









# Innovation today, healthier tomorrows





#### **Post-Merger Trajectory**

Sumitomo Dainippon Pharma Co., Ltd. was established in October 2005 through a merger between the former Dainippon Pharmaceutical Co., Ltd. and the former Sumitomo Pharmaceuticals Co., Ltd. with the aim "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."

Sumitomo Dainippon Pharma will continue to deliver innovative and useful pharmaceuticals to people around the world as well as in Japan into the future as we have done in the past.



Note: FY2005 does not include business results for the former Sumitomo Pharmaceuticals Co., Inc. from April - September 2005

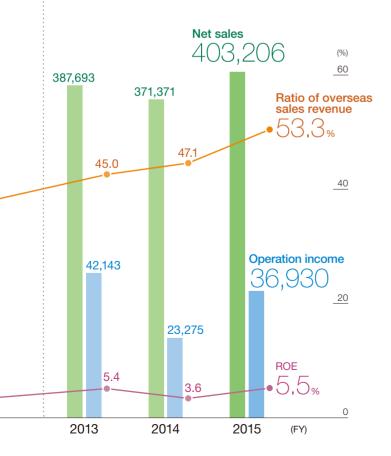
#### Third Mid-term Business Plan (FY2013-2017)

#### Sustained growth

• Establishment of Kobe Regenerative & Cellular Medicine Center



- Therapeutic agent for pruritus "REMITCH®" (additional indication) Promotion alliance
- GLP-1 receptor agonist "Trulicity®" Sales alliance
- Antiepileptic "APTIOM®"



Financial and N	Non-Financial Highl	lights for FY2015	Compared with FY 2006
Financial capital	Net sales	403,206 Millions of yen	∪p 54.4%
	Operating income	36,930 Millions of yen	Down <b>18.9</b> %
	Net income attributable to owners of the parent	24,697 Millions of yen	Up <b>9.3</b> %
	Research and development costs	82,034 Millions of yen	∪p <b>100.7</b> %
	Ratio of oversea sales revenue	53.3 <sub>%</sub>	up 44.9%
	Shareholders' equity	446,473 Millions of yen	Up 45.9%
Intellectual capital	New products (From merger up to end of FY2016)	14	_
Human capital	Number of employees	6,697	Up <b>36.3</b> %
Social and relationship capital	Countries with business operat (Own company sales)	1 ( )	Up <b>8</b>
Manufac- tured capital	Number of resea laboratories and production sites	6	_
Natural capital	Greenhouse gas emissions*	74,007 t-co <sub>2</sub>	Down <b>5.3</b> %

<sup>\*</sup> Aggregate result for business sites in Japan

#### Fiscal 2015 Topics

Sumitomo Dainippon Pharma formulated a new global slogan and held commemorative programs to mark the tenth anniversary of the merger in October 2015.

Also in fiscal 2015, LATUDA®, the atypical antipsychotic grew into our first ever blockbuster drug in the North American market. With regard to research and development, we promoted development in fields with high unmet medical needs. On the sales front, we actively pursued promotional alliances and sales alliances with other companies.

#### October 2015 -

# Holding Commemorative Programs for the Tenth Anniversary of the Merger

Since the merger in 2005, Sumitomo Dainippon Pharma has poured every effort into research and development of new drugs and has provided pharmaceuticals serving the needs of patients and medical professionals. We have also promoted the globalization of our business, notably in North America.

Marking the tenth anniversary of the merger, we formulated a new global slogan that reflects our commitment for future. To express our appreciation for the kind support and understanding shown by the local communities over the ten years, the officers and employees of Sumitomo Dainippon Pharma are conducting participation-style community service activities at welfare facilities for the disabled, senior citizens, and

children as well as satoyama conservation activities, such as bamboo clearing and thinning. Honoring our pledge "to build harmonious relationships with society" as stated in our Declaration of Conduct, we will further deepen our involvement and communication with society.



Tenth anniversary website



#### Global slogan

#### Innovation today, healthier tomorrows

The global slogan was adopted by four pharmaceutical companies of the Sumitomo Dainippon Pharma group (Sumitomo Dainippon Pharma, Sunovion Pharmaceuticals, Boston Biomedical, and Sumitomo Pharmaceuticals (Suzhou). The global slogan reflects our full commitment to deliver to society revolutionary pharmaceuticals, acquired through groundbreaking ideas and high-standard research and development by each individual employee's challenge for innovation, so as to help enable the patients and their families lead healthier and fulfilling lives.

#### July 2015

#### Research Grant Awarded for Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine

Sumitomo Dainippon Pharma, Center for iPS Cell Research and Application, Kyoto University (CiRA), and Hitachi Ltd. started collaboration in the fiscal 2015 "Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine," a fiscal 2015 program of the Ministry of Economy, Trade and Industry and the Japan Agency for Medical Research and Development.

The project is aimed at developing the base technology and the evaluation methods for establishing a production process of dopaminergic neural progenitor cells with a view toward clinical application of human iPS cell-based regenerative medicine to Parkinson's disease. The objective of the program is to establish a production method which would enable efficient mass-production and stable supply of safe and consistent quality cells.



#### December 2015

# Launched PRISM, Our Competitive Open Innovation Program

Sumitomo Dainippon Pharma launched Partnership to Realize Innovative Seeds and Medicines (PRISM), an open innovation program through which research institutions and researchers in Japan are invited to submit ideas that meet our drug discovery research needs. In fiscal 2015, we selected four out of 60 submissions and began joint research.

# TOPICS 2015

#### May 2015

# Approval of New Indication for Pruritus Treatment REMITCH® and promotion activities started

Toray Industries, Inc. obtained approval of REMITCH® CAPSULES 2.5µg for a new indication for improvement of pruritus in chronic liver disease patients. Torii Phamraceutical Co., Ltd. already sells REMITCH® CAPSULES 2.5 µg in Japan as a treatment of pruritus in hemodialysis patients. Sumitomo Dainippon Pharma provides drug information regarding the new indication to medical institutions in accordance with the promotion contract concluded with Torii Pharmaceutical.

#### August 2015

#### Approval of New Indication for Antiepileptic Drug APTIOM® as Monotherapy for Partial-Onset Seizures

U.S. subsidiary Sunovion Pharmaceuticals Inc. obtained approval for an additional indication for antiepileptic drug APTIOM® as monotherapy for partial-onset seizures.

#### September 2015

## Launch of "Trulicity®" Once-Weekly GLP-1 Receptor Agonist

Sumitomo Dainippon Pharma launched "Trulicity® Subcutaneous Injection 0.75mg Ateos®", a once-weekly GLP-1 receptor agonist indicated for type 2 diabetes. Not only accompanying its proven effect of lowering blood sugar level with only once-weekly administration, but Trulicity® comes in a unique disposable pen-type auto-injector with a pre-attached needle; Ateos®. The product is inlicensed from Eli Lilly Japan, and Sumitomo Dainippon Pharma carries out sales and distribution of the drug. Both companies provide information on Trulicity® to medical institutions.



#### LATUDA® North America Sales Amount (M\$) 1,000 800 600 400 200 0 2011 2012 2014 2015 (FY) 2013 Latuda<sup>a</sup> Latuda<sup>a</sup> Latuda<sup>a</sup> Latuda<sup>a</sup> Latuda<sup>a</sup> 40mg

#### From April 2015 to March 2016

## Atypical Antipsychotic LATUDA® Grew into Blockbuster Drug in North America

Sales of LATUDA® as a treatment for schizophrenia began in February 2011 in the United States and September 2012 in Canada. Subsequently, in June 2013, Sunovion Phamaceuticals Inc. obtained approval for two additional indications as monotherapy and adjunctive treatment in adult bipolar I depression.

As a result of enhanced promotion activities by dedicated sales representatives working since the time of the launch and an advertising campaign using television commercials and the Internet, LATUDA® grew into a blockbuster drug with annual sales of US\$ 1.0 billion in North America in fiscal 2015.

#### **Toward Further Growth**

In May 2016, we revised the management targets in the third Mid-term Business Plan, which we are currently implementing, based on such factors as developments in business activities and changes in the environment.

Moreover, during the next Mid-term Business Plan covering the period from fiscal 2018 (the year ending March 31, 2019) onward, we are expecting our business performance to decline due to the expiry of the exclusivity period for LATUDA® in 2019. However, we will aim for further growth with an early V-shaped recovery based on our aggressive strategies.

We will aim for further growth based on aggressive strategies, anticipating a decline in business performance due to the expiry of the North American exclusivity period for LATUDA® in 2019.

To achieve growth beyond the third Mid-term Business Plan, we intend to maximize strategic products in addition to investing aggressively in research and development, new in-licensing, and M&As. At the same time, we will promote strengthening of our business foundation and structural reform. In terms of our

approach to shareholder returns, in addition to paying stable dividends, we plan to increase dividends in line with improvements in business performance. See Message from the President on page 9 for details.

#### **Products strategies**

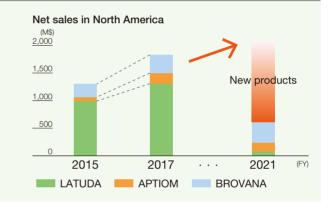
#### Sales maximization of strategic products

North America: LATUDA® (FY2017 peak sales), APTIOM®, BROVANA® Japan: Trulicity®, REMITCH®, TRERIEF®, etc.

# Launch of late-stage development products and subsequent maximization

Oncology area: napabucasin, etc.
The other areas: dasotraline, SUN-101, etc.

New in-licenses



#### Financial / investment strategies

#### Proactive R&D investments

Proactive investment at around 20% of net sales

#### Pursuing new in-licenses and M&As

Consideration of new in-licenses and M&As worth up to ¥150.0 billion - ¥200.0 billion

#### Payment of adequate dividends

Stable payment, dividend hikes as profits grow

#### Strengthening business foundation / structural reform

Optimizing the business management structure in Japan

Maximizing profits from LATUDA® and building efficient sales organization for new products in North America

#### Continuing cost reduction

In addition to reducing selling, general and administrative expenses, we will reorganize our domestic production sites into two plants.



# 2016-2021

We will maintain our aggressive investment in research and development, primarily for late-stage development products.

We will continue to invest aggressively in late-stage development products, including napabucasin in the Oncology area, to launch a large number of novel and highly competitive new drugs onto the market. Moreover, in addition to aggressive research and development, we will pursue opportunities for new in-licensing

and M&As targeting the Psychiatry & Neurology area and Specialty area in order to expand our pipeline.

Product Launch	า Pla	an (as	of July	27,	2016)
----------------	-------	--------	---------	-----	-------

Region	FY2017	FY2018	FY2019	FY2020-2022
Japan	napabucasin (Gastric and Gastroesophageal junction adenocarcinoma)	TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)	LONASEN® (Schizophrenia / Transdermal patch)  amcasertib (Solid tumors)	lurasidone (Schizophrenia /Bipolar I depression / Bipolar maintenance)  napabucasin (Colorectal cancer, etc.)  DSP-7888 (Solid tumors / Hematologic cancer)  oberticolic acid (NASH)  DSP-6952 (IBS with constipation, Chronic idiopathic constipation)  iPS cell-derived RPE cells (Age-related macular degeneration)
U.S.	napabucasin (Gastric and Gastroesophageal junction adenocarcinoma)  glycopyrronium bromide (COPD)	dasotraline (ADHD)	dasotraline (BED)  amcasertib (Solid tumors)	SB623 (Chronic stroke)  DSP-2230 (Neuropathic pain)  SEP-363856 (Schizophrenia)  napabucasin (Colorectal cancer, Pancreatic cancer, NSCLC)  DSP-7888 (Solid tumors, Hematologic cancer)
China	LONASEN® (Schizophrenia)	lurasidone (Schizophrenia)		
_ ′	atry & Neurology Oncology hemical Entities New Indication	Liver / Digestive Respiratory		

#### Contents / Editorial Policy

P01 Post-Merger Trajectory

P03 Fiscal 2015 Topics

P05 Toward Further Growth

P07 Corporate Philosophy

P09 Message from the President

We will venture to develop innovative new drugs and contribute to the future of healthcare as a global R&D-based company.

P17 Strategy in Business Processes and CSR

P19 Research & Development

P21 FOCUS Global Oncology Outlook

Napabucasin (BBI608)

Cancer Stemness Inhibitor Targeting STAT3

P23 Basic strategy / R&D organization

P25 Development Pipeline

P29 Production and Quality Control

P31 Corporate Regulatory Compliance & Quality Assurance

P33 Marketing

P35 Pharmaceutical Business: Japanese Market

P37 Pharmaceutical Business: North American Market

P39 Pharmaceutical Business: Chinese Market

P40 Related Business

P41 Corporate Governance

P47 Board Members and Executive Officers

P49 CSR Management

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

P59 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 Changes in Net Assets / Consolidated Statements of Cash Flows / Notes to Consolidated Financial Statements

P94 Shareholder Data

#### **Editorial Policy**

#### Applicable Period

This report is based on the results for fiscal 2015 (April 1, 2015 to March 31, 2016). Some of the activities described were conducted in fiscal 2016.

