiming to stabilize our business scale and improve profitability by concentrating our resources on strategic products such as the therapeutic agent for hypertension AIMIX®, the atypical antipsychotic LONASEN®, and the therapeutic agent for Parkinson's disease TRERIEF®, as well as promoting efficient business activities. To this end, we are defining the target facilities of each strategic product and also selecting and concentrating the marketing resource allocation for expenses and promotion efforts about each strategic product. For instance, regarding LONASEN®, apart from having increased the Psychiatry segment's MRs by 100, we are also aiming to increase sales by strengthening the training for regional MRs.

In addition, we are responding to an environment that is becoming harsher for MRs every year, due to visit regulations and other restrictions, while improving operating efficiency through the active promotion of "hybrid marketing" that links provision of information by MRs with e-promotions utilizing the Internet. We are also planning to differentiate our company from competitors through hybrid marketing. Furthermore, in the area of cost, we will review without exceptions and continue to reduce non-necessary and non-urgent spending while aiming to strengthen profitability.

Furthermore, apart from our own developed products, we are also actively working on promotion and sales partnerships with other companies. Regarding the therapeutic agent for pruritus REMITCH® for which we entered a promotion agreement with Torii Pharmaceutical Co., Ltd. in March 2015, we have been rolling out its promotion to chronic liver disease patients since May. While REMITCH® is a product that has been used as the therapeutic agent for pruritus for hemodialysis patients so far, it has received approval for the additional function of new therapeutic use as the therapeutic agent for pruritus in chronic liver disease patients. We are providing information on the new therapeutic use to medical institutions and planning for rapid sales expansion. While contributing to domestic sales by expanding the sales of this product, we also aim to create a synergy with DSP-1747, under development as the therapeutic agent for nonalcoholic steatohepatitis (NASH), and increase our presence in the liver segment.

In addition, in July 2015, we signed a sales collaboration agreement with Eli Lilly Japan K.K. for the GLP-1 receptor agonist TRULICITY, an injectable drug that is administered once a week with an indication for Type II diabetes. We position the diabetes segment as one of our top priority domestic business segments. We also seek to increase the treatment choices for patients and further our contribution towards diabetes treatment by adding to the lineup of currently sold diabetes treatment drugs (SUREPOST®, METGLUCO®, and GLIMICRON®) that have a different functional mechanism.

### Message from the President

 $\mathbf{Q}_{5}$ 

 $A_5$ 

Please explain the status of development for the large-scale strategic products that are to be post-LATUDA® candidates.

We are concentrating our efforts on launching globally competitive, large-scale products, particularly "first-in-class" and "first in the world" cancer treatments.

The priority targets of our research and development are focused on the psychiatry & neurology field and the oncology field. In these fields, we are aiming for an early launch of anticancer drugs BBI608 and BBI503 as the favorite post-LATUDA® candidates. These are first-in-class cancer treatments, discovered with the aim of an anti-tumor effect targeting cancer stem cell pathways. They are expected to demonstrate a high level of efficacy and safety through monotherapy or in combination with chemotherapy and other treatments. At present, we are conducting a number of global clinical studies. If these are successful, we will submit an initial application in fiscal 2017 and will seek to expand the indications to a range of cancers later. In addition, we are currently pursuing Phase I/II clinical studies on myelodysplastic syndrome (MDS) with DSP-7888, an anti-cancer drug which is the first clinical development produced by the new DSP Cancer Institute, established in 2012, and we plan to expand the indications and development regions in the future.

Meanwhile, in the psychiatry & neurology field and other fields, we have plans to develop new drugs currently under clinical development SEP-225289, a treatment for attention deficit hyperactivity disorder (ADHD), SUN-101, a treatment for chronic obstructive pulmonary disease (COPD), SB623, a stroke treatment, and DSP-1747, a treatment for nonalcoholic steatohepatitis (NASH), and APTIOM®, an antiepileptic launched in April 2014 into the next generation of large-scale products.

In addition to promoting the development of globally competitive drugs in the fields of psychiatry & neurology and oncology as well as fields with high unmet medical needs, which includes cell therapy and regenerative medicine, the company will consider proactive in-licensing and M&As.

 $Q_6$ 

 $A_6$ 



Please explain your approach to and initiatives in areas such as corporate governance, establishing the company's foundations and strengthening the management structure.

We are strengthening internal control and the corporate governance system, increasing the transparency and soundness of management while striving to foster a corporate culture that encourages the initiative to take on challenges.

The company is addressing the further strengthening of internal control as a key management challenge. In response to the enforcement of the revised Companies Act and the Enforcement Regulations for the revised Act on May 1, 2015, we revised our basic policy on the development of our internal control system. We reviewed the internal control rules for Group companies overall and strengthened the system for ensuring the effectiveness of auditing by auditors.

At present, we are pursuing investigations into compliance with the Tokyo Stock Exchange's Japan's Corporate Governance Code and plan to prepared and submit a report on corporate governance in compliance with the Code in an appropriate timeframe. We hope to further increase the transparency and soundness of management by disclosing our basic policy on corporate governance and our policy and procedures for the nomination of candidates for directors and auditors by the Board of Directors required by the Code.

In addition, we are addressing the establishment of the company's foundations and strengthening of the management structure continuously as key challenges. In April 2016, we will introduce a new system of personnel evaluation to foster a corporate climate that enables each and every employee to take the initiative in taking up challenges, including the launch of innovative new drugs and the development of new markets.

 $Q_7$ 

 $A_7$ 

Please explain your basic approach to CSR management and the initiatives that you have focused on in recent years.

While we naturally aim to broadly contribute to society through our business, we have been concentrating our efforts on diversification, primarily active participation by women.

The foundation of our CSR management is practicing our 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. Furthermore, as a company that supplies pharmaceuticals on which the lives of many depend, we position compliance with laws and social ethics as our greatest social responsibility, and the entire Group seeks to strengthen and thoroughly enforce compliance.

In recent years, we have also actively strived for diversification, particularly active participation by female employees. The company has always promoted personnel with the skills and ambition to management positions without any distinctions between men and women. As of April 2015, women accounted for approximately 12% of Director positions and approximately 9% of Managerial staff were women. With a target to double these figures by 2020, we are concentrating our efforts on measures such as career development training for female employees, training for managers about career and training support for female employees, the introduction of diverse modes of working, including working from home, and encouragement for male employees to take childcare leave.

 $Q_8$ 

 $A_8$ 

Please explain your managerial policy and achievement targets for fiscal 2015. Do you have any other messages for stakeholders?

#### In fiscal 2015, we will aim for record high consolidated net sales by steadily implementing our key strategies.

Over the next few years, we will steadily launch a succession of distinctive new products in Japan and overseas to achieve a transformation of our business structure. In addition to turning LATUDA® into a blockbuster drug, our policy is to steadily implement our key strategies to develop post-LATUDA® candidates and strengthen the domestic business foundation to make 2015, which marks the 10th anniversary of the merger between Dainippon Pharmaceutical and Sumitomo Pharmaceuticals, a year of transformation. As our consolidated earnings targets, we have projected record net sales of ¥401.0 billion and operating income of ¥27.0 billion.

The company views the increasing of shareholder value as an important issue, and we believe that we will achieve an improvement in ROE by promoting expansion in sales and enhanced profitability. The company also positions the appropriate return of profits to shareholders as one of its most important management policies. We believe that it is important to allocate profits in a way that accurately reflects business performance. We take a comprehensive view that includes giving due consideration to the importance of raising corporate value through aggressive investment in future growth, solidifying our operating base and enhancing our financial position. In fiscal 2014, we paid out a total annual dividend of ¥18 per share, the same as in fiscal 2013, in order to maintain stable dividends despite the decline in sales and profit. The total annual dividend for fiscal 2015 is expected to remain ¥18 per share.

As a globally active R&D-based company, we are committed to continuously increasing corporate value and meeting the expectations of all stakeholders. We ask for your continued support.

## **Focus**

## Global strategic product LATUDA®

# Expansion and Development of Atypical Antipsychotic Agent

# LATUDA®



# 21 million worldwide

According to the World Health Organization (WHO), there are 21 million people suffering from schizophrenia worldwide, regardless of country, region, race or gender, with the age of onset mainly occurring at 15-35 years old.

The symptoms of schizophrenia include hallucinations, reality distortion, depression, isolating self from society, and it is a serious disease that chronically impairs daily life.

In addition, it is said to shorten the average life expectancy by 10 to 22.5 years. A contributory factor to this is the side effects from antipsychotic drugs, such as weight gain, increased blood pressure and increased blood sugar level. Cardiovascular disease is the main cause of death among patients with schizophrenia, with reports stating that the percentage of cardiovascular disease as cause of death is 25 % higher when compared to the general population.



# Providing better treatment with the efficacy, safety and tolerability assessed through numerous clinical studies

Sumitomo Dainippon Pharma's LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent used in adult patients with schizophrenia. In October 2010, our U.S. subsidiary, Sunovion Pharmaceuticals Inc., obtained the approval for schizophrenia treatment from the FDA (U.S. Food and Drug Administration). LATUDA® was launched in the U.S. in February 2011, and it was also launched in Canada in September 2012.

The results of clinical studies have shown that LATUDA® is limited in its impact on the metabolic system, such as weight gain, effects on lipids and blood sugar levels, which are the problematic side effects of many existing atypical antipsychotic agents. In addition, it also has the advantage of being easy to administer (once-daily dosing, no need for initial dose titration).

With this advantage, LATUDA® is recognized as one of the options for schizophrenia treatment and sales have also grown.





## **Europe**

Schizophrenia

2013 Launched in Switzerland\*

2014 Launched in Denmark\*, Norway\*

Application made in Russia\*, Turkey\*

2014 Launched in the United Kingdom

2015 Launched in the Netherlands\*, Finland\*

\* With the end of the agreement with Takeda Pharmaceutical, the rights for joint development and exclusive commercialization will be returned to Sumitomo Dainippon Pharma.

## Japan

Schizophrenia
Phase III clinical study completed
Future development policy in review
Bipolar I depression/ Bipolar
maintenance

Phase III clinical study ongoing Application scheduled for FY2017

#### China

Schizophrenia
Phase III clinical study ongoing
Application scheduled for FY2015

#### Asia

Schizophrenia

2013 Application made in Taiwan (Standard Chem. & Pharm.)

2014 Application made in Thailand,

Hong Kong (DKSH)

2015 Application made in Singapore

#### **Australia**

Schizophrenia

March 2014 Approval obtained (Commercial Partner: Servier Australia)

# LATUDA® to become a key growth driver as a blockbuster drug

The indication for LATUDA® is not limited to schizophrenia. In June 2013, LATUDA® obtained an additional indication approval from the FDA as the first atypical antipsychotic indicated for the treatment of adult Bipolar I depression as both monotherapy and as an adjunctive therapy.

In order for LATUDA® to become a blockbuster drug with annual sales of US\$1 billion in North America, we are implementing brand penetration plans that include television commercials in the U.S. market. By increasing awareness, we will continue to convey information on LATUDA® to many of those awaiting treatment for Bipolar I depression.

Furthermore, we are working on expanding global presence of LATUDA® in order to maximize the LATUDA® business.

After North America, Sunovion Pharmaceuticals Europe Ltd., our U.K. subsidiary, launched the drug in the U.K. in August 2014. We have also entered into a joint development and exclusive commercialization agreement with Takeda Pharmaceutical Company Limited for 26 European countries excluding the U.K., as well as Switzerland, Norway, Turkey and Russia. While the drug is being sold by Takeda Pharmaceutical Company Limited in several countries, the joint development and exclusive commercialization agreement will terminate on 31st January 2016. Regarding the expansion of our LATUDA® business in

Europe, all options, including collaboration with a new partner, are currently under consideration. For markets in Europe where the drug has already been launched, we are planning for a smooth business transfer in the future, with the goal of ensuring uninterrupted access to LATUDA for patients and physicians.

For the other regions, approval for marketing in Australia was obtained in March 2014, and we entered into a commercialization partnership agreement with Servier Laboratories Australia Pty Ltd. in July 2015. In the future, we are expanding the sales region via our own subsidiary in China, as well as through partnership with other companies for South East Asia, South America, etc.

# Regarding the analysis results of the Phase III clinical study (PASTEL study) targeted for schizophrenia in Japan

For the main analysis set, although an improvement trend was recognized for the group administered lurasidone when compared to the placebo group, it was not statistically significant. Hence, applying for the approval to manufacture and market the drug in Japan based on this study would be difficult. We are reviewing the policy for future development in Japan.

Regarding the ongoing Phase III clinical study aimed at the approval of manufacturing and marketing of LATUDA® in Japan for bipolar disorder, we are scheduled to progress as planned and aiming for application in FY2017.

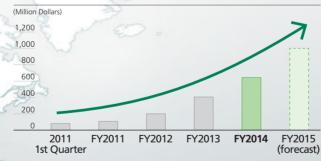
#### Canada

Schizophrenia
September 2012 Launched
Bipolar I depression
2014 Additional
indication approved

### **United States**

Schizophrenia
February 2011 Launched
Bipolar I depression
2013 Additional indication
approved

#### **LATUDA® North America Sales Amount**





## **South America**

Schizophrenia 2014 Application made in Venezuela (Daiichi Sankyo) FY2015 Application scheduled for Brazil (Daiichi Sankyo)



LATUDA.com



# Sustained Growth—Quest for Further Innovation

In our quest for innovation, we have set out a vision: "Aspire to be a globally active R&D-based company" and "Contribute to medical care through leading-edge technologies."

## The Third Mid-term Business Plan (MTBP)

(FY2013-2017)

	Net sales	Sales of pharmaceuticals	Operating income	EBITDA	R&D
FY2014	¥371.4 billion	¥330.7 billion	¥23.3 billion	¥43.1 <sub>billion</sub>	¥71.3 billion
FY2017 (Targets)	¥450.0 billion	¥400.0 billion	¥80.0 billion	¥110.0 billion	¥85.0 billion

\* Exchange rate (yen/\$) FY2014 (results):109.8 yen FY2017 (assumed):100.0 yen

Aspire to be a globally active R&D-based company

Contribute to medical care through leading-edge technologies



Sustained Growth is the theme of the third Mid-term Business Plan for the period from FY2013 (ended March 31, 2014) to FY2017 (ending March 31, 2018), and we are focusing on strategies in a Quest for Further Innovation. We also believe that it is necessary to further strengthen the business foundation as a base for implementing these strategies swiftly.

## **Research & Development**

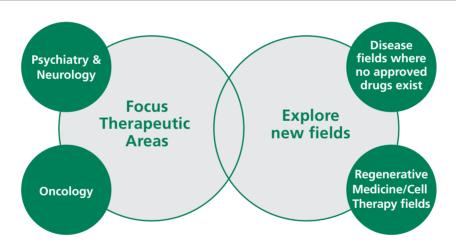
Sumitomo Dainippon Pharma is actively investing its resources in new areas such as disease fields where no approved drugs exist and Regenerative Medicine & Cell Therapy as well as the focus therapeutic areas of psychiatry & neurology and oncology.

## **Basic Strategy**

To address unmet medical needs with innovative new drugs created through leading-edge technologies,
Sumitomo Dainippon Pharma is trying to expand its global pipeline under the basic strategy of "increased speed and efficiency."

Sumitomo Dainippon Pharma is developing new drugs not only for diseases where no approved drugs exist but also for those where there are no highly satisfactory treatments.

## **Research & Development Fields**



# By fiscal 2017, we aim to start clinical studies on eight compounds in oncology and ten compounds outside oncology, including in psychiatry & neurology.

Sumitomo Dainippon Pharma invests resources in promising candidates with the priority on obtaining Proof of Concept (POC)\* as soon as possible, with the aim of creating global strategic candidate compounds following LATUDA®, an atypical antipsychotic.

In the psychiatry & neurology area, we are conducting research and development for schizophrenia, depression, Alzheimer's disease, neuropathic pain, developmental disorders and neurodegenerative disorders, with an emphasis on alleviating symptoms where current medications are unsatisfactory and finding new ways to help patients for whom the efficacy of existing treatments is insufficient.

In the oncology area, based on our global research organization, we are the global leader in cancer stem cell research and aim to successively create innovative products. We believe that anticancer drugs BBI608 and BBI503 are the most promising

post-LATUDA® candidates.

We are also proceeding with the development of a therapeutic cancer peptide vaccine.

In regenerative medicine/cell therapy fields, we established the Regenerative & Cellular Medicine Office in September 2013 to vigorously promote the business of cell therapy and regenerative medicine using induced pluripotent stem (iPS) cells and other cutting edge technologies. Through the use of such technologies, we are trying to develop treatments for disease fields where no approved drugs exist.

In the area of disease fields where no approved drugs exist, EPI-743 is in the late phase of clinical development for Leigh syndrome, and DSP-1747 is under development for nonalcoholic steatohepatitis (NASH).

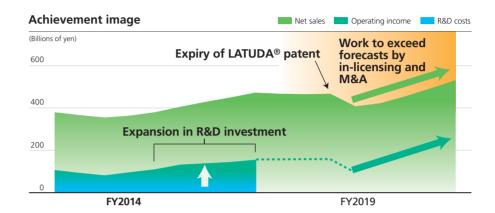
\* Proof of Concept (POC): confirmation of expected safety and efficacy in humans

### **Research & Development**

We are speeding up development, particularly late stage development programs, both in North America and Japan with an eye on finding post-LATUDA® candidates as well as aggressively engaging in new in-licensing and M&As.

As the period of exclusivity for atypical antipsychotic LATUDA® will expire in FY2018 in the U.S., a decline in sales is expected. Therefore, Sumitomo Dainippon Pharma is focusing on the development of post-LATUDA® candidates.

By speeding up development in particular for late stage programs in North America and Japan as well as aggressively engaging in new in-licensing and M&As, we are aiming to find and obtain drugs that will become the new drivers for growth.



#### Product Launch Plan (as of July 29, 2015)

Region	FY2015	FY2016	FY2017	FY2018	FY2019-2021
Japan		lurasidone* (Schizophrenia)  EPI-743* (Leigh syndrome)	ranirestat (Diabetic neuropathy)  BBI608 (Gastric and Gastroesophageal junction adenocarcinoma)	lurasidone (Bipolar I depression / Bipolar maintenance)  LONASEN® (Schizophrenia / Transdermal patch)  TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)  BBI503 (Solid tumors)	BBI608 (Colorectal cancer, etc.)  DSP-7888 (Solid tumors / Hematologic malignancies)  DSP-1747 (NASH)  DSP-6952 (IBS with constipation, Chronic idiopathic constipation)  IPS cell-derived RPE cells (Age-related macular degeneration)
U.S.	APTIOM® (Epilepsy-monotherapy)	LATUDA® (Bipolar Maintenance)	BBI608 (Gastric and Gastroesophageal junction adenocarcinoma)  SUN-101 (COPD)	dasotraline (ADHD)  BBI503 (Solid tumors)	SB623 (Chronic Stroke)  DSP-2230 (Neuropathic pain)  SEP-363856 (Schizophrenia)  dasotraline (BED)  BB1608 (Colorectal cancer, etc.)  DSP-7888 (Solid tumors / Hematologic malignancies)
China		LONASEN® (Schizophrenia)  CALSED® (Small cell lung cancer)		lurasidone (Schizophrenia)	
U.K.			idone disorder)		
	, ,,	Oncology liver/ digestive New Indication, etc.	Respiratory	* Developn	nent strategy under consideration



# Seeking early approval of BBI608 and BBI503, world first anticancer drugs aiming for anti-cancer effects by targeting cancer stem cell pathways

# Adding 8 Phase I clinical studies in FY2014, planning to initiate multiple Phase III studies in FY2015

BBI608 and BBI503 are world-first small molecular oral agents aiming to have an anti-cancer effect by targeting cancer stem cell pathways (cancer cells with stem cell properties). Clinical studies for BBI608 and BBI503 as combination therapies with other cancer treatments are currently underway targeting various cancers. In FY2014, one new Phase III, three new Phase II, and eight new Phase I studies were added.

In FY2015, Sumitomo Dainippon Pharma plans to initiate multiple Phase III studies for BBI608 and BBI503 and seeks to obtain approval as early as possible by preferentially allocating resources.

# Presentations of data on multiple types of cancers to American Society of Clinical Oncology

Sumitomo Dainippon Pharma presented data on BBI608 and BBI503 at the annual meeting of the American Society of Clinical Oncology held from May 29 to June 2, 2015.

We presented data on BBI608 that suggests the

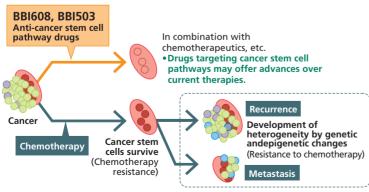
anti-cancer activity of BBI608 in combination with other chemotherapeutics for a variety of cancers, including advanced gastric and colorectal cancers. We also announced the protocol for the BRIGHTER study, a Phase III study initiated in FY2014.

For BBI503, we presented data that suggests anti-cancer activity in patients with advanced colorectal cancer.

# Seeking FY2017 approval in North America and Japan

Sumitomo Dainippon Pharma is currently conducting at least 20 clinical studies for BBI608 and BBI503 in total. These include a BBI608 Phase III global clinical trial for gastric and gastro-esophageal junction adenocarcinoma being implemented globally aiming for obtaining approval in North America and Japan in FY2017.

Globally, the oncology field is one of the areas where unmet medical need remains high, and Sumitomo Dainippon Pharma will continue to make the greatest efforts for the successful development of BBI608 and BBI503 in the future as the mission of an R&D-based pharmaceutical company.



#### Overview of BBI608 and BBI503

- First-in class molecular targeted drug (Small molecular compound, oral agent)
- Inhibits the growth of tumor cells and cancer stem cells to induce apoptosis
- Mechanisms of action are different for each compound

Cancer stem cells (indicated in red) are not controlled by existing therapy, and cancer stem cells tumorigenicity (self-renewal activity), recurrence or metastasis takes place.

# We have a research organization in place and are working to continuously create innovative new drugs.

#### **Drug Discovery**

Sumitomo Dainippon Pharma has a research organization that promotes innovation (organization by stage), and tries to create innovative new drugs. Details on p.20

#### Utilizing leading edge technologies in drug research

Innovative Drug Discovery Laboratories and Genomic Science Laboratories utilize leading edge technologies such as assay systems using iPS cells and in silico drug discovery.

We aim to shorten R&D periods and increase the probability of success in clinical studies by verifying efficacy and safety in the pre-clinical stage using iPS cells.

Compared to conventional techniques, in which drug candidates were selected by synthesizing and testing a large number of compounds based on research experience and/or new medical discoveries, genomic drug discovery, which utilizes human genomic information, is expected to offer a drastic improvement in success rates. It is also expected to reveal innovative drugs with new mechanisms that cannot be found using traditional approaches.

Moreover, to improve our success rate, we became one of the first pharmaceutical companies in Japan to pursue in silico drug discovery using a supercomputer, the "K computer," through which we are actively searching for promising candidate compounds. Based on the data on pathogens or the structures of proteins or other targets, the computer is first used to sift through a wealth of data on such factors using compound structures and their actions. Finally, computer simulations are run that test effects and safety and thus efficiently identify the most promising candidate compounds that bind with the proteins or other targets.

Traditionally, about one in every 30,000 candidate compounds actually makes it through to launch as one drug product. Moreover, it usually takes 9 to 17 years from discovery to launch. The process of selection described here will lead to higher success rates in clinical studies and shorter development periods, and it is our aim to get these promising drugs to patients faster than before.

#### **Alliances with External Research Institutions**

In the discovery of new drugs, Sumitomo Dainippon Pharma is promoting not only its own in-house research but also joint research with universities and other research institutions in Japan and overseas. We also actively maintain alliances with biotechnology companies possessing innovative technologies. In this way, we are tackling the creation of innovative new drugs based on leading-edge science.

We newly established the External Innovation Development Office in FY2014.

External Innovation Development Office: A specialist team with advanced science and business sense that can anticipate future markets

The External Innovation Development Office, established in December 2014, consists of members with wide-ranging experience who have been brought together from various departments involved in research. The office's responsibilities range from collecting information through to evaluation and



investigation concerning new candidate compounds in all fields prior to obtaining proof of concept (POC) and leading edge technologies.

Working in cooperation with relevant departments, we hope to develop in-licensing and partnerships, contributing to building Sumitomo Dainippon Pharma's research and development pipeline.

Shigeyuki Nishinaka, Director, External Innovation Development Office

#### **Intellectual Property**

#### **Main Concept**

As a pharmaceutical manufacturer, Sumitomo Dainippon Pharma recognizes that activities involving intellectual property are an essential part of its business strategy. Our basic policy is to develop our own robust intellectual portfolio, while at the same time respecting the intellectual property rights of others.

# Comprehensive Action of Intellectual Property from Research Accomplishment to Business Development

We file patent applications covering inventions and products created at each laboratory to secure Sumitomo Dainippon Pharma's leading position. We also actively file patent applications covering inventions created in cooperation with outside research institutions, including open innovation.

To comprehensively protect each of our products and promote our business strategy, we build up a patent portfolio including not only substance patent application but also patent applications that encompass uses, manufacturing processes and formulations. In addition, we are working to address themes of intellectual property regarding the regenerative medicine/cell therapy field in order to promote the business.

Furthermore, in view of our global business development, we need to protect our products using intellectual properties in countries around the world. For that purpose, we organize Patent Committee meetings with heads of research, development and business-related departments. The subjects at Patent Committee meetings include sharing of intellectual property information on individual products and discussions of future intellectual property strategies.

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

#### **Drug Discovery Research**

#### **Innovative Drug Discovery Laboratories**

Responsible for early stage drug discovery from exploratory to the LG\*1 stage, with an emphasis on innovative ideas.

#### **Drug Development Research Laboratories**

Efficiently and quickly progresses research programs and projects from the  $LO^{*2}$  stage onward, with an emphasis on clinical probability.

#### **Preclinical Research Laboratories**

Supports drug candidate compound selection and clinical development through regulatory science, leveraging its superior safety and pharmacokinetic technology.

#### **Genomic Science Laboratories**

Conducts research and development of drug discovery, diagnostic systems and diagnostic drugs using cutting-edge science and technology, including screening technologies, omics technologies and in silico drug discovery methods.

#### **Product Development Research**

#### **Process Chemistry Research & Development Laboratories**

Conducts research and development related to manufacturing active pharmaceutical ingredients using advanced synthetic chemistry technologies.

#### **Formulation Research & Development Laboratories**

Conducts state-of-the-art research and development related to dosage forms and manufacturing methods of formulations and research and development related to creative dosage forms aimed at maximizing product value.

#### **Analysis Research & Development Laboratories**

Conducts the development of quality evaluation methods for active pharmaceutical ingredients and formulations using advanced analytical technologies and creates quality control strategies aimed at investigational and new drug applications.

#### **Clinical Development**

**Drug Development Division (★)** 

#### Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (★)

★ Clinical development activities are carried out through close collaboration among our development teams. Sumitomo Dainippon Pharma Group will strengthen seamless operation to promote clinical development in a speedier and more efficient manner under the Head of Global Clinical Development.

#### Sunovion Pharmaceuticals Inc. (★)

#### DSP Cancer Institute/Boston Biomedical, Inc.

In charge of research and development aimed at continually creating innovative drugs in the oncology area.