#### Organizational Scope

The report covers the 16 companies in the Sumitomo Dainippon Pharma Group (Sumitomo Dainippon Pharma Co., Ltd., and its 15 consolidated subsidiaries). However, environmental performance data in the report are totals for major facilities in Japan only (plants, research laboratories, distribution centers, Osaka Head Office, Tokyo Head Office, branches).

### Reference guidelines regarding disclosure on non-financial information

- IIRC, International Integrated Reporting Framework
- G4 Sustainability Reporting Guideline

### Disclaimer Regarding Forward-Looking Statements

The forward-looking statements in this annual report are based on management's assumptions and beliefs in light of information available up to the date of publication, and involve both known and unknown risks and uncertainties. Actual financial results and development forecast may differ materially from those presented in this document, being dependent on a number of factors. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.







#### 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

#### **Declaration of Conduct**

At Sumitomo Dainippon Pharma, directors and employees alike are determined not only to comply with all laws and regulations, but also to ensure that all corporate activities are carried out in accordance with this Declaration of Conduct. The pledges below express our commitment to earning greater trust from society and becoming a truly innovative company.

- 1. Follow through the global slogan "Innovation today, healthier tomorrows."
- 2. Pursue trustworthy corporate activities
- 3. Positively disclose information and properly manage information.
- 4. Help employees reach their full potential
- 5. Respect human rights
- 6. Positively address global environmental issues
- 7. Build harmonious relationships with society

#### Global Slogan

#### Innovation today, healthier tomorrows

#### External Evaluations of Sumitomo Dainippon Pharma Group on Sustainability

The Sumitomo Dainippon Pharma Group's active initiatives on issues, including development of the governance system, environmental problems, and social problems are highly evaluated. We have been selected for the FTSE4Good Index Series and the MSCI Global Sustainable Indexes, which are both global indexes for socially responsible investment (SRI). (As of July 2016)





We will venture to develop innovative new drugs and contribute to the future of healthcare as a global R&D-based company.



Could you look back on fiscal 2015 (the year ended March 31, 2016) and evaluate the Group's business performance and the progress of R&D?



We achieved growth in sales and profit thanks to LATUDA®, which became a blockbuster drug, and other products.

We moved forward with a large number of clinical studies, primarily in the Oncology and Psychiatry & Neurology areas.

The consolidated financial results for fiscal 2015, the third year of the third Mid-term Business Plan, recorded ¥403.2 billion in net sales, up 8.6% year on year, ¥36.9 billion in operating income, up 58.7% year on year, and ¥24.7 billion in net income attributable to owners of the parent, up 59.9% year on year.

In Japan, although sales of strategic products such as AlMIX®, a therapeutic agent for hypertension, LONASEN®, an atypical antipsychotic, and TRERIEF®, a therapeutic agent for Parkinson's disease, expanded, sales of long-listed brands fell due to the impact of further encouragement of the switch to generic drugs and other factors. As a result, sales in Japan declined.

Overseas, in North America, annual sales of LATUDA®, an atypical antipsychotic agent, topped US\$1.0 billion, developing into the Sumitomo Dainippon Pharma Group's first blockbuster drug since our establishment. In addition to this historic achievement, sales of BROVANA®, a COPD treatment, and APTIOM®, an antiepileptic drug launched in April 2014, also steadily increased. In China, yuan-based sales of MEROPEN®, a carbapenem antibiotic, remained on a level with the previous fiscal year. This significant growth in performance overseas, primarily in North America, offset the downturn in the Japanese market, and we were able to achieve financial results that exceeded initial projections for both sales and profits overall.

As for research and development, in the Psychiatry & Neurology area, we obtained an additional indication for APTIOM® in North America. In the U.S., we commenced new Phase 2/3 studies in binge eating disorder (BED) with



dasotraline for which there are ongoing Phase 3 studies in attention deficit hyperactivity disorder (ADHD). Moreover, in addition to submitting an application for approval of lurasidone for schizophrenia in China, we launched a Phase 3 study on schizophrenia in Japan.

In the Oncology area, a large number of clinical studies were advanced, including the global Phase 3 studies of napabucasin, a cancer stemness inhibitor, in the U.S., as well as the Phase 2 studies of amcasertib, a cancer stemness inhibitor with a different mechanism of action. In the Regenerative Medicine & Cell Therapy area, Sighregen K.K., a joint venture between Sumitomo Dainippon Pharma and Healios K.K., is currently studying manufacturing processes for retinal pigment epithelial cells with a view to commercial application, and Sumitomo Dainippon Pharma has also begun the installation of new cell production equipment aimed at implementing full-scale clinical studies. Moreover, we began a Phase 2b study of SB623, a cell therapy for the treatment of chronic stroke in the U.S. in collaboration with SanBio, Inc.

(Billions of yen)

	FY2014	FY2015	Year on year			
	result	result	Change	Rate of change (%)		
Net sales	3,714	4,032	318	8.6		
Operating income	233	369	137	58.7		
Net income attributable to owners of the parent	154	247	92	59.9		



#### Please explain your strategy for fiscal 2016.



The expansion in the North America business thanks to sales growth for LATUDA® and other products will offset the sales decline for the business in Japan where the challenging environment will persist. As to our consolidated earnings forecasts, we expect record-high net sales of ¥410.0 billion and operating income of ¥40.0 billion.

#### [Japan Business]

In addition to concentrating management resources on strategic products and new products, we will aim to build a highly efficient business management structure.

The Japanese market in fiscal 2016 is expected to be even more challenging due to National Health Insurance (NHI) drug price revisions and declining sales of long-listed brands resulting from further penetration of generic drugs, among other factors. In this environment, the Japan business will concentrate management resources on strategic products including AIMIX®, LONASEN®, and TRERIEF® and new products such as REMITCH®, a therapeutic agent for pruritus and Trulicity®, a GLP-1 receptor agonist indicated for type 2 diabetes, both of which went on sales in fiscal 2015, in efforts to minimize the extent of decline in sales.

Moreover, in order to increase profitability, we will work to build a highly efficient business management structure in Japan, to include developing the capabilities of employees, streamlining through the improvement of business processes, and optimizing production sites, to strengthen the corporate foundations that underpin medium and long-term growth. In the marketing system, we will also promote more efficient marketing activities through such means as clarifying priority target facilities for each product and further priotizing and focusing the allocation of marketing resources.

In order to achieve the strengthening of the business foundation, it is essential to increase the individual capabilities of every single employee based on his or her professional expertise in addition to organizational capabilities. In April 2016, Sumitomo Dainippon Pharma introduced a new personnel system to establish a career path for the promotion of employees with a strong ability to produce results as an individual based on expertise in addition to the managerial career path. In addition to this reform of the system, we have positioned this year as "Year One for Human Resources Development" and will rebuild the company-wide training and education system. Through the implementation of these measures, we will develop employees who take the initiative in the running of business and build a robust business foundation.

#### Initiatives in Fiscal 2016

Net sales	¥ 410 billion up 1.7% year on year				
Operating income	¥ 40 billion up 8.3% year on year				
Japan	Expanding the sales of strategic products (AIMIX®, LONASEN®, and TRERIEF®) and new products (Trulicity® and REMITCH®) to minimize the decline in revenue due to NHI price revisions and drop in sales of long-listed products Optimizing SG&A expenses and the business management structure				
North America	Further boosting LATUDA® sales beyond the \$1 billion mark and fostering growth of APTIOM® and BROVANA® Developing oncology marketing system				
Research and development	Accelerating development of napabucasin and other late-stage products				

#### [North America business]

In addition to maximizing our mainstay products, we will focus on early sales expansion for new products looking to 2019 and beyond and strengthening the business system.

At the same time as working for further expansion in sales of strategic products including LATUDA® which has developed into a blockbuster product, APTIOM® and BROVANA® in the North American market in fiscal 2016, we will move forward strongly with structural business reform aimed at new growth based on the following two strategies ahead of the expiry of the exclusivity period for LATUDA® in 2019.

The first strategy is the early expansion of sales for new products. From fiscal 2017 onwards, we will make sure that we launch late-stage development products such as napabucasin, dasotraline, and SUN-101 to foster the new revenue that will underpin future growth in the North American market.

The second strategy is building a robust business structure in order to realize this future growth. We will not only maximize profit from existing products such as LATUDA®, APTIOM®, and BROVANA® through optimizing selling, general and administrative expenses and other measures, but will also build a highly efficient sales system for new products to match their respective market characteristics. In addition, we will promote the development of an oncology marketing system specializing in the Oncology area ahead of the napabucasin market launch. We plan to organize 100-150 expert staff for the napabucasin launch who we will deploy across the U.S.

#### [Research and development]

#### We will accelerate late-stage development products.

In the Oncology area, we will promote the pivotal study for napabucasin as well as the development of amcasertib and DSP-7888, a cancer peptide vaccine, in Japan and the U.S. In the Psychiatry & Neurology area, we will promote the pivotal study for dasotraline in the U.S. and a new Phase 3 study in schizophrenia for lurasidone in Japan. We will also submit an application for SUN-101, a treatment for COPD, in the U.S. in fiscal 2016.





Revisions to the third Mid-term Business Plan have been announced, but could you explain the background to that and the details of changes to management targets?



As a result of the deterioration in profitability of the Japan business and other factors, we revised the management targets for fiscal 2017 downwards, but we will further expand our pipeline with aggressive research and development.

The third Mid-term Business Plan, which we announced in February 2013, is a five-year plan covering the period from fiscal 2013 (the fiscal year ended March 31, 2014) until fiscal 2017 (the fiscal year ending March 31, 2018). It is necessary to keep revising the plan after its formulation as the business environment has continued to change, including market trends and exchange rates. We carried out the first revision in October 2014, and we have now modified the management targets for fiscal 2017 based on the subsequent progress of our business activities and changes in the environment.

The positive factors as compared with October 2014 are the new launches through alliances such as REMITCH® and Trulicity® in Japan and the stepping up of efforts to strengthen the business foundation. Furthermore, there are also positive factors overseas as exchange rates have tended toward depreciation in the value of the yen, and we have changed our forecast exchange rate from ¥100:US\$1 to ¥110:US\$1. In addition, our implementation of measures to improve profits in the North America business is a positive.

Meanwhile, negative factors in Japan include the sluggish growth of strategic products and the acceleration of the decline in sales of long-listed brands due to encouragement of the use of generic products, and delays in the launch of new products such as lurasidone. Overseas, the negative factors include the review of the lurasidone business in Europe.

As a result of these factors, we have revised the management targets for fiscal 2017, the final year of the third Mid-term Business Plan, to ¥440.0 billion in net sales, ¥50.0 billion in operating income, and ¥75.0 billion in EBITDA. Our forecast ROE for fiscal 2017 will be 6%.

The outcome is that we are revising management targets downwards from the previous review as outlined. However, we consider that the aggressive launch of new drugs is essential for the medium to long-term growth of the Sumitomo Dainippon Pharma Group, and we have kept research and development costs at the ¥85.0 billion in the previous revision.

#### The third Mid-term Business Plan: Factors behind the revision changes in FY2017 business goals February 2013: Time of formulation October 2014: Revision May 2016: Revision Management Revision Revision targets FY2017 FY2017 FY2017 Net sales 450 450 440 Positive factor Operating income 80 80 50 I ATLIDA® sales revised up in North America Research and 80 85 85 development costs • Weaker yen **FBITDA** 100 110 75 Foreign currency Napabucasin launch 80.0 ven/\$ 100.0 yen/\$ 110.0 yen/\$ delayed New launches through Streamlining Sluggish sales of strategic Delayed new launches products, etc. Lurasidone etc. • REMITCH® Accelerated decline of long-listed Japan • Trulicity® product sales due to the MHLW's initiative to promote the use of generic drugs the weaker yen Profit improvement Change of lurasidone business structure in Europe in North America Overseas (Current assumption: ¥110) (Previous assumption: ¥100)



Please explain your strategy for future growth beyond the third Mid-term Business Plan.



We will aim for sustained growth and expansion of revenues through the continuation of aggressive investment in research and development, particularly late-stage development products, and the strengthening of the business structure in Japan and overseas.

From fiscal 2018 (the fiscal year ending March 31, 2019) onwards, which will be covered by the next Mid-term Business Plan, we expect our business performance to decline in fiscal 2019 due to the expiry of the exclusivity period for LATUDA®. However, we will aim for an early V-shaped recovery from fiscal 2020 onwards through maximization of strategic products in each region, launch of late-stage development products and early expansion of sales, and active in-licensing.