#### Kobe Regenerative & Cellular Medicine Center

Conducts research for the regenerative medicine & cell therapy business using iPS and other cells.

\*1 Lead Generation \*2 Lead Optimization

#### **Main Research Partners**

Partner	Details
The Laboratory for Malignancy Control Research (the DSK Project) at Kyoto University	Kyoto University, which boasts a wealth of knowledge in basic and clinical medicine, and Sumitomo Dainippon Pharma, which focuses on oncology, have brought together their human, capital, knowledge and resources to collaborate on research and also make use of each other's intellectual property. Through this joint research, we aim to identify new drug targets and Biomarkers—the biological indicators of disease, the changes in disease status and the level of healing—and to create unique anticancer drugs, diagnostic techniques and treatments by advancing the search for candidate substances.
The Center for iPS Cell Research and Application (CiRA) at Kyoto University	Through this collaboration of academia and industry, we are focusing on a rare intractable disease that is caused by a genetic mutation and, by using disease-specific iPS cells, we will reveal the mechanism of the disease progression. Then we plan to identify disease markers specific to patients and search for therapeutic agents to control those pathways. We aim to create groundbreaking treatments that suppress the progression of the disease in patients. In March 2015, the results of joint research finding one possible cause of advancing pathological ossification in fibrodysplasia ossificans progressiva (FOP) were announced.
Edison Pharmaceuticals, Inc.	In collaboration with the U.S. biotechnology company Edison Pharmaceuticals, Inc., Sumitomo Dainippon Pharma is pursuing research and development focused on redox systems, which play a critical role in the regulation of metabolism, and aims to discover 10 novel candidate pharmaceutical compounds. Both companies are hopeful this joint research will lead to the development of treatments for intractable diseases, including mitochondrial diseases and oxidative stress-induced neuropsychiatric disorders, and rare diseases.

#### **Research & Development**

## **Development Pipeline**

#### Psychiatry & Neurology Area

This is the area of research in which Sumitomo Dainippon Pharma has most focused its efforts so far, and we believe that we have a strong competitive edge in the area. Targeting the improvement of symptoms where there are low satisfaction levels with treatments and therapies for patients who cannot obtain an adequate outcome with existing drugs, we have actively pursued development of SEP-225289 in North America and development of an additional indication for Parkinsonism accompanied by Dementia with Lewy Bodies (DLB) for TRERIEF® in Japan.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
APTIOM® (SEP-0002093)	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	U.S. / Canada				
		Schizophrenia	China				
LONASEN®	blonanserin	(Addition of pediatric usage) Schizophrenia	Japan				
LONASEN	biolianscriff	(New formulation: Transdermal patch) Schizophrenia	Japan				
		Schizophrenia	Japan *1 / China				
LATUDA® (SM-13496)	lurasidone hydrochloride	Bipolar I depression, Bipolar maintenance	Japan				
(SIVI-13496)		(New indication) Bipolar maintenance	U.S. / Europe, etc.				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				*2
		Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
SEP-225289	dasotraline	Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				*3
		Binge eating disorder (BED)	U.S.				*3
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
SB623	TBD	Chronic stroke	U.S.				
EDI EGO	TBD	Parkinson disease	U.S.				
EPI-589	עמו	Amyotrophic lateral sclerosis (ALS)	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				

(As of July 29, 2015)

- \*1 A Phase III study completed, development strategy under consideration \*2 A Phase II / III study completed, development strategy under consideration
- \*3 Phase II / III study

#### **LATUDA®** (lurasidone hydrochloride)

Atypical antipsychotic

(Developed in-house)

LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent that is believed to have an affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonist effects. In addition, LATUDA® is a partial agonist at the serotonin 5-HT1A receptor and has no appreciable affinity for histamine or muscarinic receptors.

#### AS-3201 (ranirestat) Diabetic neuropathy (Developed in-house)

AS-3201 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. This compound has a stronger inhibitory effect and is longer-acting compared to other drugs in this therapeutic area. Clinical studies have shown AS-3201 to have good penetration into nerve tissues, resulting in dose-dependent inhibition of intraneural accumulation of sorbitol and fructose. Based on the results of clinical studies, AS-3201 is expected to show improvement of neuronal function and symptoms related to diabetic neuropathy.

#### SEP-225289 (dasotraline)

Attention-deficit hyperactivity disorder (ADHD), Binge eating disorder (BED) (Developed in-house)

SEP-225289 is a DNRI that inhibits the reuptake of dopamine and norepinephrine. SEP-225289 is being developed as a once daily long-acting treatment. Due to its ability to maintain a stable concentration in blood levels all day, it is expected to be effective over the course of the day.

#### EPI-743 (vatiguinone) Mitochondrial disease **EPI-589** Neurodegenerative diseases

(In-licensed from Edison Pharmaceuticals)

EPI-743 is for synchronizing energy generation in the mitochondria with the counterbalancing of redox stress. It is expected to be the world's first treatment for mitochondrial diseases beginning with Leigh syndrome. EPI-589 is for synchronizing energy generation in the mitochondria with the counterbalancing of redox stress. It is expected to be developed for neurodegenerative indications arising through redox stress.

#### **Oncology Area**

Sumitomo Dainippon Pharma is leading the world in this area based on two innovative compounds acquired through the acquisition of Boston Biomedical, Inc. and peptide vaccines. We are continuing to focus our utmost efforts on the development of BBI608, a first-in-class anticancer drug that targets cancer stem cell pathways, and we plan to launch a new Phase III clinical study in fiscal 2015 for BBI503, an anticancer drug to follow BBI608.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED® (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
		Colorectal cancer (Monotherapy) (Global clinical trial)	U.S. / Canada / Japan, etc.	Accrual of ne	w patients has	been stopped	
		Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
BBI608	TBD	Solid tumors (Ovarian cancer, Breast cancer, Nonsmall cell lung cancer, Melanoma, etc.) (Combination therapy)	U.S. / Canada			*1	
		Malignant pleural mesothelioma (Combination therapy)	Japan			*1	
		Solid tumors (Combination therapy) *3 Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada				
		Hepatocellular carcinoma (Combination therapy)	Japan				
	TBD	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			*1	
		Solid tumors (Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy)	Canada				
BBI503		Ovarian Cancer (Monotherapy)	U.S.				
		Hepatocellular carcinoma (Combination therapy) Solid tumors (Combination therapy)	U.S.		*2		
		Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan				
BBI608+BBI503	_	Solid tumors (Combination therapy)	U.S.				
WT4869	TBD	Myelodysplastic syndromes	Japan		*2		
VV 1-4003	IBU	Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
VV 12123		Solid tumors	Japan				
DSP-7888	TBD	Myelodysplastic syndromes	Japan		*2		
23. 7000	טפו	Solid tumors, Hematologic malignancies	U.S.				

(As of July 29, 2015)

- \*1 Phase II of Phase I / II study \*2 Phase I of Phase I / II study
- ${\tt *3~Multiple~tumor~type-specific~studies~(Gastrointestinal~cancer~,~Hepatocellular~carcinoma,~Glioblastoma,~Pancreatic~cancer)}$

#### **BBI608** Anticancer drug

(Developed in-house)

BBI608 is an orally administered small molecule investigational agent that targets Stat3, leading to inhibition of the critical genes for maintaining cancer stemness. By targeting cancer stem cell pathways, it may provide a new therapeutic option against cancer challenges such as treatment resistance, recurrence and metastasis.

#### **BBI503** Anticancer drug

(Developed in-house)

BBI503 is an orally administered small-molecule investigational agent designed to inhibit Nanog and other cancer stem cell pathways by targeting kinases. By targeting cancer stem cell pathways, it may provide a new therapeutic option against cancer challenges such as treatment resistance, recurrence and metastasis.

#### **DSP-7888** Anticancer drug

(Developed in-house)

DSP-7888 is a therapeutic cancer peptide vaccine candidate derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a novel peptide vaccine candidate containing peptides that induce WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become treatment options for patients with various types of hematologic malignancies and solid tumors that express WT1, by inducing of WT1-specific CTLs that attack WT1-expressing cancer cells. By adding a helper T cell-inducing peptide, improved efficacy over that observed with a killer peptide alone treatment regimen may be achieved. DSP-7888 is expected to be an option for a wide range of patients.

### **Research & Development**

#### **Respiratory Area & Other Areas**

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
Respiratory A	rea						
SUN-101	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				
Other Areas							
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

(As of July 29, 2015)

#### **SUN-101 (glycopyrrolate bromide)**

Chronic obstructive pulmonary disease (COPD)

(Developed in-house)

SUN-101 is an inhalation solution of a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the Pari eFlow® nebulizer system, which is portable and able to deliver medication in approximately two minutes utilizing a vibrating membrane. Currently, there are no LAMAs delivered via nebulizer that are approved by the U.S. Food and Drug Administration (FDA). SUN-101 is a nebulizer delivered LAMA for COPD that the most advanced development stage.

#### **DSP-1747** (obeticholic acid)

Nonalcoholic steatohepatitis (NASH), Primary biliary cirrhosis (PBC)

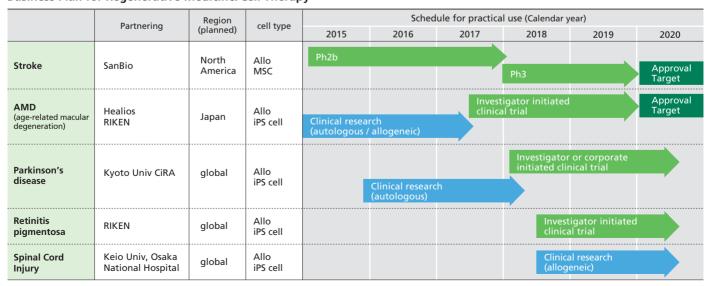
(In-licensed from Intercept Pharmaceuticals Inc.)

DSP-1747 is an agonist to farnesoid X receptor (FXR) whose ligand is the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. The compound is expected to be effective for hepatic dysfunction and hepatic fibrosis associated with an increase of bile acid in the liver.

#### Regenerative Medicine/Cell Therapy Area

Sumitomo Dainippon Pharma is also actively working in new areas such as diseases for which no treatment exists and the Regenerative Medicine/Cell Therapy area. In particular, in the Regenerative Medicine/Cell Therapy area, we have launched a Phase IIb clinical study of SB623 for chronic stroke in the U.S. as well as promoting joint development with Healios K.K. aimed at the world's first commercialization of iPS cells in the eye disease field.

#### **Business Plan for Regenerative Medicine/Cell Therapy**



(As of July 29, 2015)

Treatments utilizing autologous cells require the individualized preparation of cells and other procedures in medical institutions, which takes time and costs a lot. However, treatments utilizing allogeneic cells make it possible to reduce time and costs by supplying a uniform cell therapy to a large number of cancer patients. Sumitomo Dainippon Pharma is striving to create innovative treatments based on leading edge science utilizing allogeneic cells not only through in-house research but also in active partnerships with venture companies and academia.

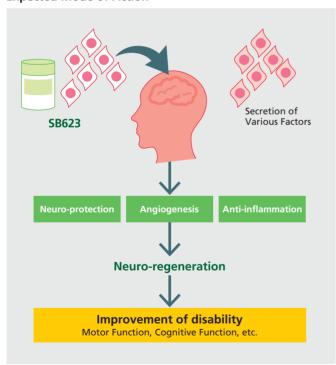
#### Chronic Stroke (SB623)

(In-licensed from SanBio)

SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. Unlike autologous cell therapy, which requires individualized cell preparation at the health care institution, SB623 production can be scaled from a single donor's cells, enabling delivery of uniform-quality products to a large number of stroke patients.

In 2014, Sumitomo Dainippon Pharma concluded a license agreement for joint development and exclusive marketing in North America and is currently conducting a Phase IIb clinical study in partnership with SanBio in the U.S. SB623 indicated outstanding results for chronic stroke in the Phase I and IIa clinical studies.

#### **Expected Mode of Action**



# AMD Retinal Pigment Epithelial (age-related macular degeneration) ("RPE") cells (iPS cell-derived)

Sumitomo Dainippon Pharma concluded a joint development agreement with Healios K.K. in December 2013, and established

the joint venture company Sighregen K.K. through joint investment with Healios K.K. in February 2014. The joint venture will promote research and development of an allogeneic iPS cell-derived retinal pigment epithelial (RPE) cell suspension (HLCR001) with a target of gaining manufacturing and sales approval in 2020.



#### Conduct manufacturing and sales promotion

#### Parkinson's disease Dopaminergic neural progenitor cells (iPS cell-derived)

Clinical research is planned at Kyoto University into the autologous transplantation of dopaminergic neural progenitor cells produced from a patient's own iPS cells as a regenerative treatment for Parkinson's Disease. For allogeneic cell transplantation to follow that, Sumitomo Dainippon Pharma is aiming to develop a treatment using dopaminergic neural progenitor cells produced from the iPS cells of healthy people.

#### Retinitis pigmentosa

Photoreceptor cells (iPS cell-derived)

In the eye disease field, Sumitomo Dainippon Pharma is conducting research into regenerative medicine for retinitis pigmentosa as well as age-related macular degeneration. In basic research, Sumitomo Chemical Co., Ltd. in partnership with RIKEN has already become the first in the world to succeed in growing a three-dimensional retina from human embryonic stem cells. Following on from this, Sumitomo Dainippon Pharma aims to create a treatment based on allogeneic cells using an iPS cell-derived three-dimensional retina.

#### Spinal Cord Injury

Neural precursor cells (iPS cell-derived)

Under the Research Center Network for Realization of Regenerative Medicine, a joint initiative between government, industry and academia, Sumitomo Dainippon Pharma, together with the National Hospital Organization Osaka National Hospital, is taking part as a contributing organization in the Keio University (Professor Hideyuki Okano) project on "Regenerative medicine for spinal cord injury and stroke using neural precursor cells of iPS cell origin" and aims to develop a treatment for the transplantation of iPS cell-derived neural precursor cells for spinal cord injury.

## **Production**

# We provide a stable supply of products based on even more rigorous quality controls.

#### A Product Supply System That Supports Global Expansion

# Strengthening the global supply chain with the aim of stable supply

Sumitomo Dainippon Pharma currently has four manufacturing bases. Suzuka Plant is our main factory serving global supply. It conducts integrated pharmaceutical manufacturing from the production of active pharmaceutical ingredients to packaging. Ibaraki Plant, which is also the main base of the Technology Research and Development Division, is a development-driven pharmaceutical plant able to flexibly accommodate new products and technologies from drug formulation research through commercial production and quality control. Ehime Plant is a manufacturing base for biopharmaceuticals and Oita Plant is our core facility for the production of active pharmaceutical ingredients.

To further strengthen our stable supply system, we will continue to reinforce our global supply chain based on the progress of globalization, including the overseas procurement of raw materials and pharmaceutical intermediates and manufacturing at overseas plants.

In fiscal 2014, we established our production system for LATUDA®, a global strategic product. With active pharmaceutical ingredients manufactured at Oita Plant, we set up a system for formulation at contract manufacturers in Japan and the U.S., in addition to our own plants.

#### Aiming for further increases in productivity

To maintain an optimal product supply system, Sumitomo Dainippon Pharma operates the four factories in Japan as its manufacturing base while promoting contract manufacturing under technology alliances in addition to production at our Group facilities.

To further strengthen our competitiveness, we work to improve cost efficiency, including reviewing expenses, as well as

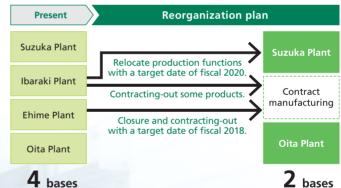
actively striving to increase productivity in our factories such as by reducing lead times.

# To respond flexibly to changes in the business environment

The environment surrounding the pharmaceuticals industry is becoming increasingly challenging. This includes encouragement of the use of generic medicines and the strengthening of controls on healthcare costs, such as NHI price reductions on long-listed brands.

To accommodate such changes in the business environment, Sumitomo Dainippon Pharma decided to reorganize its production sites in order to build a stable and efficient production system that can respond flexibly to swings in production volumes and maintain and improve our cost competitiveness. By doing this, our production sites will be integrated into two: Suzuka Plant and Oita Plant, the core facility for the production of active pharmaceutical ingredients.

Going forward, we will efficiently implement activities aimed at integrating our production sites and reduce manufacturing costs while conducting stable production and supply of safe and secure products.







The production of pharmaceuticals requires a high level of quality assurance. Consequently, rigorous GMP (Good Manufacturing Practice) standards have been established in many countries. Pharmaceuticals are exported around the world after obtaining regulatory approvals from government institutions of importing nations, including the FDA (U.S. Food and Drug Administration), EMA (the European Medicines Agency), and TGA (Australia's Therapeutic Goods Administration). Therefore, operating standards in Sumitomo Dainippon Pharma Group are consistent with the GMP standards of Europe and the U.S. Furthermore, we have established a high level of facility design and quality assurance systems that pass audits by overseas partner companies and meet strict quality standards at the global level such as guidelines from the ICH (International Conference on Harmonisation), which deliberates on the harmonization of EU, U.S. and Japanese pharmaceutical regulations.

The standards for quality assurance are expected to become increasingly rigorous. Sumitomo Dainippon Pharma Group is therefore making proactive investments in manufacturing facilities—including The New Solid Dosage Form Facility and RABS (restricted access barrier system) that increases the level of sterility assurance—to meet future standards. We are focusing our efforts on strengthening our supply system to continue providing pharmaceuticals with higher quality.

#### Promoting global supply chain management

To ensure the stable and sustainable procurement of the raw materials and other items used in its products, Sumitomo Dainippon Pharma continuously and systematically promotes measures to prevent interruption of its supply of raw materials, including the use of multiple suppliers, taking alternative materials into consideration and maintaining appropriate inventories. Currently, the company is working on measures for individual

products. In fiscal 2014, we conducted a review of production strategy accompanying the global expansion of our main products and the reorganization of our production sites.

investigational drugs, etc.

To conduct fair, open and transparent transactions, Sumitomo Dainippon Pharma 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.

In its overseas procurement, in addition to dealing speedily with problems as a matter of course, we work to prevent problems from occurring and eliminate supply uncertainties by building deeper relationships of trust through smooth communication with overseas business partners and trustworthy procurement activities.

# Efforts directed at our responsibility for product supply and environmental conservation

The four factories in Japan have obtained ISO 14001 certification, the international standard for environmental management systems. We continue to reduce production costs and conduct ecofriendly production activities through the automation of facilities and other laborsaving measures, the optimization of production sites, appropriate inventory control and the introduction of co-generation systems.

In addition to promoting management of industrial safety and health in order to run accident-free and disaster-free operations based on compliance, we work to reinforce the complementary functions of our distribution centers in east and west Japan in order to maintain stable supply even in an emergency, such as natural disasters.

## Marketing

In Japan, we are concentrating resources on growth products to expand sales. Globally we are focusing on maximizing the product value of LATUDA®.





#### Japanese Market

- Concentrate on strategic, new and specialty Products
- Raise efficiency of sales organization

#### **Main Products**



#### **AIMIX®**

Launch December 2012

Indications Hypertension

Features Combination product of irbesartan (AVAPRO®) and amlodipine besilate (AMLODIN®)



#### **LONASEN®**

Launch April 2008

Indications Schizophrenia

Features Dopamine D2 receptors and serotonin 5-HT2A receptors blocker



#### **TRERIEF®**

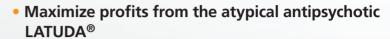
Launch March 2009

Indications Parkinson's disease

Parkinson's disease drug with levodopa-enhancing effect



#### **North American Market**



 Expand profits from the long-acting beta-agonist BROVANA® and new drug APTIOM®

#### **Main Products**



#### **LATUDA®**

Launch February 2011 (U.S.) September 2012 (Canada)

Indications Schizophrenia, Bipolar I depression

Features Affinity for dopamine D2, serotonin 5-HT<sub>2A</sub> and serotonin 5-HT7 receptors where it has antagonist effects

**APTIOM®** 

Launch April 2014 (U.S.) October 2014 (Canada)

Indications Partial-onset seizures (adjunctive treatment)

Features A voltage-gated sodium channel blocker is taken once daily and can be taken whole or crushed, with or without food

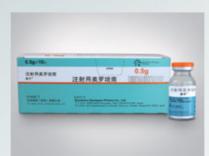


#### **Chinese Market**

- Expand profit from existing products
- Establish highly efficient business foundation

#### **Main Products**





#### **MEROPEN®** (brand name in China: MEPEM®)

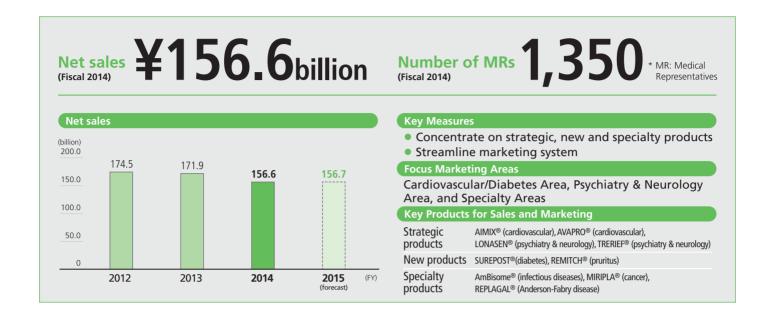
Launch 1999

Indications General infections, febrile neutropenia

Features Standard therapy for severe infections, used in many countries

## Marketing

## Pharmaceutical Business Japanese Market



#### Fiscal 2014 Main Initiatives and Business Results

Sumitomo Dainippon Pharma concentrated efforts on activities to provide product information aimed at maximizing sales of our strategic products AIMIX®, a therapeutic agent for hypertension, and TRERIEF®, a therapeutic agent for Parkinson's disease, as well as METGLUCO®, a biguanide oral hypoglycemic, and other products. However, as a result of NHI price revisions implemented in April 2014 and the spread of measures to encourage the use of generic drugs, sales of

Sales of Major Products (Before reduction of rebates; Billions of yen)

Brand Name	Therapeutic Indication	FY 2013	FY 2014	Rate of change (%)	FY 2015 forecast
AIMIX®	Therapeutic agent for hypertension	6.9	12.0	72.7	17.5
AVAPRO®	Therapeutic agent for hypertension	12.1	11.4	(5.8)	11.5
LONASEN®	Atypical antipsychotic	12.6	11.5	(9.0)	13.0
TRERIEF®	Therapeutic agent for Parkinson's disease	9.5	11.6	22.4	15.2
SUREPOST®	Rapid-acting insulin secretagogue	1.7	2.4	42.3	3.7
AmBisome®	Therapeutic agent for systemic fungal infection	4.8	4.3	(9.7)	4.9
MIRIPLA®	Therapeutic agent for hepatocellular carcinoma	1.2	0.9	(22.8)	1.0
REPLAGAL®	Anderson-Fabry disease drug	9.8	9.7	(1.2)	11.0
METGLUCO®	Biguanide oral hypoglycemic	15.8	17.1	8.4	14.0
AMLODIN®	Therapeutic agent for hypertension and angina pectoris	27.0	19.6	(27.3)	17.0

long-listed drugs fell significantly. The April 2014 medical fee revision has a particularly big impact, accelerating the use of generic drugs.

The increase in sales of AIMIX®, TRERIEF® and METGLUCO®, on which we concentrated efforts, was insufficient to offset the decline in sales of long-listed drugs, resulting in a considerable decline in sales overall.

#### Cardiovascular/Diabetes Area

In the cardiovascular area, Sumitomo Dainippon Pharma strives to be a partner in antihypertensive treatment, handling a variety of antihypertensive products with a lineup consisting of an angiotensin II receptor blocker (ARB), a calcium channel blocker (CCB), an ARB and CCB combination product, a diuretic, an angiotensin-converting enzyme (ACE) inhibitor, and an alpha-beta blocker. AlMIX®, which contains 10mg of amlodipine, and is unique among ARB and CCB combination products with expectation of a powerful hypotensive effect. We are expanding sales by providing information about the antihypertensive area as a whole, including the drugs AVAPRO® and AMLODIN®.

In the diabetes area, the change of indication to Type 2 Diabetes for SUREPOST® was approved in November 2014, and sales increased. Sales of METGLUCO®, which has been expanding until fiscal 2014, are expected to decline in fiscal 2015, due in part to the launch of a generic drug in June 2015. In addition, we concluded a sales collaboration agreement in Japan with Eli Lilly Japan K.K. for once-weekly GLP-1 receptor agonist TRULICITY® indicated for Type 2 diabetes in July 2015, adding to our product lineup in the diabetes area which is one of our focus areas.



#### **Psychiatry & Neurology Area**

Sumitomo Dainippon Pharma handles therapeutic agents for schizophrenia, Parkinson's disease, mood disorders, epilepsy and so on. Out of these, we are focusing on strategic products TRERIEF® and LONASEN®, an atypical antipsychotic.

TRERIEF® OD 25mg tablets, launched as an additional dosage formulation in February 2015, break down rapidly orally, helping the many Parkinson's disease patients who suffer from dysphagia. We are currently striving to increase the provision of product information.

# Specialty Areas (Cancer, Infectious Diseases, Rare Diseases)

Since fiscal 2013, we have also been focusing on Specialty Areas composed of cancer, infectious diseases, rare diseases and other fields.

In the cancer area, we handle MIRIPLA®, a therapeutic agent for hepatocellular carcinoma. In the area of infectious diseases, we are working to provide information mainly about AmBisome®, a therapeutic agent for systemic fungal infection, while also promoting the appropriate use of MEROPEN®, a carbapenem antibiotic.

In the area of rare diseases, we are focusing on expanding sales of REPLAGAL®, an Anderson-Fabry disease drug. In addition, we are raising awareness of rare diseases through such activities as establishing a website to provide information on rare diseases to medical professionals and patients.

#### **FY2015 Business Expansion and Outlook**

In fiscal 2015, as a result of the spread of policies to encourage the use of generic drugs, long-listed drug sales will continue to decline, and sales of METGLUCO® are also expected to fall accompanying the sales launch of generic drugs. Our aim is to maintain the size of our business by offsetting this decline with increased sales of strategic products AlMIX®, LONASEN® and TRERIEF® and the launch of promotions for REMITCH®, the first therapeutic agent with an indication for pruritus in chronic liver disease patients. In fiscal 2015, in addition to REMITCH®, we also concluded a sales collaboration agreement for TRULICITY® in July 2015. We will continue to promote alliances and in-licensing.

We will further strengthen the Psychiatry area with an additional 100 MRs bringing the number to approximately 330.

Furthermore, while implementing selection and concentration in the allocation of marketing resources, we will promote ongoing streamlining through the active use of hybrid marketing that links provision of information by MRs with e-promotions utilizing the Internet.

#### **FOCUS**

## Promoting hybrid marketing

In order to provide targeted and timely information to medical professionals, in conjunction with visits by MRs, we are using e-promotion, including MR Kun, a

tool for providing product information over the Internet operated by M3, Inc., streaming live broadcasts of lectures from our own studio and distributing a range of e-mail newsletters. In 2013, we launched MyPage, an industry-first customized webpage service for medical professionals. This system allows two-way communication between medical professionals and MRs over the Internet.