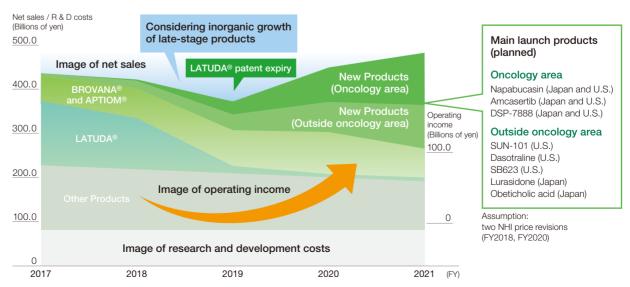
We will seek to strengthen marketing and maximize sales of products such as APTIOM® and BROVANA® in North America and Trulicity®, REMITCH®, and TRERIEF® in Japan. Moreover, we will maintain our aggressive investment in research and development, particularly on late-stage development products, with an investment target of around 20% of net sales to actively launch new drugs.

With regard to products scheduled for launch by fiscal 2019, we plan to launch napabucasin (fiscal 2017 target launch: U.S. and Japan) followed by amcasertib (fiscal 2019 target launch: U.S. and Japan) in the Oncology area. We also intend to launch many new products outside of the Oncology area, such as SUN-101 (fiscal 2017 target launch: U.S.) and dasotraline (fiscal 2018 target launch: U.S.)

We strive to continue to launch a large number of highly novel and competitive new drugs in fiscal 2020 and beyond, including DSP-7888 (U.S. and Japan), an anti-cancer drug, SB623 (U.S.), a cell therapy for treating stroke, lurasidone (Japan), and obeticholic acid (Japan), a treatment for nonalcoholic steatohepatitis (NASH).

In addition to such aggressive research and development, we will pursue opportunities for new in-licensing and M&As in the Psychiatry & Neurology and Specialty areas up to a maximum scale of ¥150 – ¥200 billion in order to expand our pipeline. Moreover, we will not only continue our efforts for strengthening our business foundation, which include building a highly efficient business management system in Japan and a highly efficient sales organization in the U.S., but will also work to reduce costs through optimization of selling, general and administrative expenses and reorganization of production sites to achieve sustained growth and improve profitability.

#### Performance forecast after the third Mid-term Business Plan





Please explain your approach to enhancing and strengthening corporate governance, including compliance with the Corporate Governance Code.



We are pursuing a more effective governance system, with a focus on such measures as the establishment of a new Nomination and Compensation Committee and strengthening of compliance on the global scale.

Sumitomo Dainippon Pharma positions building and implementing a highly effective corporate governance system as the basis of management aimed at the better realization of our Corporate Mission and Management Mission. We have endeavored to ensure the transparency and soundness of management and to strengthen internal control through such means as the appointment of a number of Outside Directors and Outside Audit & Supervisory Board Members. In October 2015, we formulated the Basic Policy on Corporate Governance and have been adressing the further strengthening of corporate governance, including compliance with the Tokyo Stock Exchange's Corporate Governance Code.

As for the governance system, although Sumitomo Dainippon Pharma has elected to be a "company with an Audit & Supervisory Board," we have also established a new Nomination and Compensation Committee as an advisory body to the Board of Directors with the aim of strengthening the objectivity and independence of the functions of the Board of Directors involving the nomination of candidates for Directors and Audit & Supervisory Board Members and determining the remuneration of Directors. Moreover, in November 2015, we restructured our existing compliance promotion organization to create a system under which the Executive Officer in charge of compliance oversees the compliance promotion system for the Sumitomo Dainippon Pharma Group with the aim of strengthening the system group-wide, including group companies in and outside Japan.

In April 2016, we established a new Corporate Governance Department. By consolidating functions related to corporate governance, which were previously under the supervision of the Global Corporate Planning Department and the Legal Affairs Department, the functions of the Corporate Communications Department, and the functions of the General Affairs Department, we will promote the further strengthening of the corporate governance system.





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



We define CSR as practicing our Corporate Mission, and in recent years we have promoted diverse initiatives, particularly active participation by women.

We define our CSR-based management as practicing our Corporate Mission, which is "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." We not only promote our corporate governance system and thoroughly ensure compliance but also fulfill our social responsibility as a corporation through wide-ranging initiatives that include social contribution activities in and outside Japan, promotion of diversification, and active communication with diverse stakeholders.

While Sumitomo Dainippon Pharma has always focused efforts on developing an environment that allows every single employee to reach their full potential regardless of gender, age, nationality, disability and so on, in recent years, we have been striving to promote active participation by women, which is the main theme of diversification. As of April 2016, women accounted for approximately 7% of Managerial staff at Sumitomo Dainippon Pharma. With a target of making this figure at least 10% by the end of 2020, we are working on company-wide reforms from the three perspectives of systems, awareness, and culture. For example, in order to allow all employees who are raising children to continue working, we established a system in April 2016 for MRs to restrict their area of responsibility on request (an MR region selection system) while raising children. In June 2016, we launched a work from home system for employees engaged in childcare and nursing care. In addition, in order to raise the awareness of employees and encourage the creation of a culture that makes it easy for women to be more active in management, we began training to support the development of female employees for Managerial staff in fiscal 2015. From fiscal 2016, we will also further expand career development training for female employees.



#### Do you have a message for stakeholders?



We will aim for record high consolidated net sales by implementing our key strategies in addition to accelerating structural transformation aimed at sustained growth.

Over the next few years, Sumitomo Dainippon Pharma will launch distinctive new products in and outside Japan and aim for a transformation of our business structure. In fiscal 2016, we will implement our key strategies which include building a highly efficient business management structure in Japan, and particularly research and development for the new post-LATUDA® products in order to further accelerate this transformation.

Regarding dividends, we believe that the appropriate allocation of profits is important in addition to taking a comprehensive view that includes such factors as aggressive investment to further increase corporate value, solidifying our management base, and enhancing our financial position. As a result, we paid out a dividend of ¥18 per share in fiscal 2015. The annual dividend per share is forecast to be ¥18 in fiscal 2016 as well.

Currently, Sumitomo Dainippon Pharma is striving to create innovative new drugs by aggressively promoting research and development in the Psychiatry & Neurology area and the Oncology area as well as disease fields where no approved drug exists, such as rare diseases, and new areas, such as regenerative medicine/cell therapy, with the aim of launching our next-generation of mainstay products. We firmly believe that through the success of these strategic investments we will be able to trace a stronger growth trajectory as an R&D-based pharmaceutical company with a distinctive presence in the global market in the near future. We ask all of our stakeholders for your continued support.

# In all business processes, Sumitomo Dainippon Pharma is pursuing innovations.

Sumitomo Dainippon Pharma is pursing innovations and promoting our Mid-term Business Plan in all business processes from creating groundbreaking new drugs at the R&D stage through production and quality control, quality assurance, provision of information to medical professionals, and marketing. At the same time, we spell out the social responsibilities that each process needs to fulfill as we address CSR.

#### **Business Processes**



#### **Strategies**

- Concentrating management resources on focus therapeutic areas and new fields
   Concentrate on focus therapeutic areas (Psychiatry & Neurology area, Oncology area) and new fields (disease fields where no approved drugs exist, Regenerative Medicine/Cell Therapy) and accelerating late-stage products to obtain earlier approvals of these products
- Utilizing leading-edge technologies in drug research In silico drug discovery methods, iPS cells etc.
- External research collaborations
   The Laboratory for Malignancy Control Research (the DSK Project) at Kyoto University, The Center for iPS Cell Research and Application (CiRA) at Kyoto University, Edison Pharmaceuticals, Inc. etc.
- Developing our own robust intellectual portfolio Building up a patent portfolio including not only substance patent application but also related patents that encompass uses, manufacturing processes and formulations

#### Main CSR Initiatives

- Human rights and ethical considerations
- Clinical Studies Put the Human Rights of Subjects First
- Ethical Approach to Human Tissue Research
- Ethical Considerations in Animal Experimentation
- Respecting intellectual property rights

# Production and Quality Control

⇒Details on p.29-30



#### **Strategies**

- Establishment of a stable supply system Reorganization of four plants in Japan, reducing lead times
- Strengthening the global supply chain
   Use of multiple suppliers, collaboration with manufacturing subcontractors inside and outside Japan
- Strengthening the distribution system

#### Main CSR Initiatives

- CSR procurement Continuously evaluating business partners Conclusions of basic agreements on transactions with business partners, and compliance with relevant laws and regulations including the Act against Delay in Payment of Subcontract Proceeds, etc. to Subcontractors
- Quality assurance system that supports safe and secure products
   Compliance with the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan and Good Manufacturing Practice (GMP)
- Prevention of medical malpractice Improvement of names and designs on product packaging and labeling
- Initiatives for environment conservation and industrial safety and health Obtained ISO 14001 certification.

#### **CSR Management** (Principal activities)

⇒Details on p.49-58

#### Human Rights

- Respect for the dignity of the individual
- · Initiatives to prevent harassment
- Respect for freedom of association

#### Labour Practices

- Creating a workplace environment that allows employees to focus confidently on their work
- Work-life balances

- Diversification (Supporting active participation by women)
- Creating a workplace environment that allows employees to focus confidently on their work

#### Corporate Governance (Principal activities)

⇒Details on p.41-46

- Establishment of the Basic Policy on Corporate Governance and a highly effective corporate governance system
- Development and implementation of internal control system
- Timely, Appropriate and Fair Disclosure of Information

# Strategy & CSR



#### **Strategies**

- Prompt responses to inquiries
   Construction of a quality information system that is accessible to the departments involved
- Promoting pharmacovigilance activities Compliance with the Pharmaceuticals, Medical devices and Other Therapeutic Products Act and Good Vigilance Practice (GVP)

Managing and evaluating all safety information on products developed and marketed in multiple countries

#### Main CSR Initiatives

- Prompt and Accurate Provision of Information to Medical Institutions
- Creation of documents and materials that are easily conveyed to medical professionals and patients
- Product information search system "DI-SaGaS" Constructed a product information search system, DI-SaGaS, to provide product information in response to inquiries from medical professionals

#### Marketing

⇒Details on p.33-40



#### **Strategies**

Japanese Market

- Concentrate marketing resources on strategic and new products to maximize product value at an early stage
- Build highly efficient sales organization

North American Market

Further expand atypical antipsychotic LATUDA®
 Expand sales of long-acting beta-agonist BROVANA® and antiepileptic drug APTIOM®

Chinese Market

- Maximize profits from existing products
- Establish highly efficient business foundation

#### Main CSR Initiatives

- Pursuing Fair Promotion Activities Complying with standards related to promotion in individual countries in Japan, North America and China
- Implementing Patient Group Activities

#### Consumer Issues

- Meeting the needs of patients
- Provision of Information to medical professionals and patients

Community Involvement and Development

- Forest Conservation Activities by Officers and Employees
- Donations and supporting activities
- International Contribution Activities (Supporting activities to eradicate Malaria etc.)

#### Environment

- Activities to Conserve Energy and Address Climate Change
- Waste Reduction
- Reduction of Chemical Substance Waste

- Compliance
- Risk management
- Business Continuity Plan (BCP)
- Information management and security

We are maintaining aggressive research & development investment in particular for late-stage development products



#### Development policy and initiatives in focus therapeutic areas and new fields

#### Psychiatry & Neurology Area / Disease fields where no approved drugs exist

- Psychiatry & Neurology Area: This area leverages our strengths and our experiences, and we will accelerate research by incorporating leading-edge science and technology.
- Our research focus is moving toward diseases with higher unmet medical needs.
- We will aggressively seek external research collaboration with biotechs and academia.
- For early-stage development products we will aim to establish POC\* quickly and for late-stage development products we will aim to submit NDA as early as possible.

# Psychiatry Treatment resistant segment (Schizophrenia, Depression) Autism spectrum, Developmental disorders Neurology Alzheimer's disease, Parkinson's disease, ALS, Intractable Epilepsy, Pain Mitochondria-related diseases Mitochondria-related diseases

#### High priority late-stage development products to seek fastest approval

- Dasotraline (SEP-225289): Adult attention-deficit hyperactivity disorder (ADHD) (Ph3),
   Pediatric attention-deficit hyperactivity disorder (ADHD) (Ph2/3), Binge eating disorder (BED) (Ph2/3) / U.S.
- TRERIEF®: Parkinsonism in Dementia with Lewy Bodies (DLB) (Ph3) / Japan
- Obeticholic acid (DSP-1747): Nonalcoholic steatohepatitis (NASH) (Ph2 completed) / Japan

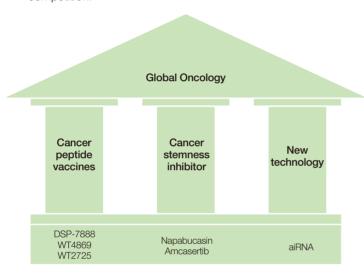
#### Early-stage development products for which we aim to obtain early POC

- EPI-589: Parkinson's disease, ALS
- DSP-2230: Neuropathic pain
- SEP-363856: Schizophrenia
- DSP-3748: Cognitive impairment associated with schizophrenia (CIAS)
- DSP-1200: Treatment-resistant depression

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

#### **Oncology Area**

- We will capitalize on our strengths such as advanced technology platforms in the oncology area.
  - Cancer stemness inhibitor
  - Cancer peptide vaccines
  - New technology (aiRNA, etc.)
- Boston Biomedical, Inc. and DSP Cancer Institute expand drug discovery activities together through cooperation and competition.



#### Regenerative Medicine / Cell Therapy Field

- We will address unmet medical needs with the aim of providing relief for patients suffering with incurable diseases.
- Going forward, we will strengthen industry-academia collaboration and partnerships with venture companies to pursue commercialization in the field, where strong market potential is expected and we can leverage our longstanding R&D expertise.

#### Progress & change in FY2015

- SB623 (for chronic stroke): A Ph2b study begun in the U.S. [156 patients (3-group double-blinded study)]
- Age-related macular degeneration: suspension chosen as formulation
- Parkinson's disease: Study begun on evaluation method of an automatic cellculture apparatus (adopted as an AMED project)
- Started production of master cell bank of iPS cells for clinical use
- A new cell processing center (CPC) under construction scheduled for full-scale operation in fiscal 2017

We will concentrate on focus therapeutic areas (Psychiatry & Neurology area and Oncology area) and new fields (Disease fields where no approved drugs exist and Regenerative Medicine/Cell Therapy) and accelerate late-stage products to obtain earlier approvals of these products.

In order to fulfil unmet medical needs with innovative new drugs created by leading-edge technology, Sumitomo Dainippon Pharma established the basic policy as "Increase speed and efficiency" to expand our pipeline.

In the Psychiatry & Neurology area, we will focus our drug research and development on diseases such as schizophrenia, depression, Alzheimer's disease, neuropathic pain, developmental disorders and neurodegenerative diseases where patients are not sufficiently treated with existing medications.

Our global research organization will enable us to lead the cancer stem research area and to continuously develop breakthrough products in the oncology area. We believe that napabucasin, a cancer stemness inhibitor, is the leading candidate to become a best-selling product post-LATUDA®. DSP-7888 is a therapeutic cancer peptide vaccine under clinical development, which we aim to launch in Japan and the U.S. in fiscal 2020.

In the Regenerative Medicine/Cell Therapy field, we established the Regenerative & Cellular Medicine Office in September 2013 in order to accelerate the development and commercialization of cell therapy and regenerative medicine using iPS cells. Moreover, we are also conducting research into treatments for intractable diseases through the application of leading-edge science, including human iPS cells.

In disease fields where no approved drugs exist, we are developing obeticholic acid for nonalcoholic steatohepatitis (NASH).

# Global Oncology Outlook Napabucasin (BBI608)

Cancer Stemness Inhibitor Targeting STAT3\*1

Napabucasin is an orally-administered small molecule agent with a new mechanism that demonstrates an anti-tumor effect on cancer stem cells (cancer cells with the characteristics of stem cells, "stemness") in addition to cancer cells by targeting STAT3. Cancer stem cells are believed to be a possible cause of recurrence, metastasis, and treatment resistance. As napabucasin works on both cancer stem cells and cancer cells, it is expected to offer a new approach to treatment resistance, recurrence, and metastasis, which are issues in cancer treatment.

\*1. A protein involved in gene transcription. STAT3 is activated in many solid tumors and has been found to play an important role in neoplastic transformation of cells.



#### Why target cancer stem cells?



Because cancer stem cells are believed to be a possible cause of cancer cell production, malignant growth, recurrence, and metastasis.

Tumor cells include "cancer stem cells," "cancer cells with a high degree of stemness," and "other bulk cancer cells with a low degree of stemness." "Cancer stem cells" and "cancer cells with a high degree stemness" are involved in the production of other bulk cancer cells and have been suggested as a cause of malignant growth, recurrence and, metastasis.

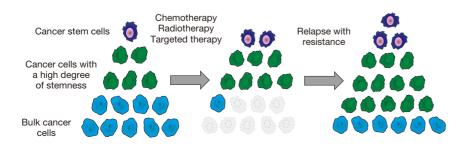
Existing treatments, including chemotherapy, radiotherapy and targeted therapy, are effective on "bulk cancer cells" and can kill many of them. However, it has been reported that "cancer stem cells" and "cancer cells with a high degree of stemness" are resistant to existing treatments, including chemotherapy, radiotherapy and targeted therapy. Therefore,

it is thought that the cancer acquires greater resistance to existing treatments and recurs.

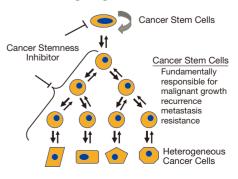
"Cancer stem cells" have already been identified in many cancer types, and cancer stem cell plasticity\*2 has been discovered recently. In other words, this means that even if "cancer stem cells" are killed, other cancer cells that are not stem cells dedifferentiate to become cancer stem cells. Sumitomo Dainippon Pharma believes that it is important to target "cancer stem cells," and "cancer cells with a high degree of stemness" to inhibit "cancer stemness."

\*2. Plasticity: Refers to the capability to change characteristics when environmental conditions change

#### Cancer stemness causes resistance



#### Inhibitor targeting cancer stemness





Chiang J. Li speaking on the outlook in the oncology area at an R&D Meeting held in December 2015 (President, CEO and CMO, Boston Biomedical Inc., Head of Global Oncology for Sumitomo Dainippon Pharma Group)



#### What are the main achievements of R&D on Napabucasin (BBI608)?

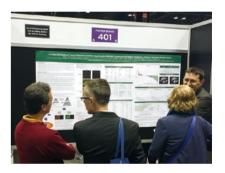


In Phase 1/2 studies, we conducted trials in a number of cancers with number of concomitant medications and proceeded with Phase 3 studies after reviewing the results and screening. We presented data from the Phase 1/2 studies at academic conferences as appropriate.

At the American Society of Clinical Oncology (ASCO) in 2014 and 2015 and the Gastrointestinal Cancers Symposium, held by the American Society of Clinical Oncology (ASCO-GI) in January 2016, we presented clinical data suggesting the anti-tumor activity of napabucasin in Phase 1/2 studies for a range of advanced cancers, including gastric, colorectal and pancreatic cancer in combination with other agents.

At the American Society of Clinical Oncology (ASCO) held in the U.S. in June 2016, we presented data on combination therapy in non-small cell lung cancer, breast cancer and ovarian cancer in addition to the cancers above.

We also announced the study protocol for the global phase 3 study (BRIGHTER) for gastric cancer and gastroesophageal junction adenocarcinoma (combination therapy).



#### [Outline of The BRIGHTER Study] Target number of cases: 700 (350 x 2 groups), Study locations: United States, Canada, Japan, etc.

- Study Design: Multicenter, double-blind, randomized global study
- Napabucasin (480mg x 2/day) + weekly paclitaxel (80mg/m2i.v.), placebo + weekly paclitaxel
- Primary endpoint: Overall Survival (OS)
- Secondary endpoint: Progression-Free Survival (PFS), Objective Response Rate, Disease Control Rate (DCR), Safety, QOL etc.



#### What are the future plans?



In addition to gastric and gastroesophageal junction adenocarcinoma, and colorectal cancer, we plan to start new pivotal studies in non-small cell lung cancer and pancreatic cancer in fiscal 2016 (both combination therapy).

In the U.S. and Japan, we aim to apply for approval for gastric and gastroesophageal junction adenocarcinoma in fiscal 2017 and for colorectal cancer in or after fiscal 2019.

The oncology area is an area of high unmet medical needs, and Sumitomo Dainippon Pharma will make the utmost efforts for success in development and will remain committed to being able to contribute to the treatment of cancer in the near future.

# Analysis Results of Global Phase 3 Study (CO.23 Study) Targeting Colorectal Cancer

In May 2016, Sumitomo Dainippon Pharma obtained the preliminary analysis results of the study for which the accrual of enrollment was prematurely stopped in May 2014.

- Among all randomized patients (n=282), there was no statistical difference in the median overall survival between napabucasin and placebo arms.
- In pre-specified subset analysis, napabucasin treatment significantly improved OS in patients with high p-STAT3 expression.

These results are scheduled to be announced at a future academic conference by the global sponsor CCTG (former name: NCIC-CTG) of Canada.

#### Basic strategy / R&D organization

#### **Drug Discovery**

#### Utilizing leading-edge technologies in drug research

Led by small-membered labs each specialized in a specific field or technology, we have focus in leading-edge technology-based drug discovery at an unprecedented level. Newly introduced personnel and organization systems since April 2016 have accelerated such activity. In addition, we are aiming to shorten the research & development period and increase the success rate by using iPS cells to investigate non-clinical efficacy and safety.

Moreover, in order to improve the research success rate, we are actively engaged in in silico drug discovery methods to search for promising candidate compounds, and are the first pharmaceutical company to use the "supercomputer "K" in drug discovery. In silico drug discovery uses a simulation technique to search for safe and effective promising compounds by calculation in computers, based on information such as chemical structures, protein structures and disease mechanisms.

About one in every 30,000 candidate compounds actually makes it through to launch as a drug product. Moreover, a long period of 9 to 17 years is usually required for the launch of one drug product. However, by using the in silico drug discovery methods we expect to effectively select fewer promising compounds, increase the success rate and shorten the overall drug development period. Through this approach, we aim to deliver promising drugs to patients more quickly.

#### Enhancing translational research

In order to increase the probability of success, we are also focusing on biomarker research and the application of clinically evaluated parameters such as blood markers, electroencephalograms, and brain imaging to non-clinical studies. Compounds identified with such parameters during non-clinical research are likely to be more efficacious than those without signals, demonstrate clear POC at earlier clinical phases and shorten overall clinical development timelines.

#### **External Research Collaborations**

For innovative, sustainable and productive new drug discovery, Sumitomo Dainippon Pharma is aggressively creating external collaboration and alliances with academia and biotechs with leading-edge technologies, in Japan and overseas, to complement its own internal research activities. In fiscal 2015, we launched PRISM, an application-based open innovation activity, commencing the incorporation of innovative external ideas into drug discovery.

In fiscal 2015, we concluded a feasibility study agreement with JCR Pharmaceuticals Co., Ltd. in the Psychiatry & Neurology area to use their blood-brain barrier penetration technology. In April 2016, we implemented the second term of joint research project (DSK Project) with Kyoto University aimed at discovering innovative anti-cancer drugs, diagnostic tools and therapeutic methods.

#### Intellectual Property

#### Main Concept

As a pharmaceutical manufacturer, Sumitomo Dainippon Pharma recognizes that activities relating to 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.

#### Main Research Partners

Partner	Details
The Laboratory for Malignancy Control Research (the DSK Project) at Kyoto University	In partnership with Kyoto University, Sumitomo Dainippon Pharma is conducting cancer drug discovery research based on immunity and stroma regulation from the approaches of molecular/cellular biology and clinical aspects. By doing this, we aim to develop and create unprecedented unique and innovative anti-cancer drugs, diagnostic tools and treatment methods from the new perspective of "cancer and host response."
The Center for iPS Cell Research and Application (CiRA) at Kyoto University	This collaboration with academia focuses on fibrodysplasia ossificans progressiva (FOP), a rare untreatable disease caused by genetic mutations. Using disease-specific iPS cells, we will investigate the mechanism for disease progression, identify disease markers specific to patients, and seek compounds capable of controlling these pathways, in order to find a breakthrough treatment option that can suppress the progression of the disease.  In December 2015, we published an article citing a new mechanism in the heterotopic osteogenesis of FOP.
Edison Pharmaceuticals, Inc.	The research collaboration with the U.S. based biotech Edison Pharmaceuticals, Inc., focuses on redox systems, which play a critical role in the regulation of energy metabolism in cells. Through the joint research collaboration we aim to discover 10 novel drug candidates, hopefully leading to the development of therapies for untreatable diseases, including mitochondrial diseasesand redox stress-induced neuropsychiatric disorders.

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

We actively file patent applications covering inventions created at each laboratory and inventions created in cooperation with outside research institutions, including open innovation.

In filing patent applications, we are building up a patent portfolio including not only substance patent application but also patent applications that encompass uses, manufacturing processes and formulations to protect comprehensively our commercial and development products. 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, we organize regular Patent Committee meetings with heads of research, development and business-related departments. The subjects at Patent Committee meetings include discussions of future intellectual property strategies in each country where we conduct business and sharing of intellectual property information on individual products.