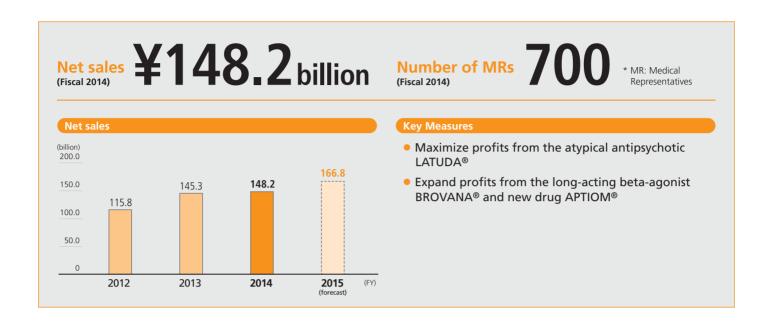
Going forward, in addition to conventional MR detailing, we will actively promote hybrid marketing, which combines diverse e-promotion, to expand sales by providing appropriate product information.



Website aimed at medical professionals

## Marketing

## Pharmaceutical Business North American Market



#### Fiscal 2014 Main Initiatives and Business Results

The subsidiary Sunovion Pharmaceuticals Inc. (Sunovion) is responsible for the Sumitomo Dainippon Pharma Group's marketing activities in North America. In fiscal 2014, the commercial organization promoted activities aimed at further expanding sales of LATUDA®, the atypical antipsychotic which is a global strategic product and gained an additional indication for bipolar depression in fiscal 2013. In addition, Sunovion delivered another year of revenue growth for COPD treatment BROVANA® and launched U.S. sales of antiepileptic drug APTIOM® in April 2014.

Although sales of sedative hypnotic LUNESTA®, whose period of exclusivity expired, declined, segment sales grew. This is partly attributable to the impact of the weakened yen in addition to considerable expansion in sales of LATUDA®, on which Sunovion has been concentrating its efforts. On the

Sales of Major Products (Billions of yen)

Brand Name	Therapeutic Indication	FY 2013	FY 2014	Rate of change (%)	FY 2015 forecast
LATUDA®	Atypical antipsychotic	42.2	82.5	95.6	120.4
BROVANA®	Long-acting beta-agonist	16.8	22.2	31.8	26.2
APTIOM®	Antiepileptic	_	2.5	_	7.0
LUNESTA®	Sedative hypnotic	58.0	11.5	(80.1)	3.9
XOPENEX®	Short-acting beta-agonist	12.1	8.5	(29.5)	2.6
CICLESONIDE®	Inhaled corticosteroid, Corticosteroid nasal spray	8.2	6.7	(17.6)	6.3

profit front, sales-related expenses, particularly advertising and publicity expenses for LATUDA® and fees related to sales of brand-name drugs sold through the government managed health insurance programs increased significantly, but profit rose due to growth in net sales and the end of the amortization of patent rights related to LUNESTA®.

In October 2014, Sunovion transferred the marketing rights for short-acting beta-agonist XOPENEX® inhalation solution (IS) for US\$45 million. XOPENEX® has made a major contribution to Sunovion's growth. However, it was sold as the patent term has expired. Sunovion will continue to sell XOPENEX HFA®.

With the aim of maximizing profit from LATUDA® efforts have been most concentrated on early market penetration for the additional indication of bipolar depression, which was approved in June 2013. The number of LATUDA® prescriptions has been increasing steadily as a result of enhanced promotion activities by MRs dedicated exclusively to LATUDA®, who have been at work since the product's launch, as well as publicity that includes television advertising and the Internet. Sunovion further aims to maximize profit from LATUDA® through the effective investment of marketing resources in order to grow it into a blockbuster drug.

In April 2014, Sunovion launched APTIOM®, an antiepileptic drug which was approved for use as adjunctive treatment of partial onset seizures. APTIOM®, a voltage-gated sodium channel blocker, is a once-daily dose antiepileptic drug that delivers ongoing reduction in seizures to patients with partial onset seizures. The tolerability and safety of APTIOM® has been recognized in clinical studies, and the U.S. Food and Drug Administration (FDA) has not classified it as a controlled substance requiring investigation by the Drug Enforcement Administration (DEA). We assigned 120 MRs dedicated



exclusively to APTIOM® and concentrated efforts on promoting it as a strategic product.

#### **FY2015 Business Expansion and Outlook**

In fiscal 2015, Sunovion will continue to focus efforts on the expansion of LATUDA®, BROVANA® and APTIOM®.

We will continue advertising and promotion for LATUDA® that includes television commercials and activities to provide information to medical professionals with plans to grow it into a blockbuster drug in fiscal 2015. In addition, generic versions of competing drugs were launched in 2015, but it is considered that the impact of these on LATUDA® will be limited.

Sunovion will execute sales and marketing strategies to

further expand sales of BROVANA®. Since its launch in 2007, BROVANA® has experienced seven years of revenue growth. Net revenue has consistently increased each year.

Sunovion is aiming to maximize sales of APTIOM® as soon as possible and will continue to focus efforts on marketing activities. Moreover, we intend to gain approval for an additional indication as a monotherapy for epileptic seizures in fiscal 2015, and we anticipate that it will contribute to expanding sales of APTIOM®. We have set a target of ¥50.0 billion in future peak sales.

Consequently, as in fiscal 2014, we will aim for sales growth as the increase for LATUDA® and APTIOM® will compensate for the impact from the fall in sales of existing products such as LUNESTA®, whose period of exclusivity has expired.

#### **FOCUS**

## Stepping up the LATUDA® promotion

Sunovion is effectively using MR activities to provide information at the same time as advertising and publicity, including television commercials and the Internet (http://www.latuda.com), to deliver information on LATUDA® to

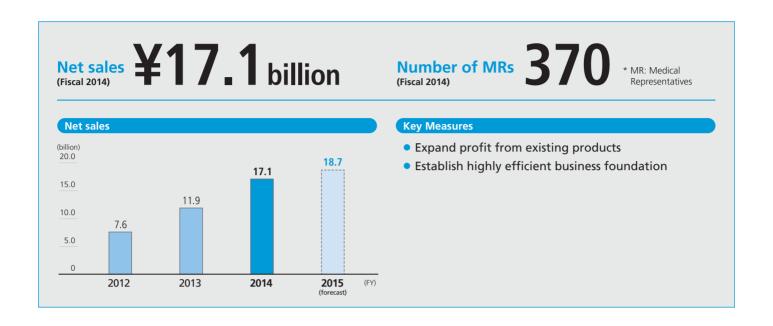
patients who have been waiting for treatments for bipolar depression. In order to improve awareness levels for LATUDA®, we have begun new direct-to-customer (DTC) advertising, which has been picked up by television, newspapers, magazines and Internet media. Apart from DTC advertising, we have also been introducing the pharmacological properties by working on such strategies as promotions to medical professionals, peer-to-peer programs, and addressing patient groups as we try to increase brand awareness.



LATUDA® commercial broadcast in the U.S.

## Marketing

## Pharmaceutical Business Chinese Market



#### Fiscal 2014 Main Initiatives and Business Results

The Sumitomo Dainippon Pharma Group conducts marketing activities in China through its local subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., which currently sells four products: MEPEM® (brand name in Japan: MEROPEN®), a carbapenem antibiotic, ALMARL®, a therapeutic agent for hypertension, angina pectoris and arrhythmia; SEDIEL®, a serotonin-agonist anti-anxiety drug, and GASMOTIN®, a gastroprokinetic.

In order to swiftly acquire a share of an enormous market,

Sales of Major Products (Billions of yen)

Brand Name	Therapeutic Indication	FY 2013	FY 2014	Rate of change (%)	
MEROPEN®	Carbapenem antibiotic	9.8	14.3	45.7	16.1



we have reinforced and enhanced the marketing structure centered on the Market Department, responsible for marketing, and the Sales Promotion Department, responsible for promotion, covering 30 provinces and cities (major cities, provinces and autonomous regions) with 370 MRs (as of March 31, 2015).

In fiscal 2014, sales, primarily of mainstay MEROPEN®, increased significantly. As a result, net sales soared 43.7% year on year. On the profit front, sales-related expenses and other expenses increased, but segment profit rose 96.4% year on year.

#### **FY2015 Business Expansion and Outlook**

We believe that sales of MEROPEN® will continue to grow as the importance of carbapenem antibiotics in the treatment of severe infections has become established. Nevertheless, the Chinese market is currently witnessing a tendency toward reduction in drug prices via the provincial tendering system. Growth is expected to slow in fiscal 2015 compared to the previous fiscal year.

In terms of candidate new products, in addition to the atypical antipsychotic blonanserin (brand name in Japan: LONASEN®) and anticancer antibiotic amrubicin HCI (brand name in Japan: CALSED®) for which we are currently applying for approval, we also intend to apply for approval of lurasidone hydrochloride (brand name in North America: LATUDA®), an atypical antipsychotic which is a global strategic product, in fiscal 2015. Going forward, we will continue promoting development in the Chinese market as well as maximizing the scale of the business and earnings by enhancing the marketing structure and continuously launching new products.

### Marketing

## **Related Business**

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

Food Ingredients, Food Additives and Chemical Product Materials DSP Gokyo Food & Chemical Co., Ltd.

http://www.dsp-gokyo-fc.co.jp/english/

The food ingredients, food additives and chemical product materials business is handled by Sumitomo Dainippon Pharma 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. DSP Gokyo Food & Chemical has launched sales of GLYLOID® in North America through a sales alliance partner.

The chemical product materials business encompasses such products as cosmetic materials, active pharmaceutical ingredients, electronic chemicals and coating materials. Leveraging Sumitomo Dainippon Pharma'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 DS Pharma Animal Health Co., Ltd. http://animal.ds-pharma.co.jp/eng/

The animal health products business is conducted by Sumitomo Dainippon Pharma subsidiary DS Pharma Animal Health Co., Ltd., and the major products are veterinary medicinal products and therapeutic nutritional formulas for companion animals, primarily dogs and cats, as well as for livestock such as cattle, swine, poultry, horses and aquacultured fish. In November 2014, DS Pharma Animal Health established a new Diagnostic Service Department to take charge of gathering information, strategy planning, marketing and research and development of new veterinary clinical tests.

In the companion animal business, its main focus, DS Pharma Animal Health provides various veterinary medicinal products, including CONSAVE®, a antiepileptic drug for dogs, PRONAMID®, a canine gastroprokinetic agent for the improvement of canine gastrointestinal motility, VICTAS®S, a series of antibacterial formulations for dogs and cats, APINAC®, a chronic heart failure ameliorating for dogs, ISOFLU®, an inhalant anesthetic, as well as medicinal products used for joint diseases in dogs, canine heartworm preventives, and in the field of ophthalmology and dentistry. In addition to its veterinary medicinal products the company supports the total wellbeing of companion animals through providing a full line of nutritious pet foods developed by Hill's Pet Nutrition. Inc. including Prescription Diet®, special foods of therapeutic nutritional formulas, and Science Diet Pro®, the ones of wellness nutritional formulas.

For the livestock industries, DS Pharma Animal Health provides VICTAS® Soluble Powder 25%, a fluoroquinolone antibiotic for

swine, URSO®, a bile acid product for cattle, EQVALAN® paste, an oral anthelmintic for horses, and other products. For the aquaculture industry, the company provides vaccines and other products including anesthetics and synthetic antibacterial drugs for fish and crustaceans, contributing to security and safety of food. In addition, the company deals in feed additives and mixed feeds for maintaining animal's health and improving productivity.

As a research and development based animal health company, we create high-quality products that deliver new value that support the well-being of animals and strive to promote a blissful society where animals and people live together harmoniously.



Diagnostics and Research Materials **DS Pharma Biomedical Co., Ltd.** 

http://www.dsp-bio.com/

Sumitomo Dainippon Pharma subsidiary DS Pharma Biomedical Co., Ltd. conducts a 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 like influenza and Streptococcus, and the Rapicheck® H-FABP diagnostics kit for acute myocardial infarction. It has also developed Osteolinks TRAP-5b® and other in-vitro diagnostic reagents for bone resorption markers, as well as the Lumipulse Presto® whole PTH DSPB, a parathyroid hormone (PTH) assay kit, and diagnostics for central nervous system disorders. The company is also developing biomarkers for use in companion diagnostics, which are performed to predict the efficacy and side-effects of drugs before they are administered.

In addition, to facilitate advanced research related to medical care, the company also develops and supplies these research materials including S-Medium, a feeder-free, chemically defined medium, and POCA®, a series of ready-to-use assay models effective in drug discovery research, can both be applied in regenerative therapy using iPS and other human stem cells. In the research and development of early-stage drug discovery assay systems related to these and other cell culture technologies, the company leverages the synergistic effects of its operations with the regenerative medicine and cell therapy business of Sumitomo Dainippon Pharma to contribute to the development of medicine.



## Corporate Governance

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

Sumitomo Dainippon Pharma strengthens the internal control system, including risk management, to ensure business soundness and transparency while enabling rapid decision making. We strive to further enhance corporate governance and continuously improve corporate value.

#### **Management Structure**

Sumitomo Dainippon Pharma has adopted the executive officer system where the Board of Directors entrusts executive officers with operational responsibilities. In addition, we have selected an Audit & Supervisory Board system, independent of the Board of Directors, to audit the execution of duties by the directors.

Sumitomo Dainippon Pharma's outside officers have no material relationship with the company, and we have registered the two outside directors, Hidehiko Sato and Hiroshi Sato, with Tokyo Stock Exchange, Inc. as independent officers.

#### **Reasons for Appointment of Outside Directors**

Both of the outside directors are independent of the company, and we have no concern of a conflict of interest with ordinary shareholders. See page 40 for the career background of the two outside directors.

#### Hidehiko Sato

Hidehiko Sato served as Counselor of the Cabinet Legislation Bureau and Commissioner General of the National Police Agency. Sumitomo Dainippon Pharma appointed him as outside director to benefit from his extensive background, broad insight, and expertise as an attorney-at-law.

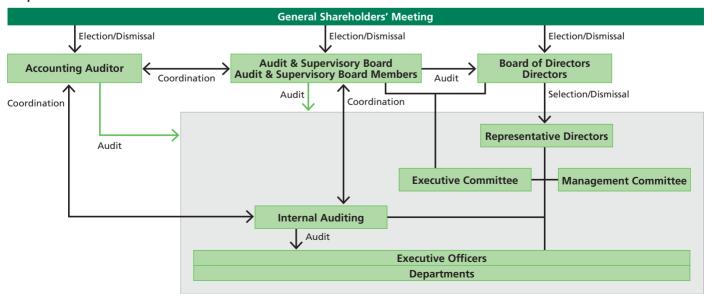
#### Hiroshi Sato

Sumitomo Dainippon Pharma appointed Hiroshi Sato as outside director to benefit from his wealth of experience, track record, and wide-ranging insight as a corporate executive.

#### Status of Convocation of the Meeting of the Board of Directors

Organizational Body	Composition	Frequency of convocation	Purpose	Convened in Fiscal 2014
The Board of Directors	The Directors 8 members, (including two outside directors)	Once a month as a rule	Resolving and reporting important management matters	14 times
The Audit & Supervisory Board	The Audit & Supervisory Board 5 members, (including three outside Audit & Supervisory Board members)	Once a month as a rule	Discussing and resolving important audit-related matters	13 times
Management Committee	The members of the Board of Directors, and Executive Officers 9 members	Twice a month as a rule	As a consultative body of the Representative Director, President and CEO for decision making and reviewing important business management matters, guided by the basic policies set by the Board of Directors	21 times
Executive Committee	Executives, including the members of the Board of Directors, the Audit & Supervisory Board, and Executive Officers 26 members (including two outside directors and three outside Audit & Supervisory Board members)	Once a month as a rule	Sharing the status of business operations and other important management matters among the company executives, including the members of the Board of Directors, the Audit & Supervisory Board, and Executive Officers	11 times

#### **Corporate Governance Structure**



#### **Audit System**

The Audit & Supervisory Board, composed of all the Audit & Supervisory Board members, reviews and sets the audit policy and audit plans, among other things. The members conduct individual interviews with the representative directors on a regular basis, receive reports from and hold discussions with the other directors and employees and collaborate with each or both of the accounting auditor and the Internal Auditing Department to enhance effectiveness of audit duties. In addition, the members attend key business meetings, including those of the Board of Directors, to review appropriateness of management decisions by the directors and audit the status of the operations of the internal control system by receiving reports from directors and employees on the status of execution of their duties, requesting explanations as necessary and reviewing important decision-making documents, among other things. The dedicated staff has been established for the Audit & Supervisory Board members to raise the effectiveness of their audits and to smoothly accomplish auditing tasks.

Accounting audits are conducted by KPMG AZSA LLC, under the audit agreement. Internal audits are carried out by the Internal Auditing Department, which reports directly to the President of Sumitomo Dainippon Pharma. The Internal Auditing Department audits basic elements for achieving the objectives of internal control for internal functions, as well as subsidiaries, from a fair and independent standpoint.

Audit & Supervisory Board members, accounting auditors and internal auditors meet periodically to exchange information.

#### **Accounting Audits, Remuneration**

	Amount to be paid (Millions of Yen)
Consideration to be paid for the services (audit attestation services) described in Paragraph 1 of Article 2 of the Certified Public Accountant Act (Act No. 103 of 1948)	77
Total amount of fees to be paid in cash or otherwise by the company or subsidiaries of the company	97

(Note) 1. Under the Audit Agreement between the company and the Accounting Auditor, there is no distinction between the compensation and the like for an audit under the Companies Act and the Financial Instruments and Exchange Act. Moreover, the two amounts cannot be substantially distinguished from each other. Thus, the amount of compensation and the like related to the audit attestation services record the total sum of these two amounts.

Among the significant subsidiaries, Sunovion Pharmaceuticals Inc., Boston Biomedical, Inc. and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. were audited by firms other than the Accounting Auditor of the Company.

## Factors That Could Significantly Influence Corporate Governance

Sumitomo Chemical Co., Ltd. is the parent company of Sumitomo Dainippon Pharma with a 50.22% share of voting rights. Respect for our autonomy is affirmed by the parent company and our management independence is maintained, with no requirements for approvals by the parent company concerning our business operations.

Furthermore, no director of Sumitomo Chemical is appointed as a director of Sumitomo Dainippon Pharma. Sumitomo Dainippon Pharma retains some personnel seconded from the parent company based on our own judgment, and believes this has no influence on our business management or operations.

Sumitomo Dainippon Pharma believes that the interests of other shareholders are not negatively affected.

#### **Subsidiary Management Structure and Governance**

Sumitomo Dainippon Pharma has had the group company management rules in place to ensure Group companies implement appropriate business operations. Each of the divisions in charge of business management of Group companies is required to monitor execution of business of Group companies and provide instruction to and support for Group companies, as appropriate.

The Sumitomo Dainippon Pharma Group is promoting a Group-wide CSR management system, including establishment and maintenance of global corporate governance structure, enhancement of global compliance system, and promotion of social contribution efforts.

#### **Major Subsidiaries**

	Name	Ownership Ratio (%)
	DSP Gokyo Food & Chemical Co., Ltd.  Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.	100
Japan	DS Pharma Animal Health Co., Ltd. Manufacturing and sales of veterinary medicines, etc.	100
	<b>DS Pharma Biomedical Co., Ltd.</b> Manufacturing and sales of diagnostics, etc.	100
	<b>Sunovion Pharmaceuticals Inc.</b> Manufacturing and sales of pharmaceuticals	100
Outside Japan	Boston Biomedical, Inc. Research and development in the oncology area	100
	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. Manufacturing and sales of pharmaceuticals	100

## **Development and Implementation of Internal Control System**

In accordance with Japan's Companies Act, the Board of Directors of Sumitomo Dainippon Pharma passed a resolution on the basic policies for the development and implementation of the internal control system for the company to carry out its operations properly. Pursuant to the basic policies, the status of implementation efforts is reported to the Board of Directors in the last month of the fiscal year. We continue evaluating and upgrading the basic policies, as appropriate.

#### **Internal Control over Financial Reporting**

In accordance with Japan's Financial Instruments and Exchange Act, Sumitomo Dainippon Pharma designs and operates a system in line with the company's basic framework for internal control over financial reporting and conducts assessment of internal control to ensure the reliability of financial reporting.

The scope of the assessment encompasses the companywide internal control system at Sumitomo Dainippon Pharma and those of its major consolidated subsidiaries, as well as business processes with the potential for significant impact on finances. Sumitomo Dainippon Pharma assesses the effectiveness of the design and implementation of internal control.

#### **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 Audit & Supervisory Board members consists of basic remuneration determined by the Audit & Supervisory Board, within the scope of total remuneration approved at the annual shareholders' meeting.

#### **Amount of Executive Remuneration**

Category	Number	Amount of Remuneration and the like (Millions of Yen)
Directors	9	354
Audit & Supervisory Board Members	5	89
Total	14	443

- (Note) 1. The table includes the amount of remuneration and the like for the five (5) Outside Officers, which is 59 million yen in total.
  - 2. The above includes the one (1) Director who retired upon the conclusion of the 194th Annual Shareholders' Meeting held on June 19, 2014.
  - 3. The respective amounts of remuneration and like for Director and Audit & Supervisory Board Members that were approved in the Shareholders' Meeting do not exceed 400 million yen annually for Directors, and 100 million yen annually for Audit & Supervisory Board Members.

#### **Appropriate Information Disclosure**

Based on the recognition that transparency is vital to being trusted by society, Sumitomo Dainippon Pharma discloses corporate information to various stakeholders in a timely, appropriate and fair manner in accordance with the in-house regulations for management and disclosure of information, which stipulate the criteria and procedures for the disclosure of information.

We promptly disclose information for which timely disclosure is required, such as determined facts, occurring facts, and account settlement-related information provided for in the Tokyo Stock Exchange's various rules concerning timely disclosure, through the Timely Disclosure Network (TDnet), the timely disclosure notification system provided by the stock exchange. With regard to information for which timely disclosure is not required, we

actively disclose information needed for stakeholders to understand Sumitomo Dainippon Pharma properly through such means as press releases and our corporate website.

#### **Efforts to Facilitate the Exercise of Voting Rights**

Sumitomo Dainippon Pharma 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, Sumitomo Dainippon Pharma posts an English translation of the convocation notice and other materials on the company's website together with the Japanese version on the day the convocation notices are sent. Methods of voting include the Electronic Voting Platform and other digital methods (such as the Internet) in addition to conventional voting in writing.

In addition, Sumitomo Dainippon Pharma takes measures to enliven its annual shareholders' meetings, such as providing video presentations of the business report and other reports during the meeting. Details of the results of resolutions on proposals at the annual shareholders' meeting are submitted to the Kanto Local Finance Bureau in an extraordinary report and disclosed on our website.

#### **Communication with Shareholders and Investors**

Sumitomo Dainippon Pharma 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. In addition, meetings focused on specific topics are held as appropriate.

We conduct regular visits for foreign shareholders, visiting investors in Europe, the U.S. and Asia in fiscal 2014. We also dub the meetings and conference calls held in Japan into English (including the Q&As) and post them on our website. We also take part in the small meetings for invited clients that securities firms hold in Japan for foreign investors.

We strive to hold meetings for individual investors once or twice a year.

We also post other materials on our website in Japanese and English as appropriate. These materials include financial results summaries and supplementary materials, materials from investor meetings (including video streaming), press releases, annual reports, factbooks and notices of convocation for the general meeting of shareholders among others.

#### **Compliance**

Sumitomo Dainippon Pharma considers the promotion of compliance the foundation of all business activities, and in its Declaration of Conduct, Sumitomo Dainippon Pharma states 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, Sumitomo Dainippon Pharma has established the Compliance Standards for business activities.

In fiscal 2014, the Compliance Committee, presided over by the executive officer in charge of compliance, met two times. The committee ascertained the status of compliance efforts throughout Sumitomo Dainippon Pharma and issued appropriate reminders, recommendations, and advice to the parties concerned.

In addition, Sumitomo Dainippon Pharma conducted education and training for all employees on many topics, including the Compliance Standards, corruption, donations in the pharmaceutical industry and the life science field. As a global initiative, the Global Compliance Committee, which is composed of members from Sumitomo Dainippon Pharma and its Group companies in the U.S., China and Europe, met two times to share information and exchange opinions. Sumitomo Dainippon Pharma 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.

#### **Risk Management**

In order to respond to risk that affects business activity, Sumitomo Dainippon Pharma enacted the internal rule "Risk Management Promotion Rule" and organized the "Risk Management Committee" led by the president. We also formulate the risk management program every year, and each section of our company is systematically working on the solution of each problem. In addition, in order to strengthen the ability to respond rapidly to crises, we consolidate the necessary regulations and documents according to the assumed individual

risk, and execute awareness raising activities for employees through concrete training and the instruction courses.

#### **Business Continuity Plan (BCP)**

Sumitomo Dainippon Pharma formulates the business continuity plan (BCP) from the viewpoint of stable supply of the pharmaceutical products that is our social mission, and assumes the occurrence of a large earthquake and an infectious disease pandemic, such as new strains of influenza.

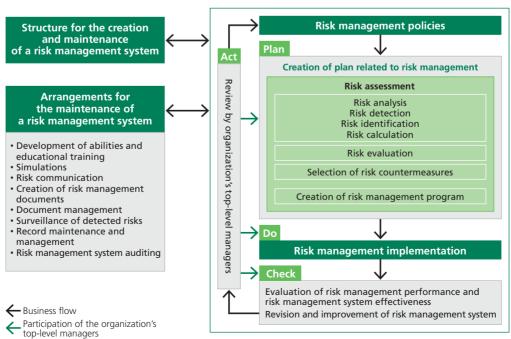
For example, in the outbreak of a pandemic, we respond with reference to the epidemic phase of WHO and Japan's Ministry of Health, Labour and Welfare to establish our own epidemic danger period phases, implement countermeasures, and prepare manuals for the set up and operational procedures of a headquarters for countermeasures.

#### **Information Management**

We perform appropriate and fair disclosure of information to society, and properly protect and manage the individual information and customers' information obtained through business activity. Moreover, in order to protect our information property from all information risks by the physical, technical, or human risks, we execute technical measures and review of rules corresponding to change in the social environment and the advancement of information technology, and promote the education for employees to recognize the importance of information security and practice the rules.

In addition, we manage insider information appropriately in accordance with our in-house regulation, the Inside Information Management Rule.

#### **Risk Management System**



## Board Members and Executive Officers (As of August 1, 2015)

#### **Board Members**



Masayo Tada Representative Director, **President and Chief Executive Officer** Executive Director, Drug Development

1968: Joined Sumitomo Chemical Co., Ltd.

2005: Managing Executive Officer of the former Sumitomo Pharmaceuticals Co., Ltd.

2005: Director of the former Sumitomo Pharmaceuticals Co. Ltd.

2005: Member of the Board of Directors and Executive Vice President of the Company

2007: Member of the Board of Directors and Senior Executive Vice President of the Company

2008: Representative Director, President and Chief Executive Officer of the Company



**Makoto Hara** Member, Board of Directors, **Executive Vice President** Sales & Marketing; Legal Affairs; Intellectual Property; International Business Management

1974: Joined Sumitomo Chemical Co., Ltd.