#### Consideration in clinical studies

#### 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 of 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 patient can safely participate in studies.

#### 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. The new Ethical Guidelines for Medical and Health Research Involving Human Subjects (Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labour and Welfare) were established for the purposes of review and enhancement in areas such as ensuring the quality of research, protecting donors of human tissue, etc., and ensuring transparency in collaborations between research institutions. In light of this. Sumitomo Dainippon Pharma established the new Rules for the Research Ethical Review Committee in July 2016 to strengthen our system by creating the Research Ethical Review Committee within the Corporate Regulatory Compliance & Quality Assurance Division in place of the previous Research Ethics Committee on Uses of Human Tissues.

The Research Ethical Review Committee reviews the appropriateness of implementing research from the perspectives of the significance and necessity of research, the scientific rationality of plans, the provision of adequate prior explanations to donors of human tissues, etc. and the acquisition of consent based on free will (informed consent), rigorous protection of personal information and other points of view. We also disclose the Rules for the Research Ethics Investigation Committee, the composition of the committee members, and the content of the committee proceedings.

#### 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.

#### **Development Pipeline**

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

This is the area of research in which Sumitomo Dainippon Pharma has focused most of its efforts so far, and we believe that we have a strong competitive edge in the area. Focusing on diseases where existing drugs do not provide adequate outcomes and where there are low levels of satisfaction with current treatment, we are actively developing dasotraline and other new products in North America and an additional indication for TRERIEF® in Parkinsonism in dementia with Lewy bodies (DLB) in Japan.

Brand name / Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
APTIOM® (SEP-0002093)	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	Canada				
LONASEN®		Schizophrenia	China				
	blonanserin	(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
		Schizophrenia	China				
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	Japan				
(0141 10430)	Try droot not de	Bipolar I depression, Bipolar maintenance	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				*1
	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
SEP-225289		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				*2
		Binge eating disorder (BED)	U.S.				*2
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
SB623	TBD	Chronic stroke	U.S.				
EPI-589	TBD	Parkinson's disease	U.S.				
EPI-309	ופט	Amyotrophic lateral sclerosis (ALS)	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S. / Japan				
SEP-363856	TBD	Schizophrenia	U.S. / Japan				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				
DSP-1200	TBD	Treatment-resistant depression	U.S.				

(As of July 27, 2016)

\*1 A Phase 2/3 study completed, development strategy under consideration \*2 Phase 2/3 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.

#### DSP-2230 Neuropathic pain

(Developed in-house)

DSP-2230 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7 and Nav1.8 with higher potencies than those against the other sodium channel subtypes studied. In addition, DSP-2230 has demonstrated antiallodynic effects in animal models of neuropathic pain that have been shown to be predictive of efficacy in humans. Due to its novel mechanism, DSP-2230 is expected not to produce central nervous system or cardiovascular system side effects, which are present with the current drugs, such as non-selective sodium channel blockers and anti-epilepsy medicines.

#### SEP-225289 (dasotraline)

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

SEP-225289 is a dopamine and norepinephrine reuptake inhibitor (DNRI). SEP-225289 has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect by dosing at 24-hour intervals.

# EPI-743 (vatiquinone) Mitochondrial disease EPI-589 Neurodegenerative diseases

(In-licensed from Edison Pharmaceuticals)

EPI-743 and EPI-589 are expected to show efficacy by removing the oxidative stress which is generated excessively by decreased mitochondrial function. EPI-743 is expected to be the world's first treatment for mitochondrial diseases beginning with Leigh syndrome for which no effective treatment exists. EPI-589 is expected to be developed for neurodegenerative indications arising through redox stress.

#### **Oncology Area**

Sumitomo Dainippon Pharma made a full-scale entry into the Oncology area with two innovative compounds obtained through the acquisition of Boston Biomedical, Inc. We have continued to put the utmost efforts into the development of napabucasin, a first-in-class cancer stemness inhibitor. With regard to amcasertib, a cancer stemness inhibitor with a different mechanism of action to follow napabucasin, we will conduct a Phase 3 study based on the results of Phase 1/2 studies which are currently underway.

Brand name / Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
		Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical study)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy) (Global clinical study)	U.S.				
		Non-small cell lung cancer (Combination therapy) (Global clinical study)	U.S.				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
BBI608	napabucasin	Solid tumors (Ovarian cancer, Breast 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				
		Solid tumors (Combination therapy) *4	Japan				
	amcasertib	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)	U.S.		*2		
		Solid tumors (Combination therapy)	U.S. / Canada				
		Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan				
BBI608+BBI503	_	Solid tumors (Combination therapy)	U.S.				
		Myelodysplastic syndromes	Japan			*1	
DSP-7888	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Pediatric malignant glioma	Japan		*2		
WT4869	TBD	Myelodysplastic syndromes	Japan		*2		
1117000	.55	Solid tumors	Japan				
WT2725	твр	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				

(As of July 27, 2016)

\*1 Phase 2 of Phase 1/2 study \*2 Phase 1 of Phase 1/2 study

\*3 A number of tumor type-specific studies (Gastrointestinal cancer , Hepatocellular carcinoma, Glioblastoma, Pancreatic cancer)

\*4 A number of tumor type-specific studies (Hepatocellular carcinoma, Colorectal cancer)

#### BBI608 (napabucasin) Cancer

(Developed in-house)

BBI608 is an orally-administered small molecule 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 the challenges in cancer treatment such as treatment resistance, recurrence and metastasis.

#### BBI503 (amcasertib) Cancer

(Developed in-house)

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

#### DSP-7888 Cancer

(Developed in-house)

DSP-7888 is a therapeutic cancer peptide vaccine derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a vaccine containing peptides that induces WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become a treatment option for patients with various types of hematologic malignancies and solid tumors that express WT1, by inducing WT1-specific CTLs that attack WT1-expressing cancers cells. By adding a helper T cell-inducing peptide, stronger efficacy is expected than with a CTL-inducing peptide alone. DSP-7888 is expected to be an option for a wide range of patients.

#### Other Areas

Brand name / Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
Respiratory Area							
SUN-101 glycopyrronium 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 27, 2016)

#### SUN-101 (glycopyrronium bromide)

#### Chronic obstructive pulmonary disease (COPD)

(Developed in-house)

SUN-101 is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the innovative, proprietary closed investigational eFlow® nebulizer system. It is a portable, hand-held nebulizer system and is designed to deliver the medication in two to three minutes. A standard jet nebulizer typically takes up to 10 minutes. 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 at the most advanced development stage.

Note: The New Drug Application (NDA) for SUN-101 was submitted to the FDA on July 29, 2016

#### DSP-1747 (obeticholic acid)

#### Nonalcoholic steatohepatitis (NASH)

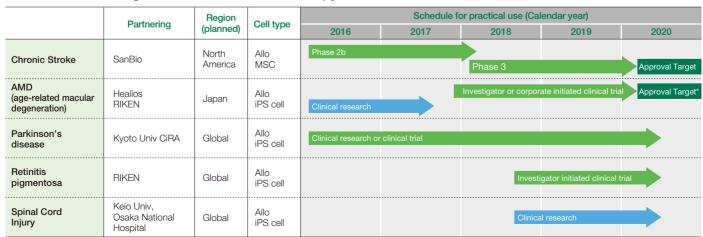
(In-licensed from Intercept Pharmaceuticals Inc.)

DSP-1747 is an agonist for 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 Field

Sumitomo Dainippon Pharma is actively working in new areas such as diseases for which no treatment exists and the regenerative medicine/cell therapy field. In particular, in the regenerative /cellular medicine area, we have stepped up initiatives, including promoting joint development with Healios K.K. aimed at the world's first commercialization of iPS cell-derived medicine in the eye disease field.

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



(As of July 27, 2016)

<sup>\*</sup> Plan to review schedule, by the implementation of tumorigenicity test in pre-clinical study

Treatments with autologous iPS cells require the individualized preparation of cells and other procedures in medical institutions. This is expensive and time-consuming. However, treatments with allogeneic iPS cells make it possible to reduce time and costs by supplying a uniform cell medicine to a large number of 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.

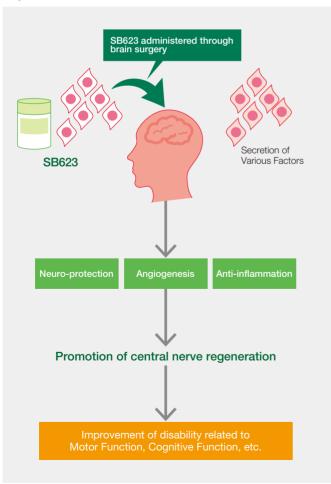
#### Chronic Stroke (SB623)

(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 up 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 2b clinical study in partnership with SanBio in the U.S. SB623 showed promising results for chronic stroke in the Phase 1 and 2a clinical studies.

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

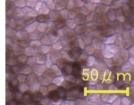


#### AMD (Age-related macular degeneration)

Retinal Pigment Epithelial (RPE) cells (iPS cell-derived)

Sumitomo Dainippon Pharma concluded a joint development agreement with Healios K.K. in December 2013, and established a joint venture company Sighregen K.K. through joint investment

with Healios K.K. in February 2014. At present, Sumitomo Dainippon Pharma and Healios K.K. are promoting research and development of an allogeneic iPS cell-derived retinal pigment epithelial (RPE) cell suspension (HLCR011). Sighregen has commenced studies aimed at preparations for manufacturing of cells. RPE cells (iPS cell-derived)



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

Kyoto University is planning to conduct clinical research for autologous transplantation of dopaminergic neural progenitor cells produced from a patient's own iPS cells or an investigator-initiated trial with allogeneic cells for developing regenerative treatments 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 donors.

#### 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. As for basic research, Sumitomo Chemical Co., Ltd. in partnership with RIKEN has already become the first in the world to succeed in generating a three-dimensional retina from human embryonic stem cells. By following on this, Sumitomo Dainippon Pharma aims to create a treatment with allogeneic 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 iPS cell-derived neural precursor cells." The goal of the project is to develop a treatment for the transplantation of iPS cell-derived neural precursor cells for spinal cord injury.

**Production and Quality Control** 

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



#### Establishment of a Stable Supply System

At Sumitomo Dainippon Pharma, our greatest mission as a pharmaceutical company is to provide a stable supply of high-quality pharmaceuticals made in fundamentally sound, safe operations. In order to fulfill this mission, we perform inspections at multiple stages for every lot of each product, verifying the quality of materials at all stages of the manufacturing process from receipt of raw materials through the final inspection of products to be delivered, to determine if the qualities are adequately kept and if the products have been manufactured according to the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan and Good Manufacturing Practice (GMP)\*1. Only products that have passed all of these inspections are shipped.

We have built a stable supply structure for products, which are manufactured at four plants in Japan—in Suzuka, Ibaraki, Ehime and Oita—and also in collaboration with contract manufacturing partners in Japan and other countries. Our plants have worked hard to increase the precision of their production plans by collaborating closely with the Sales & Marketing Division. They have also made efforts to establish backup systems such as double sourcing of active pharmaceutical ingredients and to optimize selection of formulation and packaging sites. To further strengthen our competitiveness, we work to improve cost efficiency, including review of spending, as well as actively striving to increase productivity in our factories such as by reducing lead times.

\*1: Good Manufacturing Practice: A standard for managing the manufacturing and quality of pharmaceuticals and quasi-pharmaceuticals.

#### Strengthening the Global Supply Chain

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.

To ensure the stable and sustainable procurement of the raw materials and other items used for 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 2015, we promoted a review of production strategy accompanying the global expansion of our main products and the reorganization of our production sites.

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 our 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.

#### Strengthening the Distribution System

Our east and west Japan distribution centers are located in Kobe (Hyogo Prefecture) and Kazo (Saitama Prefecture), respectively. We have been making efforts to strengthen our 24-hour delivery system, under which the time from receiving order to delivery is shortened. The ratio of delivery to customers within 24 hours has steadily increased. We offer 24-hour delivery not only in the Kinki region and the Tokyo metropolitan area (the whole of the Kanto region), but in parts of the Chugoku and Tohoku regions as well. Moreover, we are working to strengthen the supplementary functions of the east and west Japan distribution centers to maintain a stable supply not only in normal times but also in the event of a disaster or other emergency.

In fiscal 2015, we also formulated company-wide GDP\*2 guidelines and launched initiatives aimed at developing a GDP system based on the guidelines.

\*2: Good Distribution Practice: A standard for proper distribution of pharmaceuticals.

#### **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. Moreover, members of the Procurement Department act as instructors to provide internal lectures on Act against Delay in Payment of Subcontract Proceeds. Etc. to Subcontractors and the Customs Act to relevant departments with the aim of strengthening company-wide compliance.

# Quality assurance system that supports 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. Sumitomo Dainippon Pharma's products are exported around the world with the approval of the government organizations in the importing countries, including the FDA (U.S. Food and Drug Administration), the EMA (the European Medicines Agency) and the TGA (Australia's Therapeutic Goods Administration), and the GMP of Europe and the U.S. has become the operational standard for the Sumitomo Dainippon Pharma Group. 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 (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), 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.

#### Prevention of Medical Malpractice

Packaging and label designs for pharmaceuticals are highly regulated, including the display of information stipulated by law. In this situation, the packaging and labels for each company's products are becoming quite similar, and this has become a cause of drug mix ups.

Therefore, at Sumitomo Dainippon Pharma, led by the Packaging and Presentation Team from the Manufacturing

Management (Department), we are promoting initiatives to respond to the needs of medical institutions and patients such as highly distinctive packaging and improving the design of labels with aim of preventing medical malpractice. When it seems likely that a mix up will occur, we respond promptly in such ways as changing the name and design so that mix ups do not occur based on consultation with company marketing the other product.

Furthermore, in fiscal 2012, we were the first in our industry in Japan to adopt a mechanism to allow product names to be laser printed onto the lids of bottles containing tablets on the production line. This has increased convenience for medical institutions by making it easy to remove medicines from the drawers they are stored in. We have also taken other steps from the perspective of patients, such as improving PTP sheets with an emphasis on usability.

# Initiatives for environment conservation and industrial safety and health

The three 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.

We also promote industrial safety and health management in order to operate without accidents and disasters based on the observation of compliance.

#### Acquisition of ISO 14001 Certification

Plants	Date of acquisition
Suzuka Plant (Suzuka City, Mie Prefecture)	December 2000 certification acquired
Ibaraki Plant (Ibaraki City, Osaka Prefecture)	July 2000 certification acquired
Oita plant (Oita City, Oita Prefecture)	March 1998 certification acquired



Corporate Regulatory
Compliance & Quality Assurance

We assure the regulatory compliance and quality of our products from development through to post-marketing.



# Prompt Responses to Inquiries Using a Unique Quality Information System

Sumitomo Dainippon Pharma's Quality Information System is designed to ensure prompt responses to inquiries regarding product quality from medical institutions. We use this system in order to respond to Quality Information under the Good Quality Practice (GQP)\*1 ordinance.

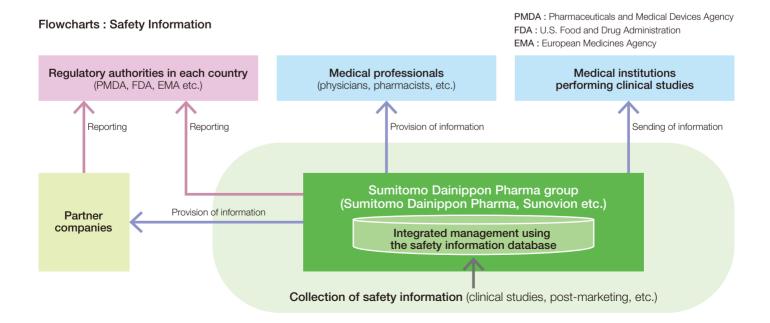
When an inquiry from a medical institution is submitted to our Quality Information System, the plant at which the product was manufactured takes immediate steps, checking reference samples from the same lot, and verifying manufacturing records to confirm the quality of the product in question. The underlying cause of the incident is also investigated, and when necessary, the plant develops and implements preventive measures.

Members of departments such as Safety Management, Sales & Marketing, Manufacturing, and Quality Assurance can access the system so that they can promptly evaluate safety and provide replacements for the products if needed. Our Quality Information System also has a search function which enables us to analyze quality issue trends per each product type and time period to prevent similar problems in the future. In addition, the tablet terminals carried by MRs (medical representatives) allow basic answers for matters with many inquiries to be accessed and disclosed, facilitating a speedier response to inquiries.

\*1 Good Quality Practice: A standard for managing the quality of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (manufacturing and marketing quality assurance standard).

#### **Global Safety Management**

Adverse reactions that were unpredictable during the development stage can appear 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 a 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 physicians and pharmacist 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 activities in compliance with the Pharmaceuticals, Medical devices and Other Therapeutic Products Act and Good Vigilance Practice (GVP)\*2.

Moreover, 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 develop the measures required for securing the safety of our pharmaceuticals.

\*2 Good Vigilance Practice: A standard for managing the post-marketing safety of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (post-marketing safety management standard).

## Prompt and Accurate Provision of Information to Medical Institutions

Sumitomo Dainippon Pharma promptly and accurately provides medical institutions with updated information on proper usage of its products in order to ensure the safety and efficacy of each pharmaceutical.

For example, when new precautions are added to package inserts, we provide "Notice of Revisions to Precautions" to physicians and pharmacists using our products and promptly introduce what kind of side effects require attention through MRs (medical representatives) and our medical information website. Furthermore, the tablet terminals carried by MRs are equipped with information for explaining "Notice of Revisions to Precautions"

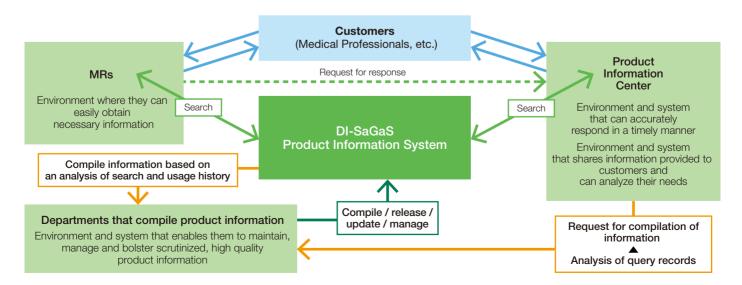
in more detail, making it possible for them to be introduced to physicians at medical institutions accurately.

We also prepare documents such as "Kusuri-no-shiori" and "Instructional Leaflets" which are distributed to medical institutions. These documents are used by medical experts in explaining to patients about how to take medications or what symptoms to watch for as a sign of a side effect. Illustrations are used in the "Instructional Leaflet" so that the elderly and children can easily understand about how to take drugs and about possible side effects.

# Providing Information Utilizing Product Information System DI-SaGaS

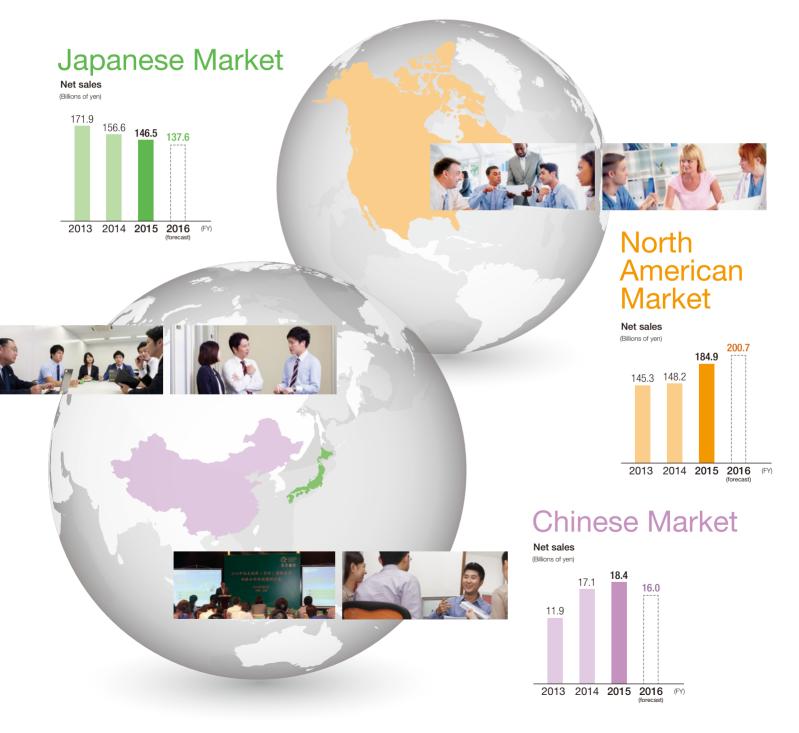
Drugs are truly effective only when users obtain information that helps them use drugs properly and safely. At Sumitomo Dainippon Pharma, we believe that prompt and accurate provision of product information will enhance the value of our drugs for customers. Therefore, in response to inquiries from medical professionals, we have constructed DI-SaGaS, a product information search system, to provide product information. In fiscal 2015, we renewed the system to facilitate faster responses by improving the search function and the linkage function with MRs' tablet terminals. We also enhanced the content based on appropriate grounds while considering the needs of medical professionals. Going forward, we will strive to increase the reliability of information and to provide information that leads to customer satisfaction.

#### Overview: Product Information System "DI-SaGaS"



We aim for early maximization of product value in each region.





#### Japanese Market

- Concentrate marketing resources on strategic and new products to maximize product value at an early stage
- Build highly efficient sales organization







#### **AIMIX®**

Launch December 2012

Indications Hypertension

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

#### **LONASEN®**

Launch April 2008

Indications Schizophrenia

Features Dopamine D<sub>2</sub> receptors and serotonin 5-HT<sub>2A</sub> receptors blocker

#### **TRERIEF®**

Launch March 2009

Indications Parkinson's disease

Parkinson's disease drug with levodopa-enhancing effect

#### **North American Market**

- Further expand atypical antipsychotic LATUDA®
- Expand sales of long-acting beta-agonist BROVANA® and antiepileptic drug APTIOM®





#### **LATUDA®**

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

Indications Schizophrenia,
Bipolar I depression

Features Affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2</sub>A and serotonin 5-HT<sub>7</sub> receptors where it has antagonist effects

#### **APTIOM®**

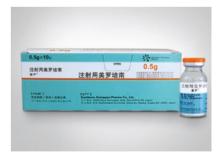
Launch April 2014 (U.S.)
October 2014 (Canada)

Indications Partial-onset seizures (Monotherapy / Combination therapy)

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

#### Chinese Market

- Maximize profits from existing products
- Establish highly efficient business foundation



#### **MEROPEN®**

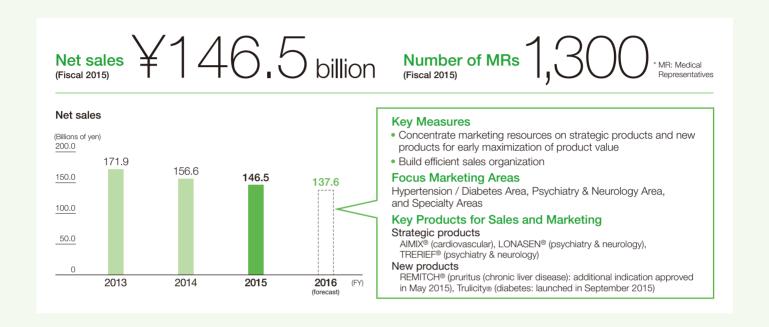
(brand name in China: MEPEM®)

Launch 1999

Indications General infections, febrile neutropenia

Features Standard therapy for severe infections, used in many countries

# Pharmaceutical Business Japanese Market



#### Fiscal 2015 Main Initiatives and Business Results

In addition to the provision of information by MRs, Sumitomo Dainippon Pharma actively promoted hybrid marketing that combined these activities with e-promotion utilizing the Internet and other means in efforts to expand sales through the appropriate provision of information. As a result, although sales of strategic

Sales of Major Products (Sales of U.S. Subsidiary, Billions of yen)

Brand Name	Therapeutic Indication	FY 2014	FY 2015	Rate of change (%)	FY 2016 forecast
AIMIX®	Therapeutic agent for hypertension	12.0	14.9	25.0	16.1
AVAPRO®	Therapeutic agent for hypertension	11.4	10.8	(4.6)	9.3
LONASEN®	Atypical antipsychotic	11.5	12.6	10.0	13.8
TRERIEF®	Therapeutic agent for Parkinson's disease	11.6	13.1	12.7	14.5
SUREPOST®	Rapid-acting insulin secretagogue	2.4	3.6	48.3	4.6
AmBisome®	Therapeutic agent for systemic fungal infection	4.3	4.3	0.6	4.3
REPLAGAL®	Anderson-Fabry disease drug	9.7	10.2	5.3	10.5
METGLUCO®	Biguanide oral hypoglycemic	17.1	14.7	(13.8)	9.8
AMLODIN®	Therapeutic agent for hypertension and angina pectoris	19.6	16.4	(16.3)	12.2

products such as AIMIX®, a therapeutic agent for hypertension, LONASEN®, an atypical antipsychotic, and TRERIEF®, a therapeutic agent for Parkinson's disease increased, this was not enough to offset the decline in sales of long-listed brands, resulting in a decline in sales.