2005: Executive Officer of Sumitomo Chemical Co., Ltd.

2008: Managing Executive Officer of Sumitomo Chemical Co., Ltd.

2010: Senior Managing Executive Officer of Sumitomo Chemical Co., Ltd.

2010: Joined the Company 2010: Senior Executive Officer of the Company

2011: Member of the Board of Directors and Senior Executive Officer of the Company

2012: Member of the Board of Directors and Executive Vice President of the Company (current)



Hiroshi Noquchi Representative Director, **Senior Executive Vice President** Executive Director, Drug Research; Global R&D Office; Global Oncology Office

1971: Joined Sumitomo Chemical Co., Ltd.

1992: Joined the former Sumitomo Pharmaceuticals Co., Ltd.

2000: Director of the former Sumitomo

Pharmaceuticals Co., Ltd. 2005: Executive Officer of the Company

2007: Member of the Board of Directors and Executive Officer of the Company

2009: Member of the Board of Directors and Senior Executive Officer of the Company

2011: Member of the Board of Directors and

Executive Vice President of the Company

2012: Representative Director and Senior Executive Vice President of the Company (current)



Yoshihiro Okada Member, Board of Directors, Senior Executive Officer Executive Director, Manufacturing; Technology Research & Development

1975: Joined the Company

2008: Executive Officer of the Company

2010: Member of the Board of Directors and **Executive Officer of the Company** 

2013: Member of the Board of Directors and Senior Executive Officer of the Company

#### **Audit & Supervisory Board Members**

#### Nobuo Takeda **Audit & Supervisory Board Member**

#### Yasuii Furutani **Audit & Supervisory Board Member**

#### Harumichi Uchida **Audit & Supervisory Board Member** (Outside)

Yutaka Atomi **Audit & Supervisory Board Member** (Outside)

Kazuto Nishikawa **Audit & Supervisory Board Member** (Outside)

#### **Executive Officers**

#### Susumu Nakaiima Senior Executive Officer Executive Director, Sales & Marketing

#### Nobuhiko Tamura

**Senior Executive Officer** Vice Chair, President, Sunovion Pharmaceuticals

#### Yoshinori Oh-e Senior Executive Officer

**Executive Director, Corporate Regulatory** Compliance & Quality Assurance; Regulatory

#### Yoshiharu Ikeda

**Executive Officer** 

Executive Director, Technology Research & Development; Corporate IT Management

#### Nobuvuki Hara

**Executive Officer** 

Deputy Executive Director, Drug Development

#### Hitoshi Odagiri **Executive Officer**

Director, Personnel; Career Development



Masaru Ishidahara Member, Board of Directors, Senior Executive Officer Corporate Communications; Personnel; General Affairs; Procurement; Corporate Service Center

1976: Joined The Sumitomo Bank, Limited (currently, Sumitomo Mitsui Banking Corporation)

2003: Joined the Company

2008: Executive Officer of the Company

2011: Member of the Board of Directors and Executive Officer of the Company

2013: Member of the Board of Directors and Senior Executive Officer of the Company (current)



#### **Hidehiko Sato** Member, Board of Directors (Outside)

1968: Joined the National Police Agency

1996: Director General of the Criminal Investigation Bureau of the National Police Agency

1999: Chief of the Osaka Prefectural Police Headquarters

2002: Commissioner General of the National Police Agency

2005: President of the Police Personnel Mutual Aid Association

2011: Admitted to the Bar (Japan)

2011: Audit & Supervisory Board Member of the

Company 2011: Director of JS Group Corporation (currently,

LIXIL Group Corporation) (current) 2013: Member of the Board of Directors of the

Company (current) 2014: Director of Resona Bank, Ltd. (current)



Hiroshi Nomura Member, Board of Directors, Senior Executive Officer

Global Corporate Planning; Global Business Development; External Affairs; Corporate Secretariat & Industry Affairs; Finance & Accounting; Regenerative & Cellular Medicine Office

1981: Joined Sumitomo Chemical Co., Ltd.

2008: Joined the Company 2008: Executive Officer of the Company

2012: Member of the Board of Directors of the Company

2014: Member of the Board of Directors and Senior Executive Officer of the Company (current)



#### Hiroshi Sato Member, Board of Directors (Outside)

1970: Joined Kobe Steel, Ltd.

1996: Director of Kobe Steel, Ltd.

1999: Director and Officer of Kobe Steel, Ltd.

1999: Senior Officer of Kobe Steel, Ltd.

2000: Director and Senior Officer of Kobe Steel, Ltd.

2002: Director and Executive Officer of Kobe Steel, Ltd.

2003: Senior Managing Director of Kobe Steel, Ltd.

2004: Executive Vice President and

Representative Director of Kobe Steel, Ltd. 2009: President and Representative Director of Kobe Steel, Ltd.

2013: Chairman of the Board and Representative Director of Kobe Steel, Ltd. (current)

2014: Member of the Board of Directors of the Company (current)

#### Kazuo Koshiya **Executive Officer** President, Boston Biomedical Pharma, Inc.; Head of Global Oncology Office

#### Hiroyuki Baba **Executive Officer**

Executive Vice President, Sunovion Pharmaceuticals Inc.; Director Global Business Development; Head of Global Business Development for Sumitomo Dainippon Pharma

#### **Toru Kimura**

**Executive Officer** 

Director, Regenerative & Cellular Medicine

#### **Hajime Kinuta**

**Executive Officer** 

Director, Global Corporate Planning

#### **Antony Loebel**

**Executive Officer** 

**Executive Vice President and Chief Medical** Officer, Sunovion Pharmaceuticals Inc.; Head of Global Clinical Development for Sumitomo Dainippon Pharma Group

#### Chiang J. Li **Executive Officer**

President, Chief Executive Officer and Chief Medical Officer, Boston Biomedical, Inc.; Head of Global Oncology for Sumitomo Dainippon Pharma Group

## **CSR Management**

#### **Basic Position on CSR**

Sumitomo Dainippon Pharma sets forth its commitment to serve society in the Company's Corporate Mission, and the aim of its operations, which are focused on its stakeholders, in the Management Mission.

Our Declaration of Conduct specifies our corporate philosophy and values in more concrete terms, and serves as our basis approach to promoting CSR. We are committed to providing through our business activities the products that are truly needed, ensuring that these activities conform to our Declaration of Conduct, and conducting all of our activities as a responsible corporate citizen.

#### **Declaration of Conduct**

- 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.
- 6 Respect human rights.
- 6 Positively address global environmental issues.
- Build harmonious relationships with society.

#### **CSR Guidelines, Approach, and Acquisition of Certifications**

Sumitomo Dainippon Pharma explicitly documents guidelines such as those described below before pursuing CSR activities in all business processes, including drug research, development, manufacturing, and sales, as well as processes related to promotion of business.

## Guidelines, philosophy, external rules and criteria to be observed for each business process

#### Research

- A standard for conducting pre-clinical studies on the safety of drugs (Good Laboratory Practice: GLP)
- Rules for the Research Ethics Committee on Uses of Human Tissues
- Ethical Rules for Human Embryonic Stem Cell Research
- Safety management Rules for Recombinant DNA Experiments
- Internal rules that comply with the Act on Welfare and Management of Animals and Basic Policies for the Conduct of Animal Experiments in Research Institutions under the Jurisdiction of the Ministry of Health, Labour and Welfare

#### **Development**

- Ministerial Ordinance on Good Clinical Practice for Drugs (GCP)
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines
- Ethical Guidelines for Medical and Health Research Involving Human Subjects

#### **Manufacturing and Quality Control**

- Good Manufacturing Practice (GMP) Standards for Drugs and Quasi-drugs
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines

#### **Corporate Regulatory Compliance & Quality Assurance**

- A standard for managing the post-marketing safety of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (Good Vigilance Practice: GVP).
- A standard for managing the quality of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (Good Quality Practice: GQP).

#### Sales

- DSP Prescription Drug Promotion Code
- DSP-GPP (Good Promotion Practice)
- Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice
- Fair Competition Code of the Ethical Drug Manufacturing

#### **Procurement**

• Ethics in Procurement

## Guidelines, philosophy, external rules and criteria to be observed related to strengthening the business foundation

#### **Protection of the Environment**

• Basic Environmental Policies

#### **Corporate Citizen Activities**

Guidelines on Partnerships with Patient Associations

#### **Health and Safety**

• Health and Safety Policy

#### Response to New Strain Influenza, etc.

• Emergency response guideline for outbreak of new strain influenza

#### **Guidelines on Transparency**

- Guidelines for Transparency in Partnerships with Medical Institutions
- Guidelines for Transparency in Partnerships with Patients Associations

#### **Information Security**

Personal Information Protection Policy

#### [Acquisition of Certifications]

 ISO 14001 certification (Suzuka Plant, Ibaraki Plant, Ehime plant, Oita plant)

#### **ISO26000 Core Themes and Principal Activities**

Furthermore, Sumitomo Dainippon Pharma utilizes the core theme framework of ISO26000 in promoting activities. In this report, we introduce the activities that we focus on in particular, and

detailed information about other CSR activities marked \* in the table below is posted on our website.

ISO26000 Core Themes	Applicable item of the "Declaration of Conduct"	Princi	pal Activities	Page
Organizational Governance	_	Corporate Governance		P35
Human Rights	Declaration of Conduct ② Declaration of Conduct ④ Declaration of Conduct ⑤	Respect for the Dignity of the Individu     Clinical Studies Put the Human Rights     Initiatives to Prevent Harassment		P43
Labour Practices	Declaration of Conduct ③ Declaration of Conduct ④ Declaration of Conduct ⑤	Creating a Workplace Environment That Allows Employees to Focus Confidently on Their Work Health and Safety Risk Assessment (*) Consideration of Mental Health (*) Creating an Environment in which Employees Can Fully Exercise Their Capabilities	<ul> <li>Promoting Employment of Persons with Disabilities (*)</li> <li>Diversification (Supporting Active Participation by Women)</li> <li>Work-Life Balance</li> <li>Establishing Consultation Desks</li> </ul>	P43
Environment	Declaration of Conduct <b>⑤</b>	Basic Environmental Policies Environmental Accounting (*) Development of Environmental Conservation Systems Overview of Environmental Impact Mid-term Environmental Plan Fostering Environmental Awareness (*)	<ul> <li>Activities to Conserve Energy and Address Climate Change</li> <li>Waste Reduction</li> <li>Reduction of Chemical Substance Waste</li> <li>Prevention of Environmental Accidents and Legal Infringements</li> <li>Environmental Conservation Effort (*)</li> </ul>	P49
Fair Operating Practices	Declaration of Conduct 2	Appropriate Information Disclosure (*)     Protecting and Managing Personal Information (*)     Preventing the Falsification and Leakage of Information (*)	Guidelines for Transparency in Partnerships with Patients and Medical Institutions Fair Promotion Activities CSR Procurement Respect for Intellectual property (*)	P45
Consumer Issues	Declaration of Conduct ① Declaration of Conduct ③	Activities to Secure Product Safety     Encouragement of Proper Use of Safety-related Information (*)     Launched a Medical Information Site for Medical Professionals     Launched a Health Information Site	<ul> <li>An Exclusive Commitment to Handling Inquiries: Product Information Center</li> <li>Recognizing and understanding the needs of our customers (*)</li> <li>Approach to Human Tissue Research</li> <li>Ethical Considerations in Animal Experimentation</li> </ul>	P46
Community Involvement and Development	Declaration of Conduct <b>7</b>	Basic Policy on Social Contribution Activities Promoting Environmental Activities at Each Workplace Donations with Employee Participation Initiatives in the Education Sector (*) The Japan Epilepsy Research Foundation (JERF)	Research Grants (*) Great East Japan Earthquake Reconstruction Support Relations with Local Communities (*) Communication with Society (*) International Contribution Activities Implementing by Group Companies	P47

<sup>\*</sup> CSR Activities: http://www.ds-pharma.com/csr/

#### **Human Rights**

#### Respect for the Dignity of the Individual

Sumitomo Dainippon Pharma respects the human rights of all people involved with the Company, and in its "Declaration of Conduct (Guidebook for Daily Application)" clearly rejects any discrimination based on race, nationality, origin, religion, ideology, creed, sex, physical disability, age or form of employment.

Power harassment and sexual harassment in the workplace, as actions that hurt the dignity of individuals, are important issues related to the violation of human rights. To prevent harassment, Sumitomo Dainippon Pharma clearly stipulates anti-harassment policies within its office regulations and makes clear that violations will result in disciplinary action. We ensure proper knowledge of issues through evaluator training and grade-specific training, and engage in raising anti-harassment awareness.

#### **Clinical Studies Put the Human Rights of Subjects First**

We conduct human clinical studies in accordance with the requirements for new drug applications and with the utmost consideration to the subjects' human rights.

Since clinical studies are conducted during the intermediate stages of confirming the efficacy (effectiveness) and safety (or side effects) of drug candidates, our clinical studies follow such regulations as Japan's ministerial ordinance on GCP (Good Clinical Practice), which was established to protect the human rights, maintain the safety and improve the welfare of subjects participating in studies.

In clinical studies, our guiding principle is "promotion of development activities based on common sense and conscience" while always keeping in mind the risk of "unpredictable side effects." In all of our studies, we secure the safety of participants by collecting, reporting and evaluating all required information, including that which is necessary for judging whether each person will be able to safety participate and improving the welfare of subjects participating in studies.

#### **Initiatives to Prevent Harassment**

In our in-house training, we provide education on the relationship between our business activities and human rights, deepening the understanding that each individual employee has about human rights. In our new employee training, we aim to foster awareness that respect for human rights is a part of drug research and development, manufacture and sales. Moreover, in addition to the acquisition of the proper knowledge and an emphasis on raising awareness about preventing harassment through grade-specific training and training for managers, we have set up consultation desks at our main business sites, including head office, creating an organization that can respond promptly and considerately to complaints and inquiries.

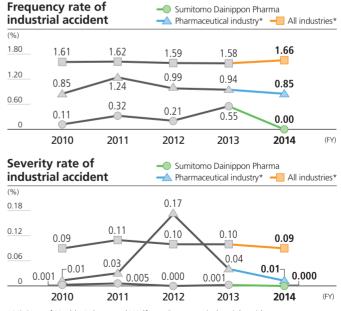
All parties related to the company are eligible for these measures and the entire company is committed to preventing any harassment.

#### **Labour Practices**

#### Creating a Workplace Environment That Allows Employees to Focus Confidently on Their Work

Sumitomo Dainippon Pharma has an established "Health and Safety Policy" on the basis of which it has enacted a variety of health and safety measures. We aim to prevent work-related accidents by identifying risks, evaluating those risks and then implementing PDCA cycles to deal with them. Moreover, to prevent the occurrence of a fire, explosion, or other major work-related accident, Sumitomo Dainippon Pharma has implemented measures to ensure the safety of operators on site by automating equipment and eliminating dangerous tasks. We have also introduced a number of measures in preparation for a large-scale natural disaster, including measures for facilities and establishment of rules regarding equipment to minimize any potential impact.

In addition to these measures, we believe it is important to instill an awareness of health and safety among employees themselves. Also, information about work-related accidents that occur at Sumitomo Dainippon Pharma is shared with the entire company via our intranet. These examples help foster awareness about health and safety among all employees through the recognition of accidents as close-at hand events. Toward this end, the Secretariat of Environmental and Safety Committee trains all new hires about workplace accident prevention, encouraging them to reexamine their assumptions and think on their own about basic concepts, such as what exactly health and safety entails and why health and safety initiatives are necessary, for the purpose of crisis prevention and management.



<sup>\*</sup>Ministry of Health, Labour and Welfare, Survey on industrial accidents http://www.mhlw.go.jp/toukei/list/44-23b.html (Japanese only)

Frequency rate = (Number of deaths and injuries due to industrial accidents / Cumulative hours worked) x 1,000,000

It indicates the frequency of occurrence of industrial accidents.

Severity rate = (Aggregated number work-days lost due to industrial accidents / Cumulative hours worked)  $\times$  1,000

It indicates the degree of seriousness of the accidents.

## Creating an Environment in which Employees Can Fully Exercise Their Capabilities

As part of our management mission, we seek "to create an environment in which employees can fulfill their potential and increase their creativity," and we therefore aim to foster a corporate climate where employees can independently pursue their own skills development, where the company actively supports employee growth, and where the corporate environment allows employees to demonstrate their full potential.

Personnel development primarily consists of OJT (on-the job training) where employees learn through doing actual tasks and taking on challenges. As a supplement to this, a variety of Off-JT (off-the-job training) programs are offered in the form of strengthening/support programs, training sessions and more. In addition, we have implemented a self-reporting system with the main objective of identifying individual circumstances, issues, and hopes for when supervisors consider training and skill development for the workers under them. The purpose of this system is for individual employees to submit the feelings and thoughts they have in the course of their day-to-day work in the form of a self-report and for supervisors to consider long-term training and skill development by conducting interviews based on the content of these reports.

Supervisors hold face-to-face meetings with individual employees based on their self-reporting, providing them with the opportunity to focus on their future in the company and to reevaluate their resolve, interests and aspirations. Supervisors reflect on the company's training policies and day-to-day duties and, by linking this to OJT and Off-OJT, support the growth of individual employees.

## **Diversification (Supporting Active Participation by Women)**

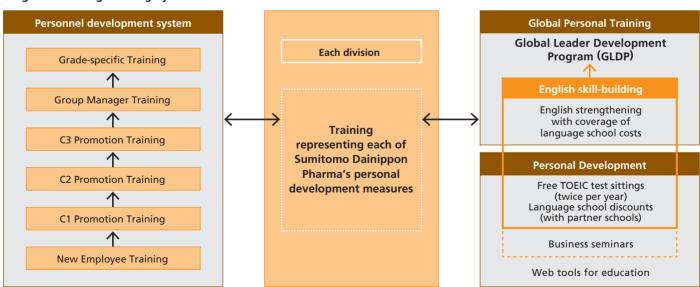
Sumitomo Dainippon Pharma believes that it is important to create an environment that allows every single employee to fully exercise their capabilities. We are providing opportunities for equal participation by changing the awareness of management and establishing systems to facilitate choice of diverse working styles to eliminate the inability to exercise capabilities due to such reasons as gender and race differences, disability, and age. We believe that creating an environment that allows the exercise of capabilities under fair conditions can connect the ideas of diverse employees to the creation of new value as well as raising productivity.

In recent years, we have also actively strived for diversification of human resources, and particularly for active participation by female employees. As of April 2015, women accounted for approximately 12% Directors positions and approximately 9% of managerial staff. Our target is to double the proportion of female executive by 2020 by promoting changes in awareness and corporate culture, increasing the number of female employees with continuous service and encouraging career development for female employees.

#### [Details of Specific Initiatives]

- Provision of training for management on careers and development for female staff they supervise
- 2. Implementation of measures to support enhancement of career orientation among female employees (training, etc.)
- 3. Introduction of various systems to accommodate diverse work styles, including shift systems (unrestricted child care and nursing care), etc.
- $4. \ \ Encouragement$  for male employees to actively take child care leave

#### **Diagram showing Training System**



#### **Work-Life Balances**

With the aim of achieving work-life balance, Sumitomo Dainippon Pharma rigorously enforces no overtime days and has a policy of encouraging employees to take their paid leave. In addition, we have held the DSP WLB Labour-Management Meeting since last year for labour and management to cooperate in considering systems and promoting understanding. Based on the shared labour-management philosophy that a fulfilling life is achievable through balance rather than conflict between work and life, we encourage individual employees to review their own work style and promote

rationalization in operations in order to realize a virtuous cycle of work enhancement and lifestyle enhancement. Furthermore, in each workplace, we promote a mindset of understanding and assistance for employees facing diverse life events who require flexible work styles.



#### **Establishing Consultation Desks**

Sumitomo Dainippon Pharma established several consultation desks to foster a workplace environment in which every employee is able to work comfortably and with a sense of security.

#### List of Consultation Desks

#### Compliance Hotline

Providing consultation or accepting reports internally or externally in the event that an employee has questions or has obtained information concerning violations related to compliance

#### Sexual Harassment Consultation Desk

Providing consultation or accepting reports internally in the event that an employee has questions or has obtained information concerning violations related to sexual harassment

#### Mental Health Consultation Desk (Outside)

Providing consultation or answering questions concerning mental health externally

#### General Consultation Desk

Providing a wide range of consultation internally concerning problems and anxieties in everyday working life not addressed in the workplace as well as problems, questions, and opinions about working life.

#### **Fair Operating Practices**

## **Guidelines for Transparency in Partnerships with Patients and Medical Institutions**

The mission of an R&D-oriented pharmaceutical company is to contribute to the health of people and medical care around the world by continually researching and developing new drugs and steadily bringing them to market with the objective of creating participatory medical care.

In order to fulfill this mission, it is essential to collaborate with research organizations, including medical institutions and universities, in at all stages from drug discovery to postmarketing information provision activities that ensure the proper use of pharmaceuticals.

With representatives of patient groups sitting on an increasing number of government committees and investigative commissions as governments and the community put greater emphasis on the "voice of the patient," patient groups have become important stakeholders in the mission to improve medical care.

At Sumitomo Dainippon Pharma, we believe that it is critical to raise awareness and increase understanding throughout society that activities designed to improve coordination between medical institutions and patient groups are undertaken in accordance with high ethical standards.

JPMA (The Japan Pharmaceutical Manufacturers Association) issued its Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions on January 19, 2011, and its Transparency Guidelines for the Relation between Corporate Activities and Patient Groups on March 14, 2012.

As a member of the JPMA, we established our own Guidelines for Transparency in Partnerships with Medical Institutions in October 2011 and Guidelines for Transparency in Partnerships with Patient Associations in April 2012.

In accordance with these guidelines, we publicly disclose information on our corporate website of our payments to medical institutions, medical professionals, patient groups and support groups.

#### **Fair Promotion Activities**

In view of the JPMA Promotion Code for Prescription Drugs, Sumitomo Dainippon Pharma has formulated the DSP Promotion Code for Prescription Drugs to specify the standards of conduct that MRs have to comply with when promoting ethical drugs with the aim of engaging in fair promotion activities.

Moreover, The Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry has specified the Fair Competition Code Concerning Restriction on Premium Offers in Ethical Drugs Marketing Industry regarding the provision of premiums to healthcare professionals. In light of the relevant legislation and these voluntary standards, Sumitomo Dainippon Pharma has formulated the DSP-GPP (Good Promotion Practice) with the objective of engaging in fair and transparent marketing activities.

In fiscal 2014, we provided monthly training for MRs that included the JPMA and its rules, transparency guidelines (for medical institutions, etc.), a Code of Practice understanding and promotion month, product explanation sessions, small sum premiums, research sessions and lectures, public servant ethics code, and in-house training sessions.

#### **CSR Procurement**

We consistently conduct "untainted transactions that are balanced, fair and transparent" based upon Sumitomo Dainippon Pharma's Ethics in Procurement. To provide high quality pharmaceuticals, we promote "stable and secure procurement" and perform CSR procurement together with our business partners.

In determining whether to partner with companies for the first time, we evaluate businesses according to the standards outlined in the criteria for selecting new business partners. These criteria provide both the standards for selecting new business partners on the basis of their CSR activities in the areas of compliance, trustworthy business activities, social contribution, information management, respect for human rights, and environmental protection and consideration and the details to be fully evaluated related to the CSR activities of business partners. We also conduct regular evaluation of our business partners in accordance with the criteria by inspecting their plants, paying visits, and conducting interviews.

#### **Information Security**

"Information" is an essential asset in our corporate activities, and how it is utilized and protected is of particular importance to the Company. We have settled global policies for records and information management as well as various rules for information security to minimize risks. In addition, each Group company enforces its own equivalent set of rules.

As part of its information security measures, Sumitomo Dainippon Pharma constantly reviews its technological protections as well as internal rules and standards in light of social changes and advances made in information technologies. We also work to maintain high levels of security at Group companies.

We also focus on education with the aim that employees strongly recognize the importance of information security and ensure full compliance with rules and regulations. Moreover, we continue providing information security training over our intranet to keep awareness about information security high.

#### **Consumer Issues**

#### **Activities to Secure Product Safety**

In some cases, some side effects that were unpredictable during the development stage can be acknowledged once pharmaceuticals have started to be used by a large number of patients under various conditions after manufacturing and marketing approval. Therefore, it is important to promote the proper use of pharmaceuticals by collecting and evaluating a wide range of information on safety and efficacy and assessing their benefit and risk in the post-marketing period. It is also important to promptly provide necessary information to medical professionals and patients for ensuring proper usage of the products. In Japan, we are working strenuously to ensure the safe and proper use of our pharmaceuticals through pharmacovigilance in compliance

with the Pharmaceuticals, Medical Devices and Other Therapeutic Products Act and the Ministerial Ordinance on Good Vigilance Practice (GVP).\*

Furthermore, we have developed a global pharmacovigilance system that covers our Group companies outside Japan. This global system helps us to manage and evaluate all safety information on products developed and marketed in multiple countries and to determine the measures required for securing the safety of our pharmaceuticals.

\* Good Vigilance Practice: a standard for managing the post-marketing safety of pharmaceuticals, guasi-pharmaceuticals, cosmetics and medical devices.

## Launched a Medical Information Site for Medical Professionals

Through this Japanese-language medical information site, we provide medical professionals with information that is useful in their line of work, including basic product information, notices of various revisions to product information and information about the seminars we hold.

https://ds-pharma.jp/ (Japanese only)

#### Launched a Health Information Site

Through this Japanese-language health information site, we provide the general public with basic information, the latest news and tips to help people enjoy healthy lives. Site content includes data on causes of and treatments for diseases, tips on healthy living and warnings about the misuse of drugs.

http://kanja.ds-pharma.jp/ (Japanese only)

#### Pages and Content on the Health Information Site

#### Disease Info

On this web site, visitors can search for information related to illness by disease name or symptom. There are also easy to understand explanations about common maladies, including lower back pain and high blood pressure. Visitors can also check out "the Message from a Doctor" to get clear explanations from specialists in their neighborhood about treatments or tips on daily activities.

#### Life Tips

This fascinating page features "The Practical Health Navigator," where you can learn about healthy living, including proper diet and exercise. There's also "Health Tips," where you can learn fun facts about clothes, food and communities through witty columns and illustrations, and "The Ah Hah! Guide to Taking Medicine" where visitors can learn about the effects, side-effects and efficacy of drugs.

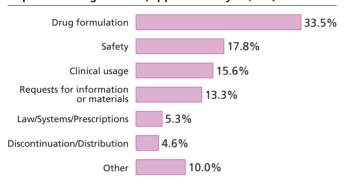
#### Medicine Guide

On this web site, visitors can search for information related to medicine, including actions, effects, side-effects, usage warnings or other key terms using the drug name.

## An Exclusive Commitment to Handling Inquiries: Product Information Center

Sumitomo Dainippon Pharma established the Product Information Center in order to respond to inquiries about its ethical pharmaceuticals. Going forward, we will continue swiftly and politely providing accurate information regarding the appropriate use of medicines to support the health of patients.

#### Inquiries during FY2014 (Approximately 53,000)



#### **Ethical Approach to Human Tissue Research**

The use of specimens taken from humans, such as blood, tissue, cells, human genetic material, and iPS cells (collectively "human tissues" below) has made it possible to elucidate phenomena distinctive to the human body which are undiscoverable in animal testing.

On the other hand, this type of research requires special ethical considerations. For this reason, we established the Rules for the Research Ethics Committee on Uses of Human Tissues on October 20, 2005 (revised on November 25, 2014) and set up a Research Ethics Committee on Uses of Human Tissues in the Drug Research Division. The rules require paying due consideration to human dignity, giving sufficient explanation in advance to the providers of human tissues and obtaining their voluntary agreement (informed consent), rigorously protecting personal information, and fairly reviewing the research plan (the significance and necessity of using human tissues and the degree of social contribution of the research) as the prerequisites for human tissue to be provided for research into drug creation.

We have articulated a clear standard for ethics review, and have been reviewing research plans in accordance with this in advance of each research project using human tissues. We have also posted the Rules for the Research Ethics Committee on Uses of Human Tissues and the membership of the committee on our website.

#### **Ethical Considerations in Animal Experimentation**

In animal experimentation, Sumitomo Dainippon Pharma follows in-house procedures that conform to Japan's Act on Welfare and Management of Animals and the Basic Policies for the Conduct of Animal Experiments in Research Institutions under the jurisdiction of the Ministry of Health, Labour and Welfare. Our Institutional

Animal Care and Use Committee carries out proper ethical review of all experimental protocols, including outsourced tests, in terms of the "3Rs" ("reduction" of the number of animals used, "replacement" with alternative testing methods, and "refinement" to relieve pain and suffering).

We also implement appropriate in-house inspection, assessment and confirmation of the animal testing process, striving to maintain and improve the ethical and scientific integrity of the animal testing system. Sumitomo Dainippon Pharma has earned accreditation from the Center for Accreditation of Laboratory Animal Care and Use within the Japan Health Sciences Foundation as an animal testing facility in compliance with the basic policies of the Ministry of Health, Labour and Welfare.

#### **Community Involvement and Development**

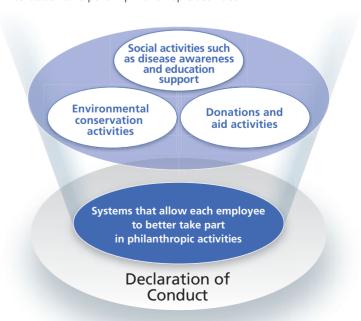
#### **Basic Policy on Social Contribution Activities**

In its Declaration of Conduct, Sumitomo Dainippon Pharma declares its intent to "7. Build harmonious relationships with society," and we engage in social contribution activities befitting a good corporate citizen.

Specifically, with our social activities centered on disease awareness and education support, environmental conservation, and donations and aid, we have identified the following pivotal categories as our basic thoughts on social contribution activities.

- constant awareness by employees that Sumitomo Dainippon Pharma runs its business supported by the trust of society
- understanding and respecting diverse values and cultures of regions and peoples
- fulfilling responsibilities and contributing as a member of society conscious of building harmonious relationships with society.

We have further established systems that allow each employee to better take part in philanthropic activities.



## Promoting Environmental Activities at Each Workplace

Environmental conservation activities

Sumitomo Dainippon Pharma values its relationship and communication with the local community and actively participates in regular clean-up and forest conservation activities, including tree planting, in the areas where workplaces are located. In addition, employees have a strong awareness of the environmental impact of every stage of our business, including research and development, production, logistics, and marketing, and make positive efforts to reduce environmental impact at each workplace.

#### **Donations Activities**

Donations and aid activities

Sumitomo Dainippon Pharma contributes both funds donated by officers and employees and corporate donations with an emphasis on education of the next generation and support for patients and their families. In fiscal 2014, we donated funds in

support of activities to the Japan Clubhouse Coalition, which works to help people with mental illness get back into society, and the Japan Association of Certified Child Life Specialists, which supports children living in hospital for prolonged periods and their families.



Presentation ceremony for donation to the Japan Association of Certified Child Life Specialists

## The Japan Epilepsy Research Foundation (JERF)

Social activities such as disease awareness and education support

The Japan Epilepsy Research Foundation (JERF), which is run based on contributions from Sumitomo Dainippon Pharma and donors, works to promote research on treatments in the field of epilepsy and was established to contribute to the health and healthcare of the public. JERF provides grants and commendations, holds meetings for reporting research results as forums for announcing its grants and commendations, and publishes an annual research newsletter.

Sumitomo Dainippon Pharma will continue to contribute to improvements in healthcare and welfare through its support for JERF.

## **Great East Japan Earthquake Reconstruction Support**

Donations and aid activities

Sumitomo Dainippon Pharma has continued to work on activities to support the people in the devastated area affected by the Great East Japan Earthquake in accordance with changes in needs accompanying the state of reconstruction. In fiscal 2014, we supported sports days for children from Ofunato city, Iwate Prefecture and Okuma town in Fukushima Prefecture and ran a self-study space for junior and senior high school students in Tome city and Minami-Sanrikucho town in Miyagi Prefecture.

We also continued donations by officers and employees through ASHINAGA in support of children who lost parents and caregivers in the Great East Japan Earthquake.

## International Contribution Activities

Donations and aid activities

Sumitomo Dainippon Pharma focuses on global health initiatives and has continued to work on the following activities to provide support to a range of stakeholders endeavoring to improve global healthcare.

Furthermore, our overseas subsidiaries Sunovion Pharmaceuticals Inc. and Sumitomo Pharmaceutical (Suzhou) Co., Ltd. participate actively in social contribution activities.

#### **Promoting the Vaccine Business**

Sumitomo Dainippon Pharma has been involved in the new tuberculosis vaccine business since fiscal 2013 as one of the new fields of business and is taking steps to contribute to global health, especially in emerging and developing countries.

## Providing Support for Tuberculosis Checkups and Human Resource Training in Developing Countries

The lack of appropriate healthcare being delivered to patients is an issue in developing countries, and a shortage of medical practitioners and facilities and opportunities for checkups has been identified as one of the reasons for that. Sumitomo Dainippon Pharma has made donations to Future Code, an NGO involved in tuberculosis checkups and human resource training in developing countries, including Haiti.

#### **Supporting Activities to Eradicate Malaria**

HIV/AIDS, tuberculosis, and malaria, the three major infectious diseases, are global problems that cannot be solved by one country alone but need international cooperation to take steps to address them.

Sumitomo Dainippon Pharma endorses the activities of Malaria No More Japan, an NPO working on awareness and government policy proposal activities with the aim of eradicating malaria worldwide, primarily in Asia and Africa, providing donations of funds to support activities.

#### **Supporting Action Against Counterfeit Pharmaceuticals**

The problem with counterfeit pharmaceuticals is not merely that they have no therapeutic effect, but that they also carry the risk of death caused by unexpected side effects. They also pose an international problem as they could easily be turned into financial resources for organized crime and terrorist organizations.

Sumitomo Dainippon Pharma is one of 29 global pharmaceutical companies that are working together to donate to the International Criminal Police Organization (INTERPOL) a total of 4.5 million Euro over a three-year period beginning in 2013. The donation will be used to fund activities to promote public awareness of counterfeit pharmaceuticals and efforts to prevent pharmaceutical crime, including the training of specialist pharmaceutical crime investigators.

#### **Environment**

#### **Environmental Management**

Sumitomo Dainippon Pharma recognizes its responsibility for its environmental impact and strives to reduce environmental impact in all areas of its business operations.

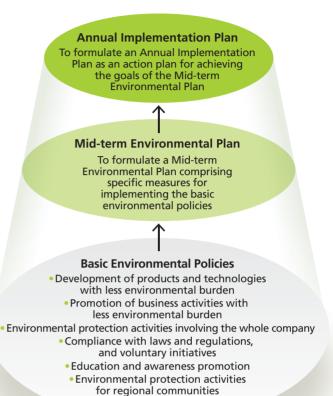
Established in fiscal 2005, our Basic Environmental Policies underpin all our environmental activities. Under the Basic Environmental Policies, we formulated a Mid-term Environmental Plan that specifies goals of special importance and objectives for three years (from fiscal 2014 to fiscal 2016).

In addition, every year we draft an Annual Implementation Plan. In this way, we ensure that our environmental activities are systematic and effective.

Sumitomo Dainippon Pharma has acquired ISO 14001 certification at its four plants (Suzuka Plant, Ibaraki Plant, Ehime Plant, and Oita Plant).

#### **Basic Environmental Policies**

Aware that the global environment is now facing a serious crisis, we at Sumitomo Dainippon Pharma will make concerted efforts to preserve the environment and help create a recycling-oriented society through all our corporate activities. Our mission is to protect human lives and promote health, thereby helping to create a prosperous and pleasant world.



Communication

#### **Overview of Environmental Impact**

#### **Business Activities OUTPUT INPUT** Released into the Atmosphere **Energy Consumption** (crude oil equivalent) Research and • CO2 emissions (from energy sources) ····· 72,981t Total energy consumption ---- 42,519kl development • Organic chlorinated chemical substances ...... 3.8t • Electric power ----- 23,230kl •SOx------0.08t • Fossil fuels ----- 19,289kl • NOx ------ 15.8t (Gasoline 1,230kl) Ash dust emissions ----- 0.8t PRTR substances ------ 4.6t **Released into Water Systems Raw Material Consumption** • Total amount of wastewater ..... 886,000 t Raw materials for products •BOD ------ 8.3t (excluding metals) 3,761t •COD ------ 6.3t Offices Manufacturing Raw materials for products • Phosphorus ······ 0.2t (metals) ------ 11t • Nitrogen ------ 1.5t PRTR substances ----- 992t PRTR substances ----- 0.0t Note: The BOD, COD, phosphorus, nitrogen and PRTR substances • Product packaging materials --- 1,132t shown here are the amounts released into public waterways and sewerage systems **Water Consumption** Waste • Amount of waste generated ..... 6,048t • Tap water ----- 262,000t • Amount recycled ······· 4,899t Logistics • Industrial water ----- 351,000t • Amount of final disposal ----- 19.8t • Ground water ----- 293,000t PRTR substances ----- 956t

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

#### Mid-term Environmental Plan (fiscal 2014-2016)

Sumitomo Dainippon Pharma has clarified key issues related to its environmental activities and has established its Mid-term Environmental Plan as an action plan to realize these goals and

make continuous improvements toward them. During fiscal 2014, we made steady progress in most areas, except for a few objectives. In the future, we will continue to pursue further improvements.

Mid-term Environmental Plan Degree of progress: 

☐ Goal achieved ☐ Steady progress made toward objective ☐ Progress somewhat behind schedule

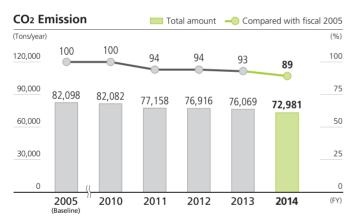
Goals of Special Importance	Objectives	Progress in FY2014	Degree of Progress
Reduce emissions of chemical substances	(1) Properly manage chemical substances, and continually strive to reduce emissions of chemical substances (PRTR substances, etc.) into the environment	(1) With decrease in the volume of PRTR substances handled, atmospheric emissions of these substances decreased approximately 88% over the previous fiscal year	0
	[1] Numerical targets:	[1] Numerical targets:	
	(1) Reduce CO <sub>2</sub> emissions for the whole Company to 23% of FY2005 levels by FY2020	(1) Company-wide CO2 emissions in FY2014 stood at 88.9% of the level in FY2005 and 95.9% of the previous fiscal year	0
	(2) Improve per-unit energy consumption and CO2 emissions for the whole Company by 1% or more per year, respectively	(2) Per-unit energy consumption: 92.7% of FY2013 Per-unit CO2 emissions: 97.0% of FY2013	0
2. Promote energy	[2] Activity targets:	[2] Activity targets:	
savings and address climate change	(1) Promote the introduction of energy-efficient equipment and machinery at the Company's work sites	(1) Invested in energy saving equipment, such as updating heat-source equipment at the Suzuka Plant and introduction of air conditioner controllers at the Central Research Laboratories	0
	(2) Promote the use of renewable energy at the Company's work sites	(2) Currently operating solar power generation equipment at the Central Research Laboratories and the Osaka Research Center	0
	(3) Promote energy saving at the Company's work sites	(3) Implemented across the whole Company and at each work site	0
	(4) Promote energy saving at the Company's work sites	(4) Considered various measures at each work site	0
3. Avert power shortages	Consider and implement measures to reduce energy use in summer and winter	Each work site set unique targets and implemented measures to reduce energy use	0
	(1) Maintain final landfill disposal by the whole Company at less than 1% of waste generated	(1) Maintained at less than 1% (FY2014 result 0.3%)	0
4. Reduce waste	(2) Plants and research laboratories: Maintain final landfill disposal of industrial waste at less than 1% of amount generated	(2) Zero emissions goal achieved at four plants and one research laboratory, but goal not achieved at one research facility in FY2014 (1.03%)	$\triangle$
	(3) Other sites: Continue complete recycling of recyclable waste	(3) Other sites made progress in recycling recyclable waste	0
5. Promote communication with Group companies	(1) Support environmental and safety activities of Group companies	(1) Conducted environmental and safety audits at two Group companies in Japan, and held meeting in September 2014 to exchange information on the environmental management of domestic Group companies	0
6. Promote	(1) Understand environmental risks that corporate activities can present to the local community	(1) Gained understanding of most risks and implemented countermeasures	0
communication with local communities	(2) Disclose information to the local community in an appropriate way	(2) Implemented appropriately	0
	(3) Participate actively in local environmental activities	(3) Actively implemented at each work site	0
7. Address biodiversity	Examine issues to be addressed and implement activities	Implementing activities to raise awareness of biodiversity at each work site and considering details of activities	0
8. Enhance environmental	(1) Establish and implement environmental education system for employees	(1) Formulated environmental education plan at each work site and implemented education in accordance with plans	0
education	(2) Train key persons in environmental management	(2) Formulated training plans at each work site and implementing training in accordance with plans	0

## **Activities to Conserve Energy and Address Climate Change**

In addition to the active introduction of new energy technologies that emit lower levels of greenhouse gas (CO<sub>2</sub>), Sumitomo Dainippon Pharma is aiming for efficient energy use in all of its business activities and working to reduce emissions of CO<sub>2</sub>.

In fiscal 2014, we added measures to conserve energy in both the summer and winter months to the initiatives already in place to introduce energy-saving equipment to operations and hybrid vehicles to our leased sales fleet. As a result, we were able to reduce companywide CO<sub>2</sub> emissions by 4.1% compared to the previous fiscal year. As of the end of fiscal 2014, hybrid vehicles accounted for about 75% of our sales fleet companywide. We have also introduced solar power generating systems at the Central Research Laboratories and the Osaka Research Center. In fiscal 2014, 133.8MWh of electricity was generated, producing an approximate 44 tons reduction in CO<sub>2</sub>.

Climate change is currently the most pressing issue worldwide. We will continue to actively introduce new technologies throughout all of our business activities, and will continue tackling the reduction of CO<sub>2</sub> emissions while using energy efficiently.



Note: We use our own fixed value for the CO<sub>2</sub> conversion coefficient. This is to eliminate the influence of external factors, such as the operational status of nuclear power plants, and to make the results of our efforts clear. As such, the figures may differ from those reported in accordance with Japan's Act on Promotion of Global Warming Countermeasures.

#### **Waste Reduction**

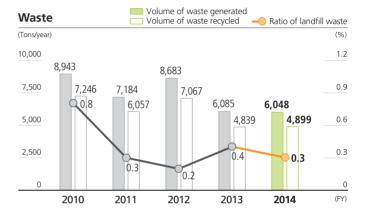
To make effective use of our limited resources, we practice the "3Rs" of waste management (reduce, reuse, recycle).

In fiscal 2014, Sumitomo Dainippon Pharma generated 6,048 tons of waste, down approximately 0.6% year-on-year. The volume of waste recycled increased by approximately 1.2% year-on-year to 4,899 tons, and the volume of landfill waste fell by approximately 21% year-on-year to 19.8 tons. The corporate percentage of landfill waste (landfill waste as a percentage of total waste generated) was approximately 0.3%, and we successfully achieved the corporate target for less than one percent landfill waste as we did in the previous fiscal year.

At our plants and research laboratories, we are pursuing zero emissions, which we have defined as a volume of final landfill industrial waste that is less than 1% of waste generated.

In fiscal 2014, zero emissions were achieved at four plants and one research laboratory, with one research laboratory falling short of the goal by generating 1.03% landfill waste. The main reason for this was the generation of non-recyclable waste.

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



#### **Reduction of Chemical Substance Waste**

Among the chemical substances frequently handled in Sumitomo Dainippon Pharma plants or research laboratories are methanol, toluene, and acetone. These chemical substances are used primarily as solvents and in almost all cases are ultimately disposed of as waste oil or other waste products. However, because some amount of dichloromethane, chloroform, 1,2-dichloroethane, and other chemicals which contribute to air pollution could leak into the atmosphere, we have taken active countermeasures, including the installation of recovery equipment for these chemical substances. In addition, all of our workplaces subject to reporting under Japan's Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (PRTR Law) submitted appropriate reports based on results in fiscal 2014.

Sumitomo Dainippon Pharma reports properly in accordance with Japan's Water Pollution Control Act and other laws and regulations. We continuously monitor wastewater through routine inspections and other means, while also working to strengthen our monitoring system by formulating measures to prevent pollution caused by toxic substances.

#### **Environmental Accidents and Legal Infringements**

In fiscal 2014, there were no environment-related legal infringements just the same as last year.



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## **Eleven-Year Summary of Selected Financial Data**

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

_	2005	2006	2007	2008	2009	
RESULTS OF OPERATIONS:						
Net sales	¥175,088	¥245,784	¥261,213	¥263,993	¥264,037	
Overseas sales revenue	3,820	9,696	22,032	24,521	22,051	
Ratio of overseas sales revenue	2.2%	3.9%	8.4%	9.3%	8.4%	
Cost of sales	111,099	130,437	99,346	99,385	103,741	
Selling, general and administrative expenses	52,404	86,461	116,312	124,794	129,130	
(Research and development costs)	17,444	29,636	40,870	47,266	52,819	
(Ratio of net sales)	10.0%	12.1%	15.6%	17.9%	20.0%	
Operating income	11,585	28,886	45,555	39,814	31,166	
Operating margin	6.6%	11.8%	17.4%	15.1%	11.8%	
Income before income taxes and minority interests	11,686	25,687	38,415	41,457	32,168	
Net income	6,924	15,377	22,605	25,592	19,988	
Comprehensive income (loss)	_		_		_	
FINANCIAL POSITION:						
Current assets	¥131,176	¥249,733	¥234,313	¥251,063	¥263,540	
Net property, plant and equipment	32,611	68,336	65,241	70,280	69,105	
Total assets	201,431	392,966	382,535	399,791	391,295	
Current liabilities	49,196	80,071	56,039	67,915	53,350	
Long-term liabilities	16,802	24,262	20,484	13,598	13,449	
Net assets	135,433	288,633	306,012	318,278	324,496	
OTHER STATISTICS:						
Capital expenditures	¥ 3,064	¥ 6,616	¥ 9,543	¥ 15,491	¥ 10,569	
Depreciation and amortization	5,233	8,901	12,008	11,870	11,455	
EBITDA	16,446	36,179	54,875	48,802	41,970	
PER SHARE OF COMMON STOCK:						
Basic net income	¥ 41.76	¥ 54.57	¥ 56.86	¥ 64.39	¥ 50.30	
Net assets	815.76	723.63	767.52	800.63	816.49	
Cash dividends applicable to the year	10.00	12.00	14.00	18.00	18.00	
FINANCIAL INDICATORS:						
ROE	5.2%	7.3%	7.6%	8.2%	6.2%	
ROA	3.5%	5.2%	5.8%	6.5%	5.1%	
Equity ratio	66.8%	73.2%	79.8%	79.6%	82.9%	
Dividend payout ratio	23.9%	22.0%	24.6%	28.0%	35.8%	

Notes 1. The U.S. dollar amounts in this report represent translations of Japanese yen solely for the reader's convenience at the rate of ¥120 to US\$1.00, the approximate rate of exchange at March 31, 2015.

<sup>2.</sup> Dainippon Pharmaceutical Co., Ltd. merged with Sumitomo Pharmaceuticals Co., Ltd. on October 1, 2005 and changed its name to Dainippon Sumitomo Pharma Co., Ltd. On June 19, 2014, the company name was changed to Sumitomo Dainippon Pharma Co., Ltd. in preparation for global development.

<sup>3.</sup> Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries adopted the new accounting standards for presentation of net assets in the balance sheet from year ended March 31, 2007. In accordance with the adoption of the new accounting standards, net assets in the financial position till year ended March 31, 2006 have been reclassified.

Millians of you						Percent change	Thousands of U.S. dollars
Millions of yen 2010	2011	2012	2013	2014	2015	2015/2014	(Note 1) <b>2015</b>
¥296,262	¥379,513	¥350,396	¥347,724	¥387,693	¥371,371	(4.2%)	\$3,094,758
53,015	152,226	130,243	133,125	174,286	174,911	0.4%	1,457,592
17.9%	40.1%	37.2%	38.3%	45.0%	47.1%		
112,263	110,030	98,857	101,686	104,100	101,228	(2.8%)	843,566
148,374	238,531	231,137	220,994	241,450	246,868	2.2%	2,057,234
51,371	68,160	56,891	59,844	69,804	71,304	2.1%	594,200
17.3%	18.0%	16.2%	17.2%	18.0%	19.2%		
35,625	30,952	20,402	25,044	42,143	23,275	(44.8%)	193,958
12.0%	8.2%	5.8%	7.2%	10.9%	6.3%		
31,423	25,050	16,328	18,158	34,709	33,755	(2.7%)	281,292
20,958	16,796	8,630	10,044	20,061	15,448	(23.0%)	128,733
27,148	(12,066)	2,396	37,174	45,165	60,108	33.1%	500,900
¥287,555	¥333,000	¥334,251	¥333,439	¥359,612	¥401,699	11.7%	\$3,347,492
74,084	69,794	66,697	69,862	72,689	65,160	(10.4%)	543,000
626,743	589,868	559,410	607,219	659,033	711,584	8.0%	5,929,867
265,000	157,204	105,966	124,831	131,208	156,844	19.5%	1,307,033
18,260	108,681	134,217	133,140	129,285	103,719	(19.8%)	864,326
343,483	323,983	319,227	349,248	398,540	451,021	13.2%	3,758,508
¥ 6,471	¥ 8,663	¥ 8,742	¥ 12,384	¥ 23,421	¥ 10,676	(54.4%)	\$ 88,967
18,650	44,628	40,232	35,085	26,777	19,226	(28.2%)	160,217
56,448	77,971	59,880	60,333	68,101	43,095	(36.7%)	359,125
Yen						Percent change	U.S. dollars
¥ 52.75	¥ 42.27	¥ 21.72	¥ 25.28	¥ 50.49	¥ 38.88	(23.0%)	\$ 0.32
864.51	815.44	803.47	879.03	1,003.11	1,135.21	13.2%	9.46
18.00	18.00	18.00	18.00	18.00	18.00	0.0%	0.15
6.3%	5.0%	2.7%	3.0%	5.4%	3.6%		
4.1%	2.8%	1.5%	1.7%	3.2%	2.3%		

<sup>4.</sup> Sumitomo Dainippon 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).

60.5%

35.7%

63.4%

46.3%

57.5%

71.2%

54.8%

34.1%

54.9%

42.6%

57.1%

82.9%

<sup>5.</sup> Sumitomo Dainippon Pharma Co., Ltd. and 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 2015.

<sup>6.</sup> EBITDA = income before income tax and minority interests + interest expense – interest income + depreciation and amortization + amortization of goodwill – extraordinary income (loss).

### **Operating Results and Financial Condition**

#### **Overview of Overall Operating Results**

In the Japanese economy during the current fiscal year, business continued to be on the track to recovery showing trends of improved corporate earnings and improved employment situation, affected by economic policies such as monetary easing, rapid progress of weakening of the yen currency and the like. In the global economy, the U.S. economy continued to enjoy steady recovery due to the increased consumer spending, and the Chinese economy stayed on its moderate growth path though its rate is slowing down. In Europe, the economy was coming back even though there was still uncertainty about the future.

In the pharmaceutical industry, while healthcare cost reduction policies were advanced globally, including the accelerated promotion of the use of generic drugs, there were trends to make an effort to pioneer new business areas such as practical realization of regenerative medical techniques as well as acquire biotechnology venture companies or enter into newly emerging markets under the situation that the research and development cost kept rising reflecting the challenges in developing new medicines to serve unmet medical needs and the requirement of higher safety.

Under these conditions, the Group, in Japan, worked to enhance the sales of strategic products, which are AIMIX®, therapeutic agent for hypertension and TRERIEF®, therapeutic agent for Parkinson's disease. In addition, the Group focused on information providing activities for the purpose of maximizing the sales of METGLUCO®, a biguanide oral hypoglycemic, and other products.

In overseas, Sunovion Pharmaceuticals Inc. (hereinafter, "Sunovion"), a subsidiary company in the U.S., made all-out efforts to further expand the sales of LATUDA® (generic name: lurasidone hydrochloride), an atypical antipsychotic which is global strategic product for the Group. LATUDA® was launched in the U.K. in August 2014 by Sunovion Pharmaceuticals Europe Ltd.

Sunovion launched APTIOM®, an antiepileptic drug in April 2014 in the U.S.

Boston Biomedical, Inc. focused development efforts for an early launch in the U.S. market of therapeutic agents for solid cancer BBI608 and BBI503.

#### **Operating Results**

#### **Net Sales**

Sales in Japan fell significantly due to severe business circumstances such as the April 2014 National Healthcare Insurance drug price revisions and the rapid spread of measures for promoting the use of generic drugs. In North America, the sales increased because of the increased sales of LATUDA® and the weakened yen, even though the sales of LUNESTA®, a sedative hypnotic, dropped significantly due to the April 2014 expiry of the exclusivity period. In China, the sales of MEROPEN®, a carbapenem antibiotic

grew strongly. Despite the above, consolidated net sales in the current fiscal year were 371,370 million yen (a 4.2% decrease from the previous fiscal year) since the significant sales decrease in Japan was greatly influenced.

#### Selling, General and Administrative Expenses

The selling, general and administrative expenses increased as a whole due to the increased sales expenses such as those for the advertisement and other sales promotion activities to achieve further sales growth of LATUDA® and the increased clinical development cost in the U.S., despite continued efforts in Japan for cost reduction centering on sales expenses.

#### **Operating Income**

As a result, the operating income was 23,275 million yen (a 44.8% decrease from the previous fiscal year).

#### **Net Income**

The net income reached 15,447 million yen (a 23.0% decrease from the previous fiscal year) after recorded extraordinary income and loss including gain on sale of fixed assets and impairment losses associated with reorganization of production sites.

#### **Financial Condition**

## Summary of assets, liabilities, and net assets -Assets

As for current assets, cash and time deposits and marketable securities increased while notes and accounts receivables decreased. As for Fixed assets, tangible fixed assets decreased due to the sales of assets held by the Company, and recognition of impairment loss relating to the reorganization of production site. Intangible assets decreased due to a significant impact of yen depreciation. As a result, total assets increased by 52,551 million yen from the previous fiscal year-end to 711,583 million yen.