#### Strategic Products

We provide information about the powerful antihypertensive effect of AlMIX $^{\otimes}$  and that the product can mitigate the medication burden, and promote sales growth.

For LONASEN®, we increased the number of MRs in the psychiatry area in fiscal 2015, to approximately 320 MRs. Furthermore, we newly assigned a marketing professional dedicated to LONASEN® in April 2016 and strengthened promotion to make it into the core of the treatment of schizophrenia. With regard to TRERIEF®, the OD tablets launched as an additional formulation in 2015 provide a dosage form that is easy to take and easy to handle, which can thus help Parkinson's disease patients. In addition, in October 2015 we increased the number of Area Academic Coordinators (AACs), who have acquired more advanced and wide-ranging academic knowledge, to further strengthen activities to provide high quality information in partnership with MRs.



#### **New Products**

Based on a promotion agreement concluded with Torii Pharmaceutical Co., Ltd., Sumitomo Dainippon Pharma provides information to medical institutions on the new indication for REMITCH®, which received approval for the additional indication of improving pruritus in chronic liver disease patients in May 2015. REMITCH® is the first medication with this indication and contributes to treatment as a new option.

Trulicity®, a once-weekly GLP-1 receptor agonist indicated for type 2 diabetes launched in September 2015, not only has an outstanding effect on lowering blood sugar levels with once-weekly administration, but is also provided with Ateos®, a unique disposable auto-injector with a pre-attached needle. At present, we are providing information to medical professionals in partnership with Eli Lilly Japan K.K.

### Aiming to Build a Highly Efficient Sales Organization

Since April 2016, Sumitomo Dainippon Pharma has progressively dissolved the region-based sub-division structure and transferred the functions such as strategy planning to the respective branches. By reducing the number of organizational layers, we have created a structure that can quickly indicate head office decision-making while reducing the number of branches and increasing the authority of each branch to enable a flexible response to changing local healthcare.

### Fiscal 2016 Business Plan and Outlook

In fiscal 2016, as a result of the impact of NHI drug price revisions and the spread of the government's policies to encourage the use of generic drugs, sales of long-listed brands such as AMLODIN® and METGLUCO® are expected to continue to fall, and sales are likely to decline. We will keep this decline to a minimum by focusing on and expanding sales of AIMIX®, LONASEN®, and TRERIEF®, which are strategic products, and Trulicity® and REMITCH®, which are new products.

Furthermore, we will continue to actively deploy e-promotion in addition to provision of information by MRs as well as promote the building of an efficient sales organization and implementing selection and concentration in the allocation of marketing resources as we aim to expand sales.



### Basic Approach

Sumitomo Dainippon Pharma believes that the very objective of our CSR management is upholding our existence "as a company that continues to be trusted by society, shareholders, and suppliers; appreciated by patients and clients; and for whom our employees are happy to work." Our aim is to provide high value added products to meet medical needs and to improve QOL for patients. In the Sales & Marketing Division, we formulate and promote DSP Ambition as a vision (Conduct Guidelines) in order to achieve "marketing from the patient's point of view that is appreciated by customers."

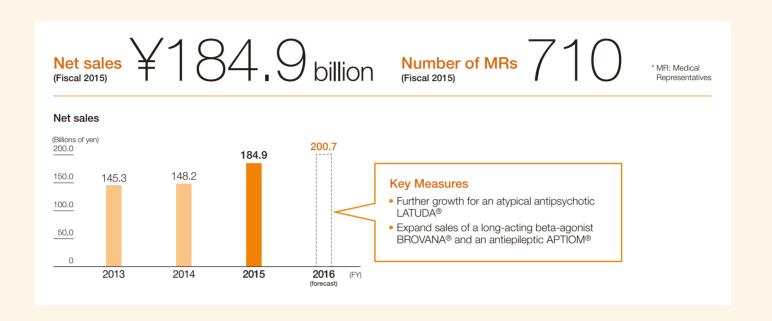
### Pursuing Fair Promotion Activities

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. 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 2015, we provided monthly training for MRs in those rules such as the Promotion Code, Fair Competition Code and the DSP-GPP, and the points to consider for the product explanation sessions, research sessions and lectures.

### Pharmaceutical Business North American Market



### Fiscal 2015 Main Initiatives and Business Results

Sumitomo Dainippon Pharma conducts marketing in North America through its subsidiary Sunovion Pharmaceuticals Inc.

An atypical antipsychotic LATUDA® grew into a blockbuster drug, surpassing annual sales of US\$1 billion in North America. The focus on early market penetration for the bipolar I depression indication for which additional approval was

Sales of Major Products (Sales of U.S. Subsidiary, Billions of yen)

Brand Name	Therapeutic Indication	FY 2014	FY 2015	Rate of change (%)	FY 2016 forecast
LATUDA®	Atypical antipsychotic	82.5	120.4	45.9	126.7
APTIOM®	Antiepileptic	2.5	7.6	20.0	13.7
BROVANA®	Long-acting beta-agonist	22.2	29.9	34.9	31.5
Ciclesonide	Inhaled corticosteroid, Corticosteroid nasal spray	6.7	7.0	4.5	6.1
XOPENEX®	Short-acting beta-agonist	8.5	6.7	(21.6)	4.7
LUNESTA®	Sedative hypnotic	11.5	4.6	(60.1)	2.9

obtained in June 2013, enhanced activities by MRs dedicated exclusively to LATUDA® since the product's launch, as well as DTC advertising on television and the Internet since 2014, and promotion activities aimed at medical professionals have all paid off.

An antiepileptic APTIOM® obtained approval for the additional monotherapy indication in August 2015, becoming the only once-daily dose, non-sustained release antiepileptic drug available for monotherapy and adjunctive therapy in the treatment of partial onset seizures. We assigned MRs dedicated exclusively to APTIOM® and significantly expanded sales as a result of concentrating efforts on promoting it as a strategic product and aggressively working on sales activities.

A long-acting beta-agonist BROVANA® is an inhalant bronchodilator used as a maintenance therapy for COPD. Its use has not only increased in hospitals and pharmacies, but also grown in the home medical care and long-term care (LTC) settings, and it has experienced eight years of continuous revenue growth since its launch in 2007.



### FY2016 Business Plan and Outlook

In fiscal 2016, Sunovion will seek further growth for LATUDA®, which developed into a blockbuster, in addition to focusing efforts on expanding sales of strategic products APTIOM® and BROVANA®.

We will aim for further growth in sales of LATUDA® by continuing to work on promotion aimed at medical professionals and DTC advertising on the treatment of bipolar I depression.

We will continue to increase product recognition for APTIOM® and promote monotherapy.

For BROVANA®, Sunovion will continue its initiatives of fiscal 2015 to further expand sales by stressing its effectiveness and convenience in COPD treatment to medical professionals. Moreover, we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in July 2016 for SUN-101, which is scheduled for launch in fiscal 2017, a long-acting muscarinic antagonist (LAMA) treatment for COPD with a different mechanism of action from BROVANA® (a long-acting beta-agonist: LABA).

Other than the above, ahead of the launch of napabucasin, the cancer stemness inhibitor for which an application is scheduled to be made in fiscal 2017, we are planning to promote the creation of a sales organization at Boston Biomedical Pharma, Inc., which intends to carry out sales of anticancer drugs in the U.S.



# Activities in Marketing

### Compliance with the PhRMA Code

Our subsidiary Sunovion is a member of the Pharmaceutical Research and Manufacturers of America (PhRMA), whose mission is to conduct effective advocacy for public policies to facilitate the discovery of new medicines for patients by pharmaceutical and biotechnology companies.

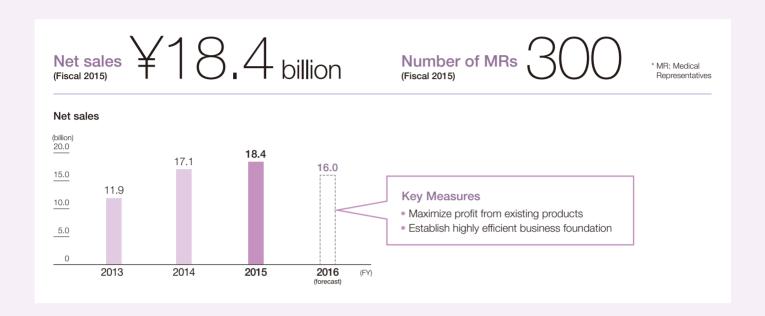
Since 2001, PhRMA has had in place the PhRMA Code on Interactions with Healthcare Professionals (the PhRMA Code), which is a voluntary standard that sets out interactions with U.S. healthcare institutions. Sunovion is a signatory company of the Code and has formulated policies and guidelines in order to comply with the PhRMA Code in its promotion activities in the U.S.

PhRMA also recommends that member companies undergo an external verification of their policies and guidelines on compliance with the PhRMA Code at least once every three years. Sunovion completed its external verification in February 2016, and it was determined that the company had policies and business processes in place to foster compliance with the PhRMA Code. Sunovion submitted the results of its external verification to PhRMA in March 2016 and is one of 23 companies to have completed the external verification.

### Implementing Patient Supports

Sunovion implements activities to provide support for patients' groups in the psychiatry & neurology area and the respiratory area, which are its business domains. For example, many of the employees participate in the annual walk events held by various patient support groups to raise awareness of mental illness and epilepsy. Employees also take part in cycling and other events to encourage respiratory health.

## Pharmaceutical Business Chinese Market



### Fiscal 2015 Main Initiatives and Business Results

Sumitomo Dainippon Pharma sells four products in the Chinese market, which are MEROPEN® (brand name in China: MEPEM®), a carbapenem antibiotic, ALMARL®, a therapeutic agent for hypertension, angina pectoris and arrhythmia, SEDIEL®, a serotonin-agonist anti-anxiety drug, and GASMOTIN®, a gastroprokinetic. The 300 MRs (as of March 31, 2016) at our subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., cover 30 provinces and cities (major cities, provinces, and autonomous regions).

In fiscal 2015, the environment continued to be extremely challenging, impacted by changes to the bidding system. However, as a result of a strong performance particularly for MEROPEN®, yuan-based sales remained the same as the previous fiscal year and increased on the yen basis with the impact of exchange rates.

### Sales of Major Products (Sales of Chinese Subsidiary, Billions of yen)

Brand Name	Therapeutic Indication	FY 2014	FY 2015	Rate of change (%)	FY 2016 forecast
MEROPEN®	Carbapenem antibiotic	143	156	9.2	137

### Fiscal 2016 Business Plan and Outlook

We expect sales to decline in fiscal 2016 as growth will tend to slow due to the continuing impact of the bidding system.

We will increase business efficiency through such initiatives as the introduction of e-promotion in addition to activities to provide information by MRs and continue working to maximize profit.



### Compliance with RDPAC Code of Practice

We have always complied with the RDPAC Code of Practice formulated by the RDPAC (China Association of Enterprises with Foreign Investment, R&D-based Pharmaceutical Association Committee) formed by foreign companies that have expanded into China to develop appropriate promotion activities. In addition, we worked to strengthen the compliance system through improvement of internal systems in FY 2015.

### **Related Business**

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

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

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

In the food ingredients and food additives business, the company develops and sells food ingredients and additives for use in manufacturing safe, high-quality foods. Products include polysaccharides, primarily GLYLOID® (tamarind seed gum), the first product of its kind successfully produced by us on an industrial scale; seasonings such as soup or bouillon. We also run the information portal site aimed at maximizing the value of polysaccharides, our core products.

The chemical product materials business encompasses such products as active pharmaceutical ingredients, cosmetic materials, electronic chemicals, coatings and industrial chemicals. 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 to a wide range of customers. We will aim to expand this business as a company that integrates research, development and sales operations to continually create value that is recognized by all.

# Animal Health Products DS Pharma Animal Health Co., Ltd. https://animal.ds-pharma.co.jp/eng/

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 its main field of business, the companion animal market, DS Pharma Animal Health launched OraStrip™, a test strip of halitosis as an indicator for canine oral health management in March 2016, and ds PIMOHEART® for chronic canine heart failure in April 2016.

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 for fish and crustaceans and synthetic antibacterial drugs, 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.

In July 2015, we concluded an agreement on joint clinical development in Japan with J-ARM Co., Ltd. in the animal cellular medicine business. Subsequently, in April 2016, we established Ikeda Regenerative and Cellular Medicine Center for Animals

(lkeda, Osaka) with the aim of early commercialization of cellular medicine for animals.

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



OraStrip<sup>TM</sup>, a test strip of halitosis as an indicator for canine oral health management, and ds PIMOHEART® for chronic canine heart failure

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

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

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 H-FABP detecting reagent as diagnostics for acute myocardial infarction, as well as bone and calcium metabolism markers and diagnostics for neuropsychiatric disorder. The company is also developing biomarkers as companion diagnostics, which are performed to predict the efficacy and/or side-effects of drugs before they are administered, and developing and selling highly-sensitive and advanced products by combining chemiluminescent/fluorescent equipment and special reagents.