#### -Liabilities

Despite the decrease of income tax payable and long-term debts, liabilities increased by 70 million yen from the previous fiscal year-end to 260,562 million yen primarily due to an increase in the reserve for sales rebates in the U.S. because of the sales growth of Latuda®.

#### -Net assets

Net assets increased by 52,481 million yen from the previous fiscal year-end to 451,021 million yen as a result of an increase in retained earnings and an increase in foreign currency translation adjustments brought about by a weakened yen. In addition, the shareholders' equity ratio as of the current fiscal year-end amounted to 63.4%.

#### Status of cash flows

#### -Net cash provided by operating activities

Despite of the decrease in notes and accounts receivable, cash flow from operating activities decreased by 19,692 million yen compared to previous fiscal year to 30,251 million yen mainly due to the decrease of non-cash expenses such as depreciation and amortization, as well as the increase in income tax paid.

#### -Net cash used in investing activities

Net cash used in investing activities increased by 49,656 million yen from the previous fiscal year to 23,447 million yen due to the increase of proceeds from sales of property, plant and equipment, as well as proceeds from redemption of marketable securities that was higher than the purchases of marketable securities.

#### -Net cash used in financing activities

Net cash used in financial activities includes repayment of long-term loans and payment of dividend.

It decreased by 11,439 million yen compared to previous fiscal year to 15,725 million yen.

#### -Cash and cash equivalents

As a result of adding an impact amount of positive 10,703 million yen as brought about by foreign currency translations applied to cash and cash equivalents, the balance of cash and cash equivalents as of the current fiscal year-end stood at 122,794 million yen for an increase of 48,875 million yen over the previous fiscal year-end.

#### Allocation of the Company's Profits

The allocation of the Company's profits in a customarily appropriate manner to its shareholders is one of the Company's fundamental management policies.

The Company's basic policy is to make dividends payments twice each year from retained earnings, including an interim dividend, as determined by the Company's Board of Directors; and a year-end dividend, as determined by the general meeting of shareholders.

In addition to stressing the distribution of surplus in a manner that reflects the Company's performance, the Company intends to make decisions on distribution from a comprehensive standpoint, while actively investing in its future growth, ensuring a solid management base and enhancing its financial condition to further increase its enterprise value. The Company believes that it is important to allocate profits to its shareholders in a consistent manner.

The Company declared a cash dividend of ¥9 per share for the current term, which is equal to the interim cash dividend for the current term, resulting in a total dividend of ¥18 per share for the current term. The Company further plans to declare a cash dividend of ¥18 per share for the next term (the same amount as declared for the current term) in order to continue to provide regular dividends to the Company's shareholders.

#### Forecasts for the Year Ending March 31, 2016

Net sales in Japan is expected to stay at the level of the previous year. Expected sales decline of long-listed product will be compensated by increased sales of strategic products, AIMIX® and an atypical antipsychotic agent LONASEN® as well as of new products. An increase is expected of North America net sales because of increased sales of LATUDA® and other products, coupled with the weaker than in the previous year exchange rate of yen against the U.S. dollar assumed in the forecast. For these and other reasons, the total net sales is forecasted to be 401.0 billion yen, an increase of 29.6 billion yen from the previous year.

Gross profit is expected to increase in line with sales expansion. In addition, selling, general and administrative expenses less R&D expenses will likely be the same level as previous fiscal year mainly due to offsetting the yen depreciation with the effort of cost reduction. However, research and development cost is expected to rise because of the increase of the products in later development phases, in addition to the yen depreciation.

As a result, we expect that operating income will be 27.0 billion yen (a 3.7 billion yen increase compared to the previous fiscal year). Net income attributable to owners of the parent will be 18.0 billion yen (a 2.6 billion yen increase compared to the previous fiscal year) including extraordinary income (loss).

Note: Foreign currency exchange rate used for the forecasts 1 USD = 120.4 yen, 1 RMB = 19.5 yen

#### **Business Risks**

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

Forward-looking statements in the discussion of risks discussed below reflect the judgment of the Group as of March 31, 2015.

#### Risk relating to research and development of new products

The Group works to research and develop highly original and globally viable products. While the Group strives to maintain an extensive product pipeline and to bring products to market as early as possible, all in the pipeline may not be successfully developed and launched to the market. It is possible that some development project may be delayed or abandoned at all. 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.

#### 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.

#### **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. Pharmaceutical products are subject to various kinds of regulations in foreign countries as well. The Group's operating results and financial position may be significantly affected, depending on the future courses of the U.S. healthcare system reform and other administrative measures overseas.

#### 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 operating results and financial position.

#### 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.

#### **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.

#### 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 "The Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices" 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.

#### 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, labour 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.

#### 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.

## 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.

#### 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.

#### 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.

#### Risk relating to overseas operation

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.

#### Risk relating to compliance

The Group makes every effort to promote the observance of laws and regulations and business ethics, being aware that compliance is the very basis of all its business activities. With all the measures, however, there is a possibility of the situation running counter to the spirit of compliance, which circumstances could result in social disgrace of the Group and could significantly affect its operating results and financial position

There are risks other than those described above, and the risks listed here do not include all of the risks faced by the Group.

## **Consolidated Balance Sheets**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries March 31, 2015 and 2014

	Million:	s of yen	Thousands of U.S. dollars (Note 1)
ASSETS	2015	2014	2015
CURRENT ASSETS:			
Cash and time deposits (Notes 3 and 5)	¥ 30,553	¥ 22,746	\$ 254,608
Marketable securities (Notes 3, 5 and 6)	111,293	81,953	927,442
Receivables:			
Trade notes (Note 5)	2,311	2,188	19,258
Trade accounts (Note 5)	101,525	110,299	846,042
Due from parent company, unconsolidated subsidiaries and			
affiliates (Notes 5 and 13)	49,131	41,803	409,425
Allowance for doubtful receivables	(126)	(120)	(1,050)
Total	152,841	154,170	1,273,675
Inventories (Note 4)	62,388	59,143	519,900
Deferred tax assets (Note 9)	38,867	37,282	323,892
Other current assets	5,757	4,318	47,975
Total current assets	401,699	359,612	3,347,492

#### PROPERTY, PLANT AND EQUIPMENT:

Land	6,298	10,339	52,483
Buildings and structures	94,185	100,804	784,875
Machinery and equipment	111,705	109,750	930,875
Construction in progress	1,245	3,081	10,375
Total	213,433	223,974	1,778,608
Accumulated depreciation	(148,273)	(151,285)	(1,235,608)
Net property, plant and equipment	65,160	72,689	543,000

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

Investment in unconsolidated subsidiaries and affiliates	1,709	1,198	14,242
Investment securities (Notes 5 and 6)	56,485	49,626	470,708
Goodwill	88,075	80,669	733,958
In-process research and development	64,456	56,072	537,133
Other intangible assets	21,332	20,055	177,767
Asset for retirement benefits (Note 10)	1,936	4,686	16,133
Deferred tax assets (Note 9)	4,794	8,602	39,950
Other assets	5,938	5,824	49,484
Total investments and other assets	244,725	226,732	2,039,375
TOTAL	¥ 711,584	¥ 659,033	\$ 5,929,867

	Millions o	Millions of yen		
LIABILITIES AND NET ASSETS	2015	2014	2015	
CURRENT LIABILITIES:				
Current portion of long-term debt (Notes 5 and 8)	¥ 36,522	¥ 10,000	\$ 304,350	
Payables:				
Trade notes (Note 5)	87	74	725	
Trade accounts (Notes 5, 6 and 7)	42,835	42,072	356,958	
Due to parent company, unconsolidated subsidiaries and affiliates (Notes 5 and 13)	1,964	1,738	16,367	
Total	44,886	43,884	374,050	
Income taxes payable (Note 5)	3,289	10,524	27,408	
Accrued expenses	65,400	53,499	545,000	
Other current liabilities	6,747	13,301	56,225	
Total current liabilities	156,844	131,208	1,307,033	
LONG-TERM LIABILITIES:				
Long-term debt (Notes 5 and 8)	50,000	85,000	416,667	
Liability for retirement benefits (Note 10)	15,274	13,892	127,283	
Deferred tax liabilities (Note9)	17,355	15,705	144,625	
Other liabilities (Note 8)	21,090	14,688	175,751	
Total long-term liabilities	103,719	129,285	864,326	
COMMITMENTS AND CONTINGENT LIABILITIES (Notes 14 and 19):  NET ASSETS:				
Shareholders' equity (Note 11)				
Common stock: authorized — 1,500,000,000 shares in the years ended March 31, 2015 and 2014; issued — 397,900,154 shares in the years ended March 31, 2015 and 2014				
	22 400	22 400	186 667	
	22,400	22,400	186,667	
Capital surplus	15,860	15,860	132,167	
Capital surplus Retained earnings	•			
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015	15,860 326,686	15,860 318,862	132,167 2,722,383	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014	15,860 326,686 (660)	15,860 318,862 (657)	132,167 2,722,383 (5,500)	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014  Total shareholders' equity	15,860 326,686	15,860 318,862	132,167 2,722,383	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014  Total shareholders' equity  Accumulated other comprehensive income (loss)	15,860 326,686 (660) 364,286	15,860 318,862 (657) 356,465	132,167 2,722,383 (5,500) 3,035,717	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014  Total shareholders' equity  Accumulated other comprehensive income (loss)  Unrealized gains (losses) on available-for-sale securities	15,860 326,686 (660) 364,286 23,099	15,860 318,862 (657) 356,465	132,167 2,722,383 (5,500 3,035,717	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014  Total shareholders' equity  Accumulated other comprehensive income (loss)  Unrealized gains (losses) on available-for-sale securities  Deferred gains (losses) on hedges	15,860 326,686 (660) 364,286 23,099	15,860 318,862 (657) 356,465 17,248 (1)	132,167 2,722,383 (5,500 3,035,717 192,491	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014  Total shareholders' equity  Accumulated other comprehensive income (loss)  Unrealized gains (losses) on available-for-sale securities  Deferred gains (losses) on hedges  Foreign currency translation adjustments	15,860 326,686 (660) 364,286 23,099 2 68,171	15,860 318,862 (657) 356,465 17,248 (1) 26,792	132,167 2,722,383 (5,500) 3,035,717 192,491 17 568,091	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014  Total shareholders' equity  Accumulated other comprehensive income (loss)  Unrealized gains (losses) on available-for-sale securities  Deferred gains (losses) on hedges  Foreign currency translation adjustments  Remeasurements of defined benefit plans	15,860 326,686 (660) 364,286 23,099 2 68,171 (4,537)	15,860 318,862 (657) 356,465 17,248 (1) 26,792 (1,964)	132,167 2,722,383 (5,500) 3,035,717 192,491 17 568,091 (37,808)	
Capital surplus  Retained earnings  Treasury stock, at cost: 596,335 shares in the year ended March 31, 2015 and 593,962 shares in the year ended March 31, 2014  Total shareholders' equity  Accumulated other comprehensive income (loss)  Unrealized gains (losses) on available-for-sale securities  Deferred gains (losses) on hedges  Foreign currency translation adjustments	15,860 326,686 (660) 364,286 23,099 2 68,171	15,860 318,862 (657) 356,465 17,248 (1) 26,792	132,167 2,722,383 (5,500) 3,035,717 192,491 17	

## **Consolidated Statements of Income**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

	Millions	Millions of yen	
	2015	2014	2015
NET SALES (Notes 12 and 13)	¥ 371,371	¥ 387,693	\$ 3,094,758
COST OF SALES (Notes 12 and 13)	101,228	104,100	843,566
Gross profit	270,143	283,593	2,251,192
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Notes 2 and 13)	246,868	241,450	2,057,234
Operating income	23,275	42,143	193,958
OTHER INCOME (EXPENSES):			
Interest and dividend income (Note 13)	1,574	1,100	13,117
Interest expense	(937)	(1,007)	(7,808)
Gain on investments in partnership	1,990	1	16,583
Gain on sales of property, plant and equipment	15,984	_	133,200
Compensation income for damage	1,711	_	14,258
Gain on sales of investment securities (Note 6)	_	2,773	_
Fair value adjustments of contingent consideration	_	1,284	_
Impairment loss (Notes 2 (h) and 16)	(5,310)	(7,638)	(44,250)
Restructuring (Note 17)	(1,961)	(2,342)	(16,342)
Other — net	(2,571)	(1,605)	(21,424)
Other income (expenses) — net	10,480	(7,434)	87,334
INCOME BEFORE INCOME TAXES	33,755	34,709	281,292
INCOME TAXES (Note 9):			
Current	14,034	14,784	116,950
Deferred	4,273	(136)	35,609
Total income taxes	18,307	14,648	152,559
NET INCOME	¥ 15,448	¥ 20,061	\$ 128,733
	Yer	า	U.S. dollars (Note 1)
PER SHARE OF COMMON STOCK:			
Basic net income	¥ 38.88	¥ 50.49	\$ 0.32
Cash dividends applicable to the year	18.00	18.00	0.15
See Notes to Consolidated Financial Statements			

See Notes to Consolidated Financial Statements.

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

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014	Millions o	Thousands of U.S. dollars (Note 1)	
	2015	2014	2015
NET INCOME	¥ 15,448	¥ 20,061	\$ 128,733
OTHER COMPREHENSIVE INCOME (LOSS):			
Unrealized gains (losses) on available-for-sale securities (Note 18)	5,851	2,854	48,759
Deferred gains (losses) on hedges (Note 18)	3	(1)	25
Foreign currency translation adjustments (Note 18)	41,379	22,251	344,825
Remeasurements of defined benefit plans (Note 18)	(2,573)	_	(21,442)
Total other comprehensive income (loss) (Note 18)	44,660	25,104	372,167
COMPREHENSIVE INCOME (LOSS)	60,108	45,165	500,900
COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO:			
Owners of the parent	60,108	45,165	500,900
Minority interests	_	_	_

# Consolidated Statements of Changes in Net Assets Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

	Thousands	of shares						Millions of ye	n				
				Sha	areholders' eq	uity		Accumulated other comprehensive income (loss)					
	Issued number of shares of common stock	Number of treasury stocks	Common stock	Capital surplus	Retained earnings	Treasury stock	Total share- holders' equity	Unrealized gains (losses) on available- for-sale securities	Deferred gains (losses) on hedges	Foreign currency translation adjustments	Remeasure- ments of defined benefit plans	Total accumulated other comprehensive income (loss)	Total net assets
BALANCE, APRIL 1, 2013	397,900	(590)	¥ 22,400	¥ 15,860	¥ 308,557	¥ (651)	¥ 346,166	¥ 14,121	_	¥ (11,039)	_	¥ 3,082	¥ 349,248
Cash dividends, ¥18.00 per share					(7,152)		(7,152)						(7,152)
Net income					20,061		20,061						20,061
Purchases of treasury stock		(4)				(6)	(6)						(6)
Sales of treasury stock		0		0		0	0						0
Decrease due to change in fiscal period of consolidated subsidiaries					(2,604)		(2,604)						(2,604)
Net change in items other than shareholders' equity								3,127	(1)	37,831	(1,964)	38,993	38,993
BALANCE, MARCH 31, 2014	397,900	(594)	¥ 22,400	¥ 15,860	¥ 318,862	¥ (657)	¥ 356,465	¥ 17,248	¥ (1)	¥ 26,792	¥ (1,964)	¥ 42,075	¥ 398,540
BALANCE, APRIL 1, 2014	397,900	(594)	¥ 22,400	¥ 15,860	¥ 318,862	¥ (657)	¥ 356,465	¥ 17,248	¥ (1)	¥ 26,792	¥ (1,964)	¥ 42,075	¥ 398,540
Cumulative effects of change in accounting policies					(199)		(199)						(199)
Restated balance	397,900	(594)	¥22,400	¥15,860	¥318,663	¥(657)	¥356,266	¥ 17,248	¥(1)	¥ 26,792	¥(1,964)	¥42,075	¥398,341
Cash dividends, ¥18.00 per share					(7,152)		(7,152)						(7,152)
Net income					15,448		15,448						15,448
Purchases of treasury stock		(2)				(3)	(3)						(3)
Sales of treasury stock		0		0		0	0						0
Change of scope of consolidation					(5)		(5)						(5)
Change of scope of equity method					(268)		(268)						(268)
Net change in items other than shareholders' equity								5,851	3	41,379	(2,573)	44,660	44,660
BALANCE, MARCH 31, 2015	397,900	(596)	¥22,400	¥15,860	¥326,686	¥(660)	¥364,286	¥ 23,099	¥ 2	¥ 68,171	¥(4,537)	¥86,735	¥451,021

		Thousands of U.S. dollars (Note 1)									
		Shareholders' equity					Accumulated other comprehensive income (loss)				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total share- holders' equity	Unrealized gains (losses) on available- for-sale securities	Deferred gains (losses) on hedges	Foreign currency translation adjustments	Remeasure- ments of defined benefit plans	Total accumulated other comprehensiv income (loss)	e Total net
BALANCE, APRIL 1, 2014	\$ 186,667	\$ 132,167	\$ 2,657,182	\$ (5,475)	\$ 2,970,541	\$143,732	\$(8)	\$ 223,266	\$ (16,366)	\$ 350,624	\$ 3,321,165
Cumulative effects of change in accounting policies			(1,658)		(1,658)						(1,658)
Restated balance	\$186,667	\$132,167	\$2,655,524	\$(5,475)	\$2,968,883	\$143,732	\$(8)	\$223,266	\$(16,366)	\$350,624	\$3,319,507
Cash dividends, U.S.\$ 0.15 per share			(59,600)		(59,600)						(59,600)
Net income			128,733		128,733						128,733
Purchases of treasury stock				(25)	(25)						(25)
Sales of treasury stock		0		0	0						0
Change of scope of consolidation			(42)		(42)						(42)
Change of scope of equity method			(2,232)		(2,232)						(2,232)
Net change in items other than shareholders' equity						48,759	25	344,825	(21,442)	372,167	372,167
BALANCE, MARCH 31, 2015	\$186,667	\$132,167	\$2,722,383	\$(5,500)	\$3,035,717	\$192,491	\$17	\$568,091	\$(37,808)	\$722,791	\$3,758,508

## **Consolidated Statements of Cash Flows**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

Adjustments for: Depreciation and amortization 13,780 12,723 114,833 Impairment loss 15,310 7,638 44,250 Amortization of goodwill 5,446 5,054 45,283 Increase (decrease) in liability for retirement benefit 181 (778) 1,508 Increase (decrease) in liability for retirement benefit 181 (778) 1,508 Intreest and dividend income (1,574) (1,100) 105,197) 105,1970 105,197		Millions o	Millions of yen		
Income before income laws		2015	2014	2015	
Adjustments for: Depreciation and amortization 13,780 12,723 114,833 Impairment loss 15,310 7,638 44,250 Amortization of goodwill 5,446 5,054 45,283 Increase (decrease) in liability for retirement benefit 181 (778) 1,508 Increase (decrease) in liability for retirement benefit 181 (778) 1,508 Intreest and dividend income (1,574) (1,100) 105,197) 105,1970 105,197	OPERATING ACTIVITIES:				
Depreciation and amoritzation   13,780   21,723   114,833   Impairment los   5,310   7,638   44,256   Amortization of goodwill   5,446   5,054   45,383   Increase (decrease) in liability for retirement benefit   181   (778)   1,508   Increase (decrease) in liability for retirement benefit   181   (778)   1,508   Increase (decrease) in liability for retirement benefit   181   (778)   1,508   Increase (decrease) in liability for retirement benefit   181   (778)   1,508   Increase (decrease) in partnership   (1,930)   21   (15,683   Interest sepense   937   1,007   7,808   Interest sepense   937   1,007   7,808   Interest sepense   0,773   (300   0,365   0,773)   (300   0,365   0,773)   (300   0,365   0,773)   (300   0,365   0,365   0,373)   (300   0,365	Income before income taxes	¥ 33,755	¥ 34,709	\$ 281,292	
Impairment loss	Adjustments for:				
Amortization of goodwill   5,446   5,054   43,388	Depreciation and amortization	13,780	21,723	114,833	
Increase (decrease) in lability for retirement benefit	Impairment loss	5,310	7,638	44,250	
Interest and dividend income	Amortization of goodwill	5,446	5,054	45,383	
Loss (gain) on investments in partnership   (1,930)   21   (16,083   Interest expense   937   1,007   7,888   Interest expense   937   1,007   7,888   Loss (gain) on sales of property, plant and equipment   (15,982)   (31)   (133,183   Loss (gain) on sales of investment securities   (36)   (2,773)   (300   (86,000)   (300   (300)	Increase (decrease) in liability for retirement benefit	181	(778)	1,508	
Interest expense	Interest and dividend income	(1,574)	(1,100)	(13,117)	
Loss (gain) on sales of property, plant and equipment   (15,982)   (31)   (133,183   Loss (gain) on sales of investment securities   (36)   (2,773)   (300   Restructuring   1,961   2,342   16,342   1	Loss (gain) on investments in partnership	(1,930)	21	(16,083)	
Loss (gain) on sales of investment securities   1,961   2,342   16,342		937	1,007	7,808	
Loss (gain) on sales of investment securities   1,961   2,342   16,342	Loss (gain) on sales of property, plant and equipment	(15,982)	(31)	(133,183)	
Changes in assets and liabilities:   Increase (decrease) in receivables   13,075 (15,113)   108,958     Decrease (increase) in inventories   (790)   4,919 (6,583     Increase (decrease) in inventories   (2,269) (5,773) (18,908     Other — net   415 9,658 3,458     Subtotal   52,279 (61,503 435,658     Interest and dividend received   1,824 1,309 15,200     Interest paid   (887) (963) (7,392     Payment for restructuring   (1,589) (4,874) (13,241     Income taxes paid   (21,376) (7,032) (178,133     Net cash provided by operating activities   30,251 49,943 252,092     INVESTING ACTIVITIES:   Subtotal   Subtotal     Purchases of intengible assets   (3,705) (11,225) (30,875     Proceeds from sales of property, plant and equipment   (3,662) (10,332) (72,183     Purchases of intangible assets   (3,705) (11,225) (30,875     Proceeds from sales of property, plant and equipment   (3,662) (10,332) (72,183     Purchase of investment securities   (1,667) (9,144) (13,892     Purchase of investment securities   (1,667) (9,144) (13,892     Purchase of investment securities   (1,667) (9,144) (13,892     Purchase of investments in subsidiaries   (2,273) 94 (18,942     Purchase of investments in subsidiaries   (3,605) (3,494     Purchase of investments in subsidiaries   (3,605) (3,494     Purchase of investments in subsidiaries   (3,605) (3,494     Purchase of investments in subsidiaries   (3,605) (3,605     Other — net   7 (49) (5,805     Other — net   7 (4		(36)	(2,773)	(300)	
Increase (decrease) in receivables   13,075 (15,113)   108,958     Decrease (increase) in inventories   (790)   4,919 (6,558     Increase (decrease) in payables   (2,269) (5,773) (18,908     Other — net   415 9,658 3,458     Subtotal   52,279 61,503 435,658     Interest and dividend received   1,824 1,309 15,200     Interest and dividend received   1,824 1,309 15,200     Interest paid   (887) (963) (7,392     Payment for restructuring   (1,589) (4,874) (13,241     Income taxes paid   (21,376) (7,032) (178,133     Net cash provided by operating activities   30,251 49,943 252,092     INVESTING ACTIVITIES:	Restructuring	1,961	2,342	16,342	
Decrease (increase) in inventories   (790)   4,919   (6,583   1,650   1,673)   (18,908   1,673   1,650   1,673   1,650   1,673   1,650   1,673   1,6	Changes in assets and liabilities:				
Increase (decrease) in payables	Increase (decrease) in receivables	13,075	(15,113)	108,958	
Increase (decrease) in payables   (2,269)   (5,773)   (18,908   Other—net   415   9,658   3,458   Subtotal   52,279   61,503   435,658   Interest and dividend received   1,824   1,309   15,200   Interest paid   (887)   (963)   (7,329   Payment for restructuring   (1,589)   (4,874)   (13,241   Income taxes paid   (21,376)   (7,032)   (178,133   Net cash provided by operating activities   30,251   49,943   252,099   Substitution   252,099   S	Decrease (increase) in inventories	(790)	4,919	(6,583)	
Other—net         415         9,658         3,458           Subtotal         52,279         61,503         455,658           Interest and dividend received         1,824         1,309         15,200           Interest paid         (887)         (963)         (7,392           Payment for restructuring         (1,589)         (4,874)         (13,241)           Income taxes paid         (21,376)         (7,032)         (178,133)           Net cash provided by operating activities         30,251         49,943         252,092           INVESTING ACTIVITIES:           Net decrease (increase) in time deposits         —         6,170         —           Purchases of property, plant and equipment         (8,662)         (10,332)         (72,188           Purchases of intangible assets         (3,705)         (11,225)         (30,875           Proceeds from sales of property, plant and equipment         20,014         51         166,703           Purchases of investment securities         15,261         4,650         127,175           Proceeds from sales of investment securities         1,202         2,809         10,017           Purchase of investment securities         1,202         2,809         10,017           Purchase of inve	Increase (decrease) in payables			(18,908)	
Interest and dividend received   1,824   1,309   15,200     Interest paid   (887)   (963)   (7,392)     Payment for restructuring   (1,589)   (4,874)     Income taxes paid   (21,376)   (7,032)   (178,133     Net cash provided by operating activities   30,251   49,943   252,092     INVESTING ACTIVITIES:				3,458	
Interest and dividend received   1,824   1,309   15,200     Interest paid   (1,589)   (4,874)   (13,241     Income taxes paid   (21,376)   (7,032)   (178,133     Net cash provided by operating activities   30,251   49,943   252,092     INVESTING ACTIVITIES:	Subtotal	52,279		435,658	
Interest paid   (887)   (963)   (7,392   Payment for restructuring   (1,589)   (4,874)   (13,241   Income taxes paid   (21,376)   (7,032)   (178,133   Net cash provided by operating activities   30,251   49,943   252,092	Interest and dividend received			15,200	
Payment for restructuring		-	•	(7,392)	
Income taxes paid   (21,376) (7,032) (178,133   Net cash provided by operating activities   30,251   49,943   252,092		(1,589)	(4,874)	(13,241)	
Net cash provided by operating activities   30,251   49,943   252,092	, ,				
INVESTING ACTIVITIES:   Net decrease (increase) in time deposits					
Purchases of intangible assets         (3,705)         (11,225)         (30,875)           Proceeds from sales of property, plant and equipment         20,014         51         166,783           Net decrease (increase) in marketable securities         15,261         4,650         127,175           Proceeds from sales of investment securities         1,202         2,809         10,017           Purchases of investment securities         (1,667)         (9,144)         (13,892           Proceeds from redemption of investment securities         2,273         94         18,942           Purchase of investments in subsidiaries         (729)         (2,826)         (6,075)           Purchase of investments in subsidiaries         (729)         (2,826)         (6,075)           Payment of loan receivable         (546)         (6,407)         (4,550)           Other — net         7         (49)         58           Net cash provided (used) in investing activities         23,448         (26,209)         195,400           FINANCING ACTIVITIES:           Proceeds from long-term loans payable         1,786         —         14,883           Repayment of long-term borrowings         (10,349)         (10,000)         46,242           Redemption of bonds         — <td< th=""><th></th><th>_</th><th>6,170</th><th>_</th></td<>		_	6,170	_	
Proceeds from sales of property, plant and equipment         20,014         51         166,783           Net decrease (increase) in marketable securities         15,261         4,650         127,175           Proceeds from sales of investment securities         1,202         2,809         10,017           Purchases of investment securities         (1,667)         (9,144)         (13,892           Proceeds from redemption of investment securities         2,273         94         18,942           Purchase of investments in subsidiaries         (729)         (2,826)         (6,077)           Payment of loan receivable         (546)         (6,407)         (4,550           Other — net         7         (49)         58           Net cash provided (used) in investing activities         23,448         (26,209)         195,400           FINANCING ACTIVITIES:         Proceeds from long-term loans payable         1,786         —         14,883           Repayment of long-term borrowings         (10,349)         (10,000)         —           Redemption of bonds         —         (10,000)         —           Increase in treasury stock         (3)         (6)         (25           Dividends paid         (7,152)         (7,152)         (59,600           O	Purchases of property, plant and equipment	(8,662)	(10,332)	(72,183)	
Net decrease (increase) in marketable securities		(3,705)	(11,225)	(30,875)	
Proceeds from sales of investment securities   1,202   2,809   10,017	Proceeds from sales of property, plant and equipment	20,014	51	166,783	
Purchases of investment securities         (1,667)         (9,144)         (13,892           Proceeds from redemption of investment securities         2,273         94         18,942           Purchase of investments in subsidiaries         (729)         (2,826)         (6,075           Payment of loan receivable         (546)         (6,407)         (4,550           Other — net         7         (49)         58           Net cash provided (used) in investing activities         23,448         (26,209)         195,400           FINANCING ACTIVITIES:           Proceeds from long-term loans payable         1,786         —         14,883           Repayment of long-term borrowings         (10,349)         (10,000)         66,242           Redemption of bonds         —         (10,000)         —           Increase in treasury stock         (3)         (6)         (25           Dividends paid         (7,152)         (7,152)         (59,600           Other — net         (7)         (6)         (58           Net cash used in financing activities         (15,725)         (27,164)         (131,042           EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS         10,703         7,951         89,192           N			4,650	127,175	
Proceeds from redemption of investment securities  Purchase of investments in subsidiaries  Purchase of investments in subsidiaries  Payment of loan receivable  Other — net  Total (49)  EFINANCING ACTIVITIES:  Proceeds from long-term loans payable  Repayment of long-term borrowings  Repayment of long-term borrowings  Repayment of long-term borrowings  Reading in the saury stock  Other — net  Total (10,000)  Redemption of bonds  Total (71,52)  Proceeds in treasury stock  Repayment of long-term borrowings  Reading in financing activities  Proceeds in financing activities  Repayment of long-term borrowings  Reading in financing activities  Repayment of long-term borrowings  Reading in financing activities  Repayment of long-term borrowings  (10,349)  (10,000)  Redemption of bonds  Total (10,000)  Redemption of (10,000			2,809	10,017	
Purchase of investments in subsidiaries         (729)         (2,826)         (6,075)           Payment of loan receivable         (546)         (6,407)         (4,550)           Other — net         7         (49)         58           Net cash provided (used) in investing activities         23,448         (26,209)         195,400           FINANCING ACTIVITIES:           Proceeds from long-term loans payable         1,786         —         14,883           Repayment of long-term borrowings         (10,349)         (10,000)         (86,242)           Redemption of bonds         —         (10,000)         —           Increase in treasury stock         (3)         (6)         (25           Dividends paid         (7,152)         (7,152)         (59,600)           Other — net         (7)         (6)         (58           Net cash used in financing activities         (15,725)         (27,164)         (131,042           EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS         10,703         7,951         89,192           NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS         48,677         4,521         405,642           CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR         73,919         71,434         615,991		(1,667)	(9,144)	(13,892)	
Payment of loan receivable	Proceeds from redemption of investment securities	2,273	94	18,942	
Other — net         7         (49)         58           Net cash provided (used) in investing activities         23,448         (26,209)         195,400           FINANCING ACTIVITIES:           Proceeds from long-term loans payable         1,786         —         14,883           Repayment of long-term borrowings         (10,349)         (10,000)         (86,242           Redemption of bonds         —         (10,000)         —           Increase in treasury stock         (3)         (6)         (25           Dividends paid         (7,152)         (7,152)         (59,600           Other — net         (7)         (6)         (58           Net cash used in financing activities         (15,725)         (27,164)         (131,042           EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS         10,703         7,951         89,192           NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS         48,677         4,521         405,642           CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR         73,919         71,434         615,991           Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation         198         —         1,650           Increase(decrease) in cash and cash equivalents resulting from change in the fiscal		(729)	(2,826)	(6,075)	
Net cash provided (used) in investing activities  Proceeds from long-term loans payable Repayment of long-term borrowings Redemption of bonds Repayment of long-term borrowings Redemption of long-term borrowings Repayment of long-term borrowings Redemption of long-ter				(4,550)	
FINANCING ACTIVITIES:  Proceeds from long-term loans payable Repayment of long-term borrowings Redemption of bonds Redemption of long-term borrow Redemption of long-ter		7	(49)	58	
Proceeds from long-term loans payable Repayment of long-term borrowings Redemption of bonds Redemption of long. Redemption of	Net cash provided (used) in investing activities	23,448	(26,209)	195,400	
Proceeds from long-term loans payable Repayment of long-term borrowings Redemption of bonds Redemption of long. Redemption of	EINANCING ACTIVITIES				
Repayment of long-term borrowings (10,349) (10,000) (86,242) Redemption of bonds — (10,000) — Increase in treasury stock (3) (6) (25) Dividends paid (7,152) (7,152) (59,600) Other — net (7) (6) (58) Net cash used in financing activities (15,725) (27,164) (131,042) EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS 10,703 7,951 89,192 NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS 48,677 4,521 405,642 CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR 73,919 71,434 615,991 Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation 198 — 1,650 Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries — (2,036) —		1 726		1// 992	
Redemption of bonds — (10,000) — Increase in treasury stock — (3) (6) (25    Dividends paid — (7,152) (7,152) (59,600    Other — net — (7) (6) (58    Net cash used in financing activities — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS — (15,725) (27,164) (131,042    EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENT			(10,000)		
Increase in treasury stock  Dividends paid  Other — net  Other — net  Net cash used in financing activities  FFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS  NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS  NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS  CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR  Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation  Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries  (3) (6) (25  (59,600  (7,152)  (7,152)  (59,600  (15,725)  (27,164)  (131,042  (131,042  (15,725)  (27,164)  (131,042  (131,042  (15,725)  (27,164)  (131,042  (131,042  (131,042  (15,725)  (27,164)  (131,042  (131,042  (15,725)  (27,164)  (131,042  (131,042  (15,725)  (27,164)  (131,042  (131,042  (13,042  (15,725)  (27,164)  (131,042  (131,042  (15,725)  (27,164)  (131,042  (131,042  (15,725)  (27,164)  (131,042  (131,042  (13,042  (15,725)  (27,164)  (131,042  (131,042  (131,042  (14,042)  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (131,042  (14,042)  (14,042)  (15,725)  (27,164)  (131,042  (131,042  (14,042)  (14,042)  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (14,042)  (15,725)  (15,725)  (27,164)  (131,042  (14,042)  (15,725)  (27,164)  (131,042  (14,042)  (14,042)  (15,725)  (14,042)  (14,042)  (15,042)		(10,545)		(00,242)	
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Other — net (7) (6) (58  Net cash used in financing activities (15,725) (27,164) (131,042)  EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS 10,703 7,951 89,192  NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS 48,677 4,521 405,642  CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR 73,919 71,434 615,991  Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation 198 — 1,650  Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries — (2,036) —					
Net cash used in financing activities (15,725) (27,164) (131,042)  EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS 10,703 7,951 89,192  NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS 48,677 4,521 405,642  CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR 73,919 71,434 615,991  Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation 198 — 1,650  Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries — (2,036) —					
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NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS  CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR  Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation  Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries  48,677  4,521  405,642  73,919  71,434  615,991  198  — 1,650					
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR73,91971,434615,991Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation198—1,650Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries—(2,036)—					
Increase(decrease) in cash and cash equivalents resulting from change of scope of consolidation  198 — 1,650  Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries  — (2,036) —					
change of scope of consolidation  Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries  — (2,036) —		75,515	, 1,454	013,331	
change in the fiscal period of subsidiaries — (2,036) —	change of scope of consolidation	198		1,650	
	Increase(decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries	_	(2.036)	_	
	CASH AND CASH EQUIVALENTS, END OF YEAR (Note 3)	¥ 122,794	¥ 73,919	\$ 1,023,283	

#### **Notes to Consolidated Financial Statements**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

# 1. BASIS OF PRESENTING CONSOLIDATED FINANCIAL STATEMENTS

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

The accounts of consolidated subsidiaries in the 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 Sumitomo Dainippon 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 ¥120 to U.S.\$1.00, the approximate rate of exchange on March 31, 2015. 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 2014 consolidated financial statements to conform to the classifications applied in 2015. These reclassifications have had no effect on the previously reported net income or retained earnings.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### a. Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and significant subsidiaries over which the Company has control through majority of voting rights or certain other conditions evidencing control by the Company.

The consolidated financial statements include the accounts of the Company and its 16 significant subsidiaries. Under the control concept, those companies in which the Company directly or indirectly is able to exercise control over operations are consolidated. Sunovion Pharmaceuticals Europe Limited has been included in the scope of consolidation since the beginning of this fiscal year because of the increase in importance resulting from the start of sales.

Investments in unconsolidated subsidiaries and affiliates over which the Company has the ability to exercise significant influence in operating and financial policies are accounted for by the equity method. The equity method is applied to 2 significant affiliates. Investments in the unconsolidated subsidiaries and affiliates other than 2 companies are not accounted for by equity method since the effect on the accompanying consolidated financial statements is not material.

Material intercompany balances, transactions and unrealized profit included in assets have been eliminated in consolidation.

There are 13 consolidated overseas subsidiaries. Among the consolidated subsidiaries, Boston Biomedical, Inc. ("BBI") and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., have a fiscal accounting year-end date of December 31.

In the preparation of the consolidated financial statements, the Company used BBI's financial statements as of BBI's fiscal accounting year-end date with necessary adjustments for material transactions arising in the period between its fiscal accounting year-end date and the Group's balance sheet date. Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. prepared a set of financial statements based on a provisional statement of accounts at March 31 for consolidation purpose.

#### **Notes to Consolidated Financial Statements**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

#### 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 and short term, highly liquid investments, all of which mature within three months from the date of acquisition.

#### c. Marketable and Investment Securities

All marketable and investment securities are available-for-sale securities, which are not classified as either trading securities or held-to-maturity debt securities. Available-for-sale securities are reported at fair value with unrealized gains and losses net of applicable taxes shown as a separate component of net assets. Non-marketable available-for-sale securities are stated at cost, determined using the moving average method. If the fair value of investment securities declines below cost and the decline is material and other than temporary, the carrying value is impaired 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 for which inventories are stated at the lower of cost or net realizable value.

#### e. Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation and accumulated impairment losses. Depreciation of all tangible fixed assets is computed using the straight-line method over the estimated useful life of the asset. 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 using the straight-line method over the estimated useful lives from the date they are available for use.

#### 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. Impairment of 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 or amortization 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 amount by which the carrying amount exceeds its recoverable amount. The recoverable amount of an asset is the greater of its discounted cash flows and its fair value less cost to sell.

#### i. 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 asset and liability for retirement benefit is recognized based on projected benefit obligations and the fair value of plan assets at the balance sheet date.

The company and certain consolidated subsidiaries have retirement benefits plans that primarily consist of a lump-sum payment plan, defined benefit plans, and a defined contribution pension program.

The estimated amount of all retirement benefit to be paid at future retirement dates is allocated to periods of service based on the plan's benefit formula. Past service costs are amortized using the straight-line method over a period of 15 years, which is within the average of the estimated remaining services years commencing with the current period. Actuarial gains and losses are amortized using the straight-line method over a period of 15 years, which is within the average of the estimated remaining service years commencing in the following period. Some domestic consolidated subsidiaries use the simplified method for the calculation of projected benefit obligation.

#### j. 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, 2015 and 2014 were ¥71,304 million (\$594,200 thousand) and ¥69,804 million, respectively.

#### k. Income Taxes

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 at the tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted by the balance sheet date.

#### I. Foreign Currency Translation

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 consolidated 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.

#### m. Derivative Financial Instruments

Foreign exchange contracts are utilized to hedge the exposure risk arising from fluctuations in foreign exchange rates. Derivative financial 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 loss or gain on the related hedged item is recognized if the derivative financial instrument is used as a hedge and meets the hedging criteria. Foreign exchange contracts that the 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 effectiveness of hedges has been evaluated by comparing the accumulated changes in market value of hedged items with the accumulated changes in market value of hedging instruments. With regard to foreign exchange forward contracts, the effectiveness of such contracts has not been evaluated as critical terms for hedged items and hedging instruments are the same. 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 any derivative financial instruments for speculative trading purposes.

#### **Notes to Consolidated Financial Statements**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

#### n. Per Share Information

Basic net income per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding for the period. The number of shares used in the calculation of net income per share was 397,305 thousand and 397,308 thousand for the years ended March 31, 2015 and 2014, 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.

#### o. 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.

#### p. Changes in Accounting Policies

The Company has applied the "Accounting Standard for Retirement Benefits" (Accounting Standard Board of Japan "ASBJ" Statement No. 26, May 17, 2012) and the "Guidance for the Accounting Standard for Retirement Benefits" (ASBJ Guidance No. 25, May 17, 2012) from the beginning of the current fiscal year, and revised the calculation method for retirement benefit obligations and current service cost according to the provisions found in Paragraph 35 of the Accounting Standard for Retirement Benefits and Paragraph 67 of the Guidance for the Accounting Standard for Retirement Benefits. The method of attributing expected benefit to periods of service has been changed from straight-line basis to benefit formula basis, and the method of determining discount rate has also been changed from using the bond rate determined by reference to the terms closely related to average remaining working lives of the employees, to using a single weighted average discount rate that reflects the estimated timing and amount of benefit payments.

With regard to the application of the Accounting Standard for Retirement Benefits, in accordance with the provisions on transitional implementation indicated in Paragraph 37 of the Accounting Standard for Retirement Benefits, the effect of changing the determination of retirement benefit obligations and current service costs has been recognized in retained earnings at the beginning of the fiscal year.

As a result of application, at the beginning of current fiscal year, the amount of assets for retirement benefit decreased by 245 million yen, the amount of liabilities for retirement benefit increased by 62 million yen, retained earnings decreased by 199 million yen. The impact on the profit and earnings per share for the fiscal year are immaterial. Information of the impact on segment information is omitted because the impact is insignificant.

#### q. Accounting standards that have not been applied yet

Accounting Standard for Business Combinations (Accounting Standards Board of Japan [ASBJ] statement No. 21, September 13, 2013)

Accounting Standard for Consolidated Financial Statements (ASBJ statement No.22, September 13, 2013)

Accounting Standard for Business Divestitures (ASBJ statement No.7, September 13, 2013)

Accounting Standard for Earnings Per Share (ASBJ statement No.2, September 13, 2013)

Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures" (ASBJ Guidance No.10 September 13, 2013)

Guidance on Accounting Standard for Earnings Per Share (ASBJ Guidance No.4 September 13, 2013)

#### (1) Summary

These accounting standards and guidance were revised on the following points.

- (i) Accounting treatment for changes in ownership interests in subsidiaries for situation where the control of the subsidiaries in retained after an additional acquisition of the subsidiaries' stocks
- (ii) Accounting treatment for the acquisition-related expenses
- (iii) Presentation of net income, and the change from minority interest to non-controlling interest
- (iv) Provisional accounting treatment

#### (2) Scheduled date of application

The applications of these accounting standards above are scheduled for implementation from the beginning of the fiscal year ending March 31, 2016. As for the provisional accounting treatment, it will be applied for business combinations after the beginning of fiscal year ending March 31, 2016.

#### (3) Impact from application of the relevant accounting standards

The management is currently still assessing the financial impact from application of the relevant accounting standards at the time of preparing these consolidated financial statements.

#### r. Reclassifications

Certain reclassifications of the financial statements and accompanying footnotes for the year ended March 2014 have been made to conform the presentation for the year ended March 31, 2015.

## 3. SUPPLEMENTARY CASH FLOW INFORMATION

Cash and cash equivalents as at March 31, 2015 and 2014 for purposes of the consolidated statements of cash flows consisted of the following:

	Millions	of yen	U.S. dollars
	2015	2014	2015
Cash and time deposits	¥ 30,553	¥ 22,746	\$ 254,608
Time deposits with maturities over three months	(511)	(447)	(4,258)
Marketable securities with a maturity of three months or less when purchased	92,752	51,620	772,933
Cash and cash equivalents	¥122,794	¥ 73,919	\$ 1,023,283

As at March 31, 2015 and 2014, a time deposit of ¥511 million (\$4,258 thousand) and ¥447 million is pledged as collateral for a letter of credit issued by a bank, respectively.

#### 4. INVENTORIES

Inventories at March 31, 2015 and 2014 consisted of the following:

	Millions	Thousands of U.S. dollars	
	2015	2014	2015
Finished goods and semi-finished goods	¥ 50,750	¥ 46,378	\$ 422,917
Work-in-process	1,626	2,409	13,550
Raw materials and supplies	10,012	10,356	83,433
Total	¥ 62,388	¥ 59,143	\$ 519,900

#### **Notes to Consolidated Financial Statements**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

## 5. FINANCIAL INSTRUMENTS

#### 1) Policies for using financial instruments

The Group procures funds through bank loans and the issuance of corporate bonds. The funds 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 financial instruments with low risk. 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 customer credit risk exposure of notes and accounts receivable, due dates and amounts outstanding balances are monitored by each customer in accordance with the company's procedures for credit management. In addition, the company periodically monitors the credit standing of major customers.

Marketable securities and investment securities consist primarily of negotiable certificates for deposit and stocks issued by the business partners. Stocks are exposed to risks associated with changes in market prices. The market values of the stocks and the financial condition of the issuers of these stocks are regularly monitored. The company regularly reviews holding status in consideration of relationships with the business partners.

Trade notes and trade accounts payable are all due within one year. Some of these payables consist of notes and accounts payable that are denominated in foreign currencies due to the import of raw materials, and they are exposed to exchange rate fluctuation risk. These risks, if significant, are hedged using foreign exchange forward contracts.

Loans payable and bonds are primarily for working capital and the last maturity date of the debt is four years from March 31, 2015. A portion of such debt is exposed to interest fluctuation risks.

Income taxes payable are mainly due within two months.

Trade accounts payable, loans payable and bonds are exposed to liquidity risks. These risks are managed by preparing cash flow plans on a monthly basis.

Derivative financial instruments of the Group include foreign exchange forward contracts for the purpose of hedging risks of fluctuations in exchange rates of receivables and payables denominated in foreign currencies. With respect to foreign exchange forward contracts, the Finance & Accounting Division formulates an implementation plan for hedging foreign currency risks every six months pursuant to the company's policies in respect of management of foreign currency risks. Upon reporting to the Representative Director and President, transactions are then executed and the related entries posted. The results of derivative transactions are also reported to the Representative Director and President. 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 fair values of financial instruments

The fair values of financial instruments are based on market prices. Reasonably estimated values are used as fair values for financial instruments with no available fair market prices. Various assumption used in the calculation of the reasonably estimated values may affect calculation of values.

Book values and fair values of the financial instruments on the consolidated balance sheet as of March 31, 2015 and 2014 were as follows:

	Millions of yen					
		2015				
	Book values	Fair values	Difference			
(1) Cash and time deposits	¥ 30,533	¥ 30,533	¥ —			
(2) Trade notes	2,311	2,311	_			
(3) Trade accounts	101,525	101,525	_			
(4) Due from parent company, unconsolidated subsidiaries and affiliates	49,131	49,131	_			
(5) Marketable securities and investment securities	157,629	157,629	_			
Total assets	¥ 341,149	¥ 341,149	¥ —			
(1) Trade notes	87	87	_			
(2) Trade accounts	42,835	42,835	_			
(3) Due to parent company, unconsolidated subsidiaries and affiliates	1,964	1,964	_			
(4) Income taxes payable	3,289	3,289	_			
(5) Bonds payable (*1)	60,000	60,680	680			
(6) Long-term borrowings (*2)	26,522	26,602	80			
Total liabilities	¥ 134,697	¥ 135,457	¥ 760			
Derivative transactions	¥ 2	¥ 2	¥ —			

<sup>(\*1)</sup> Bonds payable include the amount of current portion of long-term bonds payable.

<sup>(\*2)</sup> Long-term borrowings include the amount of current portion of long-term borrowings.

		Millions of yen	
		2014	
	Book values	Fair values	Difference
(1) Cash and time deposits	¥ 22,746	¥ 22,746	¥ —
(2) Trade notes	2,188	2,188	_
(3) Trade accounts	110,299	110,299	_
(4) Due from parent company, unconsolidated subsidiaries and affiliates	41,803	41,803	_
(5) Marketable securities and investment securities	120,945	120,945	
Total assets	¥ 297,981	¥ 297,981	¥ —
(1) Trade notes	74	74	
(2) Trade accounts	42,072	42,072	
(3) Due to parent company, unconsolidated subsidiaries and affiliates	1,738	1,738	_
(4) Income taxes payable	10,524	10,524	_
(5) Bonds payable	60,000	60,895	895
(6) Long-term borrowings (*)	35,000	35,099	99
Total liabilities	¥ 149,408	¥ 150,402	¥ 994
Derivative transactions	¥ 0	¥ 0	¥ —

<sup>(\*)</sup> Long-term borrowings include the amount of current portion of long-term borrowings.

#### **Notes to Consolidated Financial Statements**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

	Thousands of U.S. dollars						
				2015			
		Book values		Fair values	Diffe	rence	
(1) Cash and time deposits	\$	254,608	\$	254,608	\$	_	
(2) Trade notes		19,258		19,258		_	
(3) Trade accounts		846,042		846,042		_	
(4) Due from parent company, unconsolidated subsidiaries and affiliates		409,425		409,425		_	
(5) Marketable securities and investment securities	1	,313,575	1,	313,575		_	
Total assets	\$ 2	,842,908	\$ 2,	842,908	\$	_	
(1) Trade notes		725		725		_	
(2) Trade accounts		356,958		356,958		_	
(3) Due to parent company, unconsolidated subsidiaries and affiliates		16,367		16,367		_	
(4) Income taxes payable		27,408		27,408		_	
(5) Bonds payable (*1)		500,000		505,667		5,667	
(6) Long-term borrowings (*2)		221,017		221,683		666	
Total liabilities	\$ 1	,122,475	\$ 1,	128,808	\$	6,333	
Derivative transactions	\$	17	\$	17	\$	_	

<sup>(\*1)</sup> Bonds payable include the amount of current portion of long-term bonds payable.

(A) Methods of determining fair value of financial instruments, and matters related to securities and derivative transactions

#### Assets

- (1) Cash and time deposits
  - The fair value of time deposits is approximately equal to book value.
- (2) Trade notes, (3) Trade accounts, (4) Due from parent company, unconsolidated subsidiaries and affiliates
  - The fair value of these assets due within a year is approximately equal to book value.
- (5) Marketable securities and investment securities

The fair value of equity securities with fair value is based on the quoted market price. The fair value of bonds is based on the price offered by the corresponding financial institutions. The fair value of negotiable certificates of deposit is approximately equal to book value. See Note 2 (c), "Summary of Significant Accounting Policies — Marketable and Investment Securities" for notes related to securities according to the purpose for which they are held.

#### Liabilities

- (1) Trade notes, (2) Trade accounts, (3) Due to parent company, unconsolidated subsidiaries and affiliates, (4) Income taxes payable
  - The fair value of these liabilities due within a year is approximately equal to book value.
- (5) Bonds payable
  - The fair value of corporate bonds is calculated according to market price.
- (6) Long-term borrowings

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

#### **Derivative transactions**

See note 7 on "Derivative Transactions."

<sup>(\*2)</sup> Long-term borrowings include the amount of current portion of long-term borrowings.

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

	Amount on consolidated balance sheet			
	Million	Thousands of U.S. dollars		
	2015	2014	2015	
Unlisted shares	¥ 8,319	¥ 7,464	\$ 69,325	
Investment in unconsolidated subsidiaries and affiliates	1,709	1,198	14,242	
Investment in limited partnership	1,830	3,170	15,250	

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.

(C) Maturity analysis for monetary claims and marketable securities and investment in securities

	Millions of yen					
	2015					
	Wit	hin 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years	
Cash and time deposits	¥	30,553	¥ —	¥ —	¥ —	
Trade notes		2,311	_	_	_	
Trade accounts	•	101,525	_	_	_	
Due from parent company, unconsolidated subsidiaries and affiliates		49,131	_	_	_	
Marketable securities and investment securities:						
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)		27,424	_	_	_	
Available-for-sale securities with terms of maturity (Bonds)		18,084	_	_	49	
Total	¥ 2	229,028	¥ —	¥ —	¥ 49	

_	Millions of yen					
	2014					
	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years		
Cash and time deposits	¥ 22,746	¥ —	¥ —	¥ —		
Trade notes	2,188	_	_	_		
Trade accounts	110,299	_	_			
Due from parent company, unconsolidated subsidiaries and affiliates	41,803		_	_		
Marketable securities and investment securities:						
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)	15,439		_			
Available-for-sale securities with terms of maturity (Bonds)	28,958	_	_	48		
Total	¥ 221,433	¥ —	¥ —	¥ 48		

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

	Thousands of U.S. dollars					
	2015					
	٧	Vithin 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years	
Cash and time deposits	\$	254,608	<b>\$</b> —	<b>\$</b> —	\$ —	
Trade notes		19,258	_	_	_	
Trade accounts		846,042	_	_	_	
Due from parent company, unconsolidated subsidiaries and affiliates		409,425	_	_	_	
Marketable securities and investment securities:						
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)		228,534	_	_	_	
Available-for-sale securities with terms of maturity (Bonds)		150,700	_	_	408	
Total	\$ 1	1,908,567	<b>\$</b> —	<b>\$</b> —	\$ 408	

### 6. MARKETABLE **SECURITIES AND INVESTMENT SECURITIES**

Marketable securities and investment securities as of March 31, 2015 and 2014 consisted of the following:

	Millions	Thousands of U.S. dollars	
	2015	2014	2015
Current:			
Government / local government bonds	¥ 6,268	¥ 15,947	\$ 52,233
Corporate bonds	11,817	13,011	98,475
Negotiable certificates of deposits	27,424	15,439	228,533
MMF	65,784	37,556	548,201
Total	¥ 111,293	¥ 81,953	\$ 927,442
Noncurrent:			
Equity securities	¥ 46,287	¥ 38,944	\$ 385,725
Trust fund investments and other	49	48	408
Total	¥ 46,336	¥ 38,992	\$ 386,133

The carrying amount and aggregate fair value of marketable securities and investment securities as at March 31, 2015 and 2014 were as follows:

Millions of yen					
2015					
Cost	Unrealized gains	Unrealized losses	Fair value		
¥ 14,444	¥ 31,844	¥ 1	¥ 46,287		
6,268	_	0	6,268		
11,820	0	3	11,817		
31	18	0	49		
	¥ 14,444 6,268 11,820	Cost Unrealized gains  ¥ 14,444 ¥ 31,844 6,268 — 11,820 0	2015       Cost     Unrealized gains     Unrealized losses       ¥ 14,444     ¥ 31,844     ¥ 1       6,268     —     0       11,820     0     3		

		Millions of yen					
		2014					
	Cost	Unrealized gains	Unrealized losses	Fair value			
Available-for-sale securities:							
Equity securities	¥ 14,414	¥ 24,558	¥ 28	¥ 38,944			
Government / local government bonds	15,947	1	1	15,947			
Corporate bonds	13,010	2	1	13,011			
Other securities	29	19	0	48			

	Thousands of U.S. dollars					
		2015	i			
	Cost	Unrealized gains	Unrealized losses	Fair value		
Available-for-sale securities:						
Equity securities	\$ 120,367	\$ 265,366	\$8	\$ 385,725		
Government / local government bonds	52,233	_	0	52,233		
Corporate bonds	98,500	0	25	98,475		
Other securities	258	150	0	408		

Proceeds from sales of available-for-sale securities were ¥2,908 million (\$24,233 thousand) and ¥6,312 million for the years ended March 31, 2015 and 2014, respectively. Realized gains from sales of available-for-sale securities were ¥36 million (\$300 thousand) and ¥2,770 million for the years ended March 31, 2015 and 2014, and costs on sales of available-for-sale securities were ¥2,872 million (\$23,933 thousand) and ¥3,542 million for the years ended March 31, 2015 and 2014, respectively. The cost of securities sold in computing realized gains was determined using the moving average method. On March 31, 2015, investment securities of ¥67 million (\$558 thousand) were pledged as collateral for accounts payable of ¥82 million (\$683 thousand). On March 31, 2014, investment securities of ¥53 million were pledged as collateral for accounts payable of ¥81 million.

### 7. DERIVATIVE **TRANSACTIONS**

The Group is exposed to certain market risk arising from its foreign exchange forward 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 they are financial institutions with high credit ratings.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

> Derivative transactions to which hedge accounting is applied as of March 31, 2015 and 2014 were as follows: Currency related transactions

### 2015

Hedge accounting method	Transaction type	Main hedged items	Cont	ract amount		on over year	Fair v	alue
Deferred hedge accounting	Foreign exchange contracts		Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars
	Buy contract	ts						
	USD	Trade	¥ 2,014	\$ 16,783	_	_	¥ 12	\$ 100
	EUR	accounts	250	2,083	_	_	(10)	(83)
	THB	payable	150	1,251	_	_	0	0
	Total		¥ 2,414	\$ 20,117	_	_	¥ 2	\$ 17
Allocation method of foreign	Foreign exchange contracts		Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars
exchange forward	Buy contract	ts						
contracts	USD	Trade	¥ 639	\$ 5,325	_	_	(*)	(*)
	EUR	accounts	75	625	_	_	(*)	(*)
	GBP	payable	2	17	_	_	(*)	(*)
	THB		17	141	_	_	(*)	(*)
	Total		¥ 733	\$ 6,108	_	_		

### 2014

Hedge accounting method	Transaction type	Main hedged items	Contr	act amount		on over year	Fair v	alue
Allocation method of foreign	Foreign exchange contracts		Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars
exchange	Buy contract	S						
contracts	USD	Trade	¥ 479	\$ 4,650	_	_	(*)	(*)
EUR GBP	EUR	accounts	54	524	_	_	(*)	(*)
	GBP	payable	8	78	_	_	(*)	(*)
	Total		¥ 541	\$ 5,252	_	_		

<sup>(\*)</sup> As foreign exchange forward 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. (See note 5)

### 8. LONG-TERM DEBT

Long-term debt at March 31, 2015 and 2014 were as follows:

	Millions	s of yen	Thousands of U.S. dollars
	2015	2014	2015
Unsecured loans from banks and financial institutions, due 2014 to 2017 with average interest rate of 0.6–0.7%	¥ 26,522	¥ 35,000	\$ 221,018
Unsecured bonds due 2016 with average interest rate of 0.78%	30,000	30,000	250,000
Unsecured bonds due 2016 with average interest rate of 0.54%	10,000	10,000	83,333
Unsecured bonds due 2018 with average interest rate of 1.11%	10,000	10,000	83,333
Unsecured bonds due 2018 with average interest rate of 0.82%	10,000	10,000	83,333
Total	¥ 86,522	¥ 95,000	\$ 721,017
Less current portion	(36,522)	(10,000)	(304,350)
Long-term debt, less current portion	¥ 50,000	¥ 85,000	\$ 416,667

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

Year Ending March 31	Millions of yen	Thousands of U.S. dollars
2016	¥ 36,522	\$ 304,350
2017	22,000	183,334
2018	18,000	150,000
2019	10,000	83,333
Total	¥ 86,522	\$ 721,017

Other liabilities include deposits received from customers in the amount of ¥5,756 million (\$47,967 thousand) as of March 31, 2015, bearing interest at an average rate of 4.29%, and ¥5,181 million as of March 31, 2014, bearing interest at an average rate of 4.55%.

### 9. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in aggregate, resulted in a statutory tax rate of approximately 35.6% and 38.0% for the years ended March 31, 2015 and 2014 respectively. Overseas subsidiaries are subject to income taxes of the countries in which they operate.

Major components of deferred tax assets and liabilities as of March 31, 2015 and 2014 were as follows:

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Deferred tax assets:			
Liability for retirement benefits	¥ 4,315	¥ 3,277	\$ 35,958
Accrued enterprise taxes	252	847	2,100
Accrued bonuses to employees	2,216	2,698	18,467
Reserve for sales rebates	13,270	11,134	110,583
Loss on devaluation of investment securities	587	647	4,892
Research and development costs	9,546	10,736	79,550
Inventories	2,698	2,842	22,483
Net operating loss carried forward	3,003	1,481	25,025
Amortization of intangible assets	14,388	13,655	119,900
Tax credit for research and development costs of overseas subsidiaries	6,298	8,227	52,483
Other	16,747	14,813	139,559
Gross deferred tax assets	73,320	70,357	611,000
Valuation allowance	(7,586)	(5,850)	(63,217)
Total deferred tax assets	¥ 65,734	¥ 64,507	\$ 547,783
Deferred tax liabilities:			
Unrealized gains on available-for-sale securities	¥ (10,246)	¥ (8,377)	\$ (85,383)
Deferred gain on sales of fixed assets	(766)	(882)	(6,383)
Tax effect of intangible assets related to			
business combination	(26,966)	(24,022)	(224,717)
Refund of capital surplus of a subsidiary	(426)	(471)	(3,550)
Undistributed earnings of foreign subsidiaries	(381)	(213)	(3,175)
Other Other	(643)	(1,075)	(5,358)
Total deferred tax liabilities	¥ (39,428)	¥ (35,040)	\$ (328,566)
Net deferred tax assets	¥ 26,306	¥ 29,467	\$ 219,217

A reconciliation between the statutory tax rates and the effective tax rates reflected in the accompanying consolidated statements of income for the years ended March 31, 2015 and 2014 was as follows:

	2015	2014
Normal statutory tax rate	35.6%	38.0%
Increase (decrease) in taxes due to:		
Expenses not deductible for tax purposes	6.6	3.3
Non-taxable dividend income	(0.9)	(0.5)
Tax credits for research and development costs	(8.8)	(9.2)
Amortization of goodwill	5.7	5.5
Change in valuation allowance	5.2	3.0
Effect of revised corporate tax rate	6.4	2.0
Tax effects attributable to investments in subsidiaries	0.5	0.3
Other	3.9	(0.2)
Effective tax rate	54.2%	42.2%

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

The liability for retirement benefits as at March 31, 2015 and 2014 consisted of the following:

### 1. Defined benefit plans

1) Movement in retirement benefit obligations, excluding retirement plans for which the simplified method is applied

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Balance at the beginning of the fiscal year	¥ 83,703	¥ 80,676	\$ 697,525
Cumulative effects of changes in accounting policies	308		2,567
Restated balance	84,011	_	700,092
Service cost	3,145	3,094	26,208
Interest cost	1,260	1,613	10,500
Actuarial gain	7,218	4,295	60,150
Benefits paid	(3,602)	(4,165)	(30,017)
Prior service cost	_	(1,806)	_
Other	10	(4)	84
Balance at the end of fiscal year	¥ 92,042	¥ 83,703	\$ 767,017

### 2) Movement in plan assets, excluding retirement plans for which the simplified method is applied

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Balance at the beginning of the fiscal year	¥ 74,485	¥ 71,357	\$ 620,708
Expected return on plan assets	1,377	1,326	11,475
Actuarial gain	3,074	1,473	25,617
Contributions paid by the employer	2,403	3,396	20,025
Benefits paid	(2,810)	(3,027)	(23,417)
Other	_	(40)	_
Balance at the end of the fiscal year	¥ 78,529	¥ 74,485	\$ 654,408

### 3) Movement in liability for retirement benefits for which the simplified method is applied

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Balance at the beginning of the fiscal year	¥ (12)	¥ 83	\$ (100)
Retirement benefit costs	(128)	(7)	(1,067)
Benefits paid	(2)	(3)	(17)
Contributions paid by the employer	(41)	(44)	(342)
Other	9	(41)	76
Balance at the end of the fiscal year	¥ (174)	¥ (12)	\$ (1,450)

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

### 4) Reconciliation from retirement benefit obligations and plan assets to liability (asset) for retirement benefits

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Funded retirement benefit obligations Plan assets	¥ 78,149 (80,085)	¥ 71,105 (75,791)	\$ 651,242 (667,375)
	(1,936)	(4,686)	(16,133)
Unfunded retirement benefit obligations	15,274	13,892	127,283
Total Net liability (asset) for retirement benefits at the end of the fiscal year	13,338	9,206	111,150
Liability for retirement benefits Asset for retirement benefits	15,274 (1,936)	13,892 (4,686)	127,283 (16,133)
Total Net liability (asset) for retirement benefits at the end of fiscal year	¥ 13,338	¥ 9,206	\$ 111,150

Note: Includes plan applied simplified method.

### 5) Retirement benefit costs

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Service cost	¥ 3,145	¥ 3,094	\$ 26,208
Interest cost	1,260	1,613	10,500
Expected return on plan assets	(1,377)	(1,326)	(11,475)
Net actuarial loss amortization	836	649	6,967
Past service costs amortization	(336)	(216)	(2,800)
Retirement benefit costs applied simplified method	(128)	(6)	(1,067)
Total retirement benefit costs for the fiscal year	¥ 3,400	¥ 3,808	\$ 28,333

### 6) Remeasurements of defined benefit plans included in other comprehensive income, before tax effect

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Past service costs	¥ (336)	¥ —	\$ (2,800)
Actuarial gains and losses	(3,308)	_	(27,567)
Total	¥ (3,644)	¥ —	\$ (30,367)

### 7) Remeasurements of defined benefit plans included in accumulated other comprehensive income, before tax effect

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Unrecognized past service costs	¥ (1,786)	¥ (2,122)	\$ (14,883)
Unrecognized actuarial gains and losses	8,479	5,171	70,658
Total	¥ 6,693	¥ 3,049	\$ 55,775

#### 8) Plan assets

i) Plan assets comprise:

	Millions of yen	
	2015	2014
Bonds	45.5%	58.2%
Equity securities	15.2%	14.2%
Cash and cash equivalents	14.5%	6.7%
General account	11.4%	11.8%
Other	13.4%	9.1%
Total	100.0%	100.0%

Note: "Other" mainly consists of investment trust.

Retirement benefit trusts set up for corporate pension plans account for 8.2 percent and 7.6 percent of total plan assets at March 31, 2015 and 2014, respectively.

### ii) Long-term expected rate of return

Current and target asset allocations, historical and expected returns on various categories of plan assets have been considered in determining the long-term expected rate of return.

#### 9) Actuarial assumptions

The principal actuarial assumptions as at March 31, 2015 and 2014 (expressed as weighted averages) were as follows:

	Millions of yen	
	2015	2014
Discount rate	1.0%	1.5%
Long-term expected rate of return	2.0%	2.0%
Estimated salary increase rate	$3.8\sim5.8\%$	3.9 ~ 5.4%

### 2. Defined contribution plans

The amount of required contributions to the defined contribution plans of the Company and consolidated subsidiaries was ¥2,624 million (\$21,867 thousand) and ¥2,399 million for the years ended March 31, 2015 and 2014, respectively.

### 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 50% 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 Law, 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 the Law and regulations.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

At the annual shareholders' meeting held on June 19, 2015, the shareholders approved year-end cash dividends of ¥9.00 (\$0.08) per share, amounting to ¥3,576 million (\$29,800 thousand). These appropriations have not been accrued in the consolidated financial statements as of March 31, 2015. Such appropriations are recognized in the period in which they are approved by the shareholders. Together with the interim cash dividends, the total annual dividends were ¥18.00 (\$0.15) per share.

# 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, 2015 and 2014 were as follows:

	Million	Millions of yen	
	2015	2014	2015
Sales	¥ 258	¥ 315	\$ 2,150
Purchases	8,210	6,386	68,417

### 13. RELATED PARTY TRANSACTIONS

Major transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., for the years ended March 31, 2015 and 2014 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Purchases of products	¥ 3,902	¥ 2,160	\$ 32,517
Payment of other expenses	1,209	1,219	10,075
Loans	546	6,407	4,550
Interest income	204	133	1,700

The balances due to or from the parent company, Sumitomo Chemical Co., Ltd., as at March 31, 2015 and 2014 were as follows:

	Millions	s of yen	Thousands of U.S. dollars
	2015	2014	2015
Receivables	¥ 49,154	¥ 41,811	\$409,617
Payables	1,034	1,216	8,617

#### 14. LEASES

The minimum lease payments under non-cancelable operating leases as of March 31, 2015 and 2014 were as follows:

	Millions	Thousands of U.S. dollars	
	2015	2014	2015
Due within one year	¥ 924	¥ 209	\$ 7,700
Due after one year	8,273	6,683	68,942
Total	¥ 9,197	¥ 6,892	\$ 76,642

### 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 its pharmaceutical business performance according to the reportable segments of the Group which consist of the following four segments: Japan, North America, China, Other regions.

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

Accounting method for business segment reporting is the same as presented in Note 2 "Summary of Significant Accounting Policies." Income by reportable segment 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 such information is not used to make decisions regarding resource allocation and performance measurement.

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

Segment information for the Group for the years ended March 31, 2015 and 2014 were as follows:

		Millions of yen					
				2015			
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Net sales							
Sales to customers	¥ 156,564	¥ 148,178	¥ 17,146	¥ 8,785	¥ 330,673	¥ 40,698	¥ 371,371
Intersegment sales and transfers	132	_	_	_	132	62	194
Total	156,696	148,178	17,146	8,785	330,805	40,760	371,565
Income of segment	50,571	34,716	6,249	836	92,372	2,207	94,579
Others							
Depreciation and amortization	3,675	3,909	384	344	8,312	202	8,514

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 yen						
		2014					
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Net sales							
Sales to customers	¥ 171,898	¥ 145,271	¥ 11,928	¥ 16,713	¥ 345,810	¥ 41,883	¥ 387,693
Intersegment sales and transfers	161	_	_	_	161	69	230
Total	172,059	145,271	11,928	16,713	345,971	41,952	387,923
Income of segment	60,827	33,877	3,182	11,359	109,245	2,673	111,918
Others							
Depreciation and amortization	3,925	12,965	347	258	17,495	196	17,691

	Thousands of U.S. dollars						
	2015						
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Net sales							
Sales to customers	\$ 1,304,700	\$ 1,234,817	\$ 142,883	\$ 73,208	\$ 2,755,608	\$ 339,150	\$ 3,094,758
Intersegment sales and transfers	1,100	_	_	_	1,100	517	1,617
Total	1,305,800	1,234,817	142,883	73,208	2,756,708	339,667	3,096,375
Income of segment	421,425	289,300	52,075	6,967	769,767	18,391	788,158
Others							
Depreciation and amortization	30,625	32,575	3,200	2,867	69,267	1,683	70,950

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

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

Net sales	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Reportable segments total	¥ 330,805	¥ 345,971	\$ 2,756,708
Net sales of "Other Business" category	40,760	41,952	339,667
Elimination of intersegment transactions	(194)	(230)	(1,617)
Net sales in the consolidated statements of income	¥ 371,371	¥ 387,693	\$ 3,094,758

Income	Millions	Thousands of U.S. dollars	
	2015	2014	2015
Reportable segments total	¥ 92,372	¥ 109,245	\$ 769,767
Income of "Other Business" category	2,207	2,673	18,391
Research and development costs	(71,304)	(69,804)	(594,200)
Elimination of intersegment transactions	0	29	0
Operating income in the consolidated statements of income	¥ 23,275	¥ 42,143	\$ 193,958

Other items	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Depreciation and amortization			
Reportable segments total	¥ 8,312	¥ 17,495	\$ 69,267
Other Business	202	196	1,683
Adjustment	3,332	2,898	27,767
The amount in the consolidated financial statements	¥ 11,846	¥ 20,589	\$ 98,717

Amortization of goodwill			
Reportable segments total	¥ 5,446	¥ 5,054	\$ 45,383
Other Business	_	_	_
Adjustment	_	_	_
The amount in the consolidated financial statements	¥ 5,446	¥ 5.054	\$ 45,383

### 5) Other information

Sales information by product or service for the Group for the years ended March 31, 2015 and 2014 were as follows:

Sales to customers	Millions	Thousands of U.S. dollars	
	2015	2014	2015
Pharmaceuticals	¥ 330,673	¥ 345,810	\$ 2,755,608
Other products	40,698	41,883	339,150
Total	¥ 371,371	¥ 387,693	\$ 3,094,758

Geographical segment information for the Group for the years ended March 31, 2015 and 2014 were as follows:

Net sales	Million:	Millions of yen		
	2015	2014	2015	
Japan	¥ 198,560	¥ 214,704	\$ 1,654,667	
U.S.	144,792	141,547	1,206,600	
Other regions	28,019	31,442	233,491	
Total	¥ 371,371	¥ 387,693	\$ 3,094,758	

Property, plant and equipment	Millions	s of yen	Thousands of U.S. dollars
	2015	2014	2015
Japan	¥ 54,151	¥ 62,849	\$ 451,258
U.S.	9,176	7,948	76,467
Other regions	1,833	1,892	15,275
Total	¥ 65,160	¥ 72,689	\$ 543,000

Sales information by major customer for the Group for the years ended March 31, 2015 and 2014 were as follows:

Net sales	Million	s of yen	Thousands of U.S. dollars
Name of major customer and related segment	2015	2014	2015
McKesson Corporation / North America	¥ 46,561	¥ 48,062	\$ 388,008
Cardinal Corporation / North America	36,024	41,030	300,200

### 6) Information on impairment loss of non-current assets, amortization and unamortized balance of goodwill by reportable segment.

				Millions of yen			
				2015			
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	¥ 5,194	¥ 116	¥ —	¥ —	¥ 5,310	¥ —	¥ 5,310
Amortization of goodwill	_	5,446	_	_	5,446	_	5,446
Balance of goodwill	_	88,075	_	_	88,075	_	88,075

				Millions of yen			
				2014			
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	¥ 2,999	¥ 4,639	¥ —	¥ —	¥ 7,638	¥ —	¥ 7,638
Amortization of goodwill	_	5,054	_		5,054	_	5,054
Balance of goodwill	_	80,669	_	_	80,669	_	80,669

				The	ousands of U.S. de	ollars		
					2015			
	Japan	North	n America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	\$ 43,283	\$	967	<b>\$</b> —	\$ <i>—</i>	\$ 44,250	<b>\$</b> —	\$ 44,250
Amortization of goodwill	_	4	5,383	_	_	45,383	_	45,383
Balance of goodwill	_	73	3,958		_	733,958	_	733,958

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2015 and 2014

### **16. IMPAIRMENT LOSS**

Impairment loss of tangible assets and intangible assets for the years ended March 31, 2015 was as follows:

			Millions of yen	Thousands of U.S. dollars
Usage for	Item	Location	2015	2015
Production facilities	Buildings and structures, Machinery, equipment and carriers, Construction in progress and Others	Japan	¥ 5,128	\$ 42,733
Research and development with respect to compound in development	In-process research and development	U.S.	116	967
Idle assets	Land, Machinery, equipment and carriers	Japan	66	550

The Company and its consolidated subsidiaries impaired the book value of idle and unused-in-the-future tangible assets, as well as tangible assets and in-process research and development costs of which future economic benefits were expected to be less than the recoverable amount.

The recoverable amount of production facilities of the plants which we plan to close in connection with reorganization of production sites was measured based on net realizable value and determined as zero.

The recoverable amount of idle land was measured based on net realizable value appraised by a third-party real-estate appraiser.

The recoverable amount of idle tangible assets except for idle land was measured based on value-in-use, which was determined as zero.

The recoverable amount of in-process research and development costs was also measured based on value-in-use using a discount rate of 8.0%.

Impairment loss of tangible assets and intangible assets for the years ended March 31, 2014 was as follows:

			Millions of yen	Thousands of U.S. dollars
Usage for	Item	Location	2014	2014
Research and development with respect to compound in development	In-process research and development	U.S.	¥ 4,272	\$ 41,476
Welfare facilities	Building and structures, Land and Others	Japan	2,984	28,970
Production facilities	Construction in progress	U.S.	367	3,563
Production facilities	Buildings and structures, Machinery, equipment and carriers and Others	Japan	15	146

The Company and its consolidated subsidiaries impaired the book value of idle and unused-in-the-future tangible assets, as well as tangible assets and in-process research and development costs of which future economic benefits were expected to be less than the recoverable amount.

The recoverable amount of idle assets was measured based on net realizable value appraised by a third-party real-estate appraiser.

The recoverable amount of tangible assets without future economic benefit expected was measured based on value-in-use, which was determined as zero.

The recoverable amount of in-process research and development costs was also measured based on value-in-use, using the discount rate of 11.5%.

### 17. RESTRUCTURING

Restructuring carried out in the year ended March 31, 2015 was for the purpose of improving the business structure and organization, as well as reorganization of production site in the Company. Restructuring carried out in the year ended March 31, 2014 was for the purpose of improving the business structure and organization in the Company and its subsidiaries.

## 18. OTHER COMPREHENSIVE INCOME (LOSS)

Components of other comprehensive income (loss) for the years ended March 31, 2015 and 2014 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2015	2014	2015
Unrealized gains on available-for-sale securities			
Amount arising during the period under review	¥ 9,687	¥ 6,489	\$ 80,725
Reclassification adjustment for gains (losses) included in net income	(1,966)	(2,778)	(16,383)
Before income tax effect adjustment	7,721	3,711	64,342
Amount of income tax effect	(1,869)	(857)	(15,575)
Unrealized gains on available-for-sale securities, net of tax	¥ 5,852	¥ 2,854	\$ 48,767
Deferred gains or losses on hedges			
Amount arising during the period under review	¥ 3	¥ (1)	\$ 25
Amount of income tax effect	(1)		(8)
Deferred gains or losses on hedges	¥ 2	¥ (1)	\$ 17
Foreign currency translation adjustment			
Amount arising during the period under review	¥ 41,379	¥ 22,251	\$ 344,825
Foreign currency translation adjustment	41,379	22,251	344,825
Demonstranents of defined benefit plans			
Remeasurements of defined benefit plans	V (A 4 4 A A)		¢ (24 524)
Amount arising during the period under review	¥ (4,144)		\$ (34,534)
Reclassification adjustment for gains (losses) included in net income	500	_	4,167
Before income tax effect adjustment	(3,644)		(30,367)
Amount of income tax effect	1,071	_	8,925
Remeasurements of defined benefit plans	¥ (2,573)	_	\$ (21,442)
Total other comprehensive income (loss)	¥ 44,660	¥ 25,104	\$ 372,167

### 19. CONTINGENT LIABILITIES

Contingent liabilities for guarantees as of March 31, 2015 and 2014 were as follows:

	Millions	s of yen	Thousands of U.S. dollars
	2015	2014	2015
Guarantees of indebtedness— Bank loans guaranteed for an affiliate	¥ 3	¥ 31	\$ 25
Loans guaranteed— Employee's housing loans guaranteed	109	119	908

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

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

We have audited the accompanying consolidated financial statements of Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at March 31, 2015 and 2014, and the consolidated statements of income, statements of comprehensive income (loss), 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 Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries as at March 31, 2015 and 2014, and their financial performance and cash flows for the years then ended in accordance with accounting principles generally accepted in Japan.

#### **Convenience Translation**

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2015 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

June 19, 2015 Osaka, Japan

### **Shareholder Data**

### **Principal Shareholders**

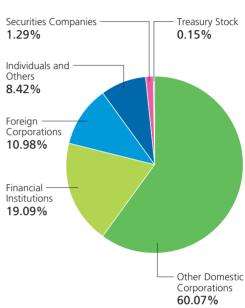
(As of March 31, 2015)

Name	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)	13,241	3.33
Japan Trustee Services Bank, Ltd. (Trust account)	10,615	2.67
Nippon Life Insurance Company	7,581	1.91
Japan Trustee Services Bank, Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa Insurance Co., Ltd.	4,435	1.12
Sumitomo Dainippon Pharma Employee shareholders' association	4,127	1.04
Japan Trustee Services Bank, Ltd. (Trust account)	2,482	0.62

Note: Percentage of shareholding is calculated excluding treasury stock (596,335 shares).

### **Composition of Shareholders**

(As of March 31, 2015)



### **Share Price Range and Trading Volume**





### Corporate Data As of March 31, 2015

Name	Sumitomo Dainippon Pharma Co., Ltd.
Establishment	May 14, 1897
Date of Merger	October 1, 2005
Osaka Head Office	6-8 Doshomachi 2-chome, Chuo-ku, Osaka 541-0045, Japan TEL: +81-6-6203-5321 FAX: +81-6-6202-6028
Tokyo Head Office	13-1, Kyobashi 1-chome, Chuo-ku, Tokyo 104-8356, Japan TEL: +81-3-5159-2500 FAX: +81-3-5159-2945
Capital	¥22.4 billion
Total Number of Shares Issued	397,900,154
Stock Exchange Listing	Tokyo Stock Exchange
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, Limited
Lead Managers	(Main) Daiwa Securities Co., Ltd.; (Sub) SMBC Nikko Securities Inc., Nomura Securities Co., Ltd.
Main Banks	Sumitomo Mitsui Banking Corporation Sumitomo Mitsui Trust Bank, Limited The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Key Facilities	Osaka Head Office (Osaka), Tokyo Head Office (Tokyo), 20 Branches, 4 Plants (Mie, Osaka, Ehime, Oita), 2 Research Laboratories (Osaka), 2 Distribution Centers (Saitama, Hyogo)
Major Consolidated Subsidiaries	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.) Boston Biomedical Pharma, Inc. (U.S.) Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (China)















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