Meanwhile, in a sector that achieves synergies with Sumitomo Dainippon Pharma's Regenerative Medicine & Cell Therapy Business, the company also develops and supplies S-Medium, a serum- and feeder-free, chemically defined medium, that can be applied in regenerative therapy using human stem cells, including ES/iPS cells, and POCA®, a series of ready-to-use assay models effective in drug discovery research. In July 2015, the company commenced sales of POCA® HAND1-EST, a developmental toxicity evaluation kit.



### [Corporate Governance]

The Company posts on the website the summary for its basic concept and basic policy titled the "Basic Policy on Corporate Governance" (the "Basic Policy").

### **Basic Concept on Corporate Governance**

Sumitomo Dainippon Pharma commits itself to continuously pursuing the establishment of a corporate governance system which is highly effective, aiming for the fuller realization of our Corporate Mission and Management Mission.

### Corporate Governance System

Sumitomo Dainippon Pharma has elected the organizational structure of a "Company with an Audit & Supervisory Board" to audit the execution of duties by the Directors, independent of the Board of Directors. In addition, the Company has adopted an executive officer system to separate management supervision from business execution. The Board of Directors consists of eight members, including two Independent Outside Directors. The Board of Directors holds a meeting once a month, in principle, and resolves and reports on material

#### business matters.

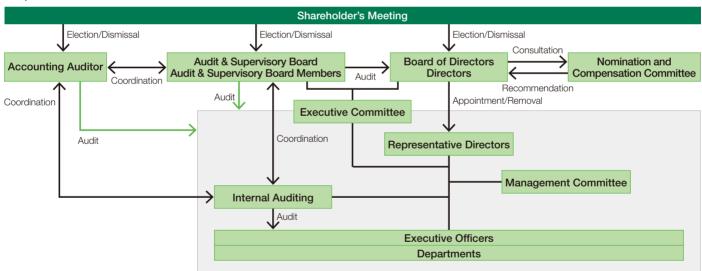
The Company has the Nomination and Compensation Committee\*, which holds a meeting as necessary, as a consultative body to the Board of Directors.

The Management Committee holds meetings twice a month, in principle, as a consultative body to the Representative Directors, President and CEO for the decision making for important business matters, based on the basic policy determined by the Board of Directors. In addition, the Executive Committee holds a meeting once a month, in principle, for the purpose of appropriately sharing among the Directors and Audit & Supervisory Board Members, including the Outside Directors and the Outside Audit & Supervisory Board Members, the status of the execution of business and material matters relating to the execution of business.

#### \* Nomination and Compensation Committee

The Company has the Nomination and Compensation Committee, which holds a meeting as necessary, as a consultative body to the Board of Directors for enhancing the objectivity and independence of the functions of the Board of Directors on matters such as nomination of the candidates for Directors and Audit & Supervisory Board Members, and decisions on compensation of Directors. The Committee consists of three members, the majority of which being two Independent Outside Directors, and the chairperson be appointed from the Independent Outside Directors.

### Corporate Governance Structure



### Reasons for Appointment of Outside Directors

#### Hidehiko Sato

Hidehiko Sato has considerable experience and a wide range of knowledge, which he has acquired in the course of his career during which he held various positions such as the Counselor of the Cabinet Legislation Bureau and the Commissioner General of the National Police Agency. He also has expertise as an attorney. The Company has nominated him as a candidate for Outside Director, finding that he will be able to contribute to the management of the Company with his experience, knowledge and expertise.

### Hiroshi Sato

Hiroshi Sato has considerable experience and a wide range of knowledge, which he has acquired in his career as a corporate executive. The Company has nominated him as a candidate for Outside Director, finding that he will be able to contribute to the management of the Company with his experience and knowledge.

### Reasons for Appointment of Outside Audit & Supervisory Board Members

#### Harumichi Uchida

Harumichi Uchida has considerable experience and expertise which he has acquired as an attorney. He has been appointed as an Outside Audit & Supervisory Board Member in the hope that he will contribute to the auditing of the Company using his experience and expertise.

### Yutaka Atomi

Yutaka Atomi has considerable experience and expertise which he has acquired as a medical doctor. He has been appointed as an Outside Audit & Supervisory Board Member in the hope that he will contribute to the auditing of the Company using his experience and expertise.

#### Kazuto Nishikawa

Kazuo Nishikawa has considerable experience and expertise which he has acquired as an expert in the fields of finance and accounting. He has been appointed as an Outside Audit & Supervisory Board Member in the hope that he will contribute to the auditing of the Company using his experience and expertise.

### **Audit System**

The Audit & Supervisory Board consists of five members, including three Outside Audit & Supervisory Board Members. The Audit & Supervisory Board holds a meeting once a month, in principle, discusses and resolves material matters relating to auditing, and also examines in advance to be submitted to the Board of Directors for discussion. The Audit & Supervisory Board, composed of all the Audit & Supervisory Board members, determines audit policy, task allocation among members and other matters. The Audit & Supervisory Board shall evaluate the Accounting Auditor based on the evaluation standards established by it, and determine proposals regarding the appointment, dismissal and non-reappointment of the Accounting Auditor to be resolved at the annual shareholders' meetings.

Accounting audits are handled by KPMG AZSA LLC, based on an audit agreement. Internal audits are carried out by the Internal Auditing Department, which reports directly to the President of Sumitomo Dainippon Pharma. The basic elements for achieving the objectives of internal control, including subsidiaries, are audited from a fair and independent standpoint. Internal Auditing also evaluates the development and implementation status of internal control for financial reporting based on the Financial Instruments and Exchange Act.

### Accounting Audits, Remuneration (FY2015)

	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	118

- (Note) 1. The Audit & Supervisory Board of the Company has determined to consent to the amount of the remuneration and the like for the Accounting Auditor after performing necessary verifications on the details of the Accounting Auditor's audit plan, status of performance of accounting audit duties, and the appropriateness of the basis for calculating the remuneration.
  - 2. 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 reflects the total sum of these two kinds of amounts.
  - Among the significant subsidiaries, Sunovion, BBI and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. were audited by auditing firms other than the Accounting Auditor of the Company.

### Status of Convocation of the Meeting of the Board of Directors (FY2015)

Organizational Body	Composition	Frequency of convocation	Purpose
The Board of Directors	The Directors 8 members, (including two outside directors)	Once a month as a rule	Resolving and reporting important management matters Met 14 times in fiscal 2015
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 Met 13 times in fiscal 2015
Nomination and Compensation Committee	The Directors 3 members, (Includes two Independent Outside Directors)	Meets as necessary	Deliberating on matters related to nomination of candidates for Directors and Audit & Supervisory Board Members and compensation, etc. of Directors
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 Met 21 times in fiscal 2015
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 Met 11 times in fiscal 2015

### The Principal Activities of the Outside Directors and Outside Audit & Supervisory Board Members

Category	Name	Name Principal Activities
Outside Director	Hidehiko Sato	He attended all the fourteen (14) meetings held by the Board of Directors during the fiscal year under review, and he made statements at those meetings as necessary, primarily based on his extensive experience and broad perspective gained at government agencies and from the professional standpoint of an attorney.
Director	Hiroshi Sato	He attended all the fourteen (14) meetings held by the Board of Directors during the fiscal year under review, and he made statements at those meetings as necessary, primarily based on his extensive experience and broad perspective as a company manager.
	Harumichi Uchida	He attended all the fourteen (14) meetings held by the Board of Directors and all the thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review, and he made statements at those meetings as necessary, primarily from the professional standpoint of an attorney.
Outside Audit & Supervisory Board Members	Yutaka Atomi	Among the fourteen (14) meetings held by the Board of Directors and the thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review, he attended thirteen (13) meetings held by the Board of Directors and twelve (12) meetings held by the Audit & Supervisory Board, and he made statements at those meetings as necessary, primarily from the professional standpoint of a medical doctor.
	Kazuto Nishikawa	He attended all the fourteen (14) meetings held by the Board of Directors and all the thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review, and he made 21 statements at those meetings as necessary, primarily from the professional standpoint of an expert in the fields of finance and accounting.

#### **Directors**

The Directors shall prepare well for meetings of the Board of Directors by proactively collecting the information necessary for promoting discussions at the meetings. The Directors shall also actively contribute to swift and proper decision making for achieving the Company's sustainable growth and the enhancement of the corporate value over the mid to long term. In addition, The Directors shall perform their duties for the common interests of both the Company and the shareholders, recognizing their fiduciary responsibilities to shareholders and fully understanding the importance of appropriate communication and cooperation with stakeholders. At present, two of the Outside Directors satisfy the Company's Independence Criteria for Outside Directors, and having determined that there is no possibility of conflict of interest with ordinary shareholders, the Company has designated them as Independent Outside Directors.

From the independent standpoint, the Independent Outside Directors shall strive to fulfill their expected roles in decision making at meetings of the Board of Directors and supervision of conflicts of interest, among others, based on their knowledge, experience and insights in their respective fields of expertise.

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

The Audit & Supervisory Board Members work to create an environment for greater audit effectiveness, including regular meetings with the representative directors, proactive reporting from and discussions with the other directors and employees, cooperation with the accounting auditor and the Internal Auditing Department, and furthermore, cooperation among all parties involved in auditing. In addition, members attend key business meetings including those of the Board of Directors to confirm the legality and appropriateness of management decisions by the directors and proactively audit the operational status of the internal control system through measures including receiving reports from directors and employees on the status of task execution, requesting explanation as necessary and viewing significant approval forms and other documents.

### **Executive Remuneration**

Remuneration for directors includes performance-linked remuneration aimed at increasing the incentive for enhancing shareholder value and achieving sustained growth. Decisions on remuneration for directors are made by the Board of Directors based on the deliberations and report of the Nomination and Compensation Committee for which the Independent Outside Directors make up the majority of the members.

The structure of remuneration for directors consists of basic remuneration and a bonus, the amount of which is set within the scope of total remuneration approved at the annual shareholders' meeting. Basic remuneration is a standard amount set according to position while bonuses are determined based on company and individual performance depending on the level of achievement of performance goals in mid to long-term management plans. The Directors contribute a

certain percentage of basic remuneration to the Sumitomo Dainippon Pharma Officer shareholders' association every month to acquire the Company's shares. The shares that are acquired are held continuously during tenure in office and for one year following retirement from office.

Remuneration for Outside Directors consists of basic remuneration and does not reflect business performance from the perspective of their supervisory functions and securing independence.

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 (FY2015)

Category	Number	Amount of Remuneration (Millions of Yen)
Directors (excluding Outside Directors)	8	346
Audit & Supervisory Board Members	5	90

(Note) 1. The above includes the amount of remuneration and the like for Outside Directors and Outside Audit & Supervisory Board Members, five persons in total, which is 62 million yen in total.

 The respective amounts of remuneration and the like for Directors and Audit & Supervisory Board Members that were determined in the annual shareholders' meeting do not exceed 400 million yen annually for Directors, and 100 million yen annually for Audit & Supervisory Board Members.

### Analysis and Evaluation of the Effectiveness of the Board of Directors

The Company conducted a questionnaire survey on all the Directors and Audit & Supervisory Board Members during the period from February 2016 to March 2016 in order to find out: (i) whether there are any differences between the ideal status of the roles and duties, etc. of the Board of Directors of the Company that are set forth in the Basic Policy and the actual circumstances of the Board of Directors in the fiscal year ending March 2016; and (ii) matters to be discussed for the further enhancement of the effectiveness of the Board of Directors. The major topics of the questionnaire were as follows:

- 1) Composition of the Board of Directors;
- 2) Roles and duties of the Board of Directors;
- 3) Status of the operations of the Board of Directors;
- 4) Support system for Outside Directors and Outside Audit & Supervisory Board Members;
- 5) Roles of Independent Outside Directors;
- 6) Roles of Audit & Supervisory Board Members and the expectations for the Audit & Supervisory Board Members; and
- 7) Relationship with stakeholders.

Based on the analyzed results of the questionnaire, opinions were exchanged at the meeting of the Board of Directors in April 2016. It was confirmed that the effectiveness of the Board of Directors of the Company has been ensured in general, and suggestions were made regarding issues and materials that should be discussed, which would be helpful to further stimulate the discussion at the meeting of the Board of

Directors. In the fiscal year ending March 2017, the Company will consider these suggestions as presenting an important agenda, and will take action based on these suggestions.

### Strategic Shareholdings

Sumitomo Dainippon Pharma shall not hold any shares of other companies except when such shareholding supports the sustainable enhancement of its corporate value, such as establishment or maintenance of corporate alliances and other types of relationships with important business partners and customers. The Company shall have the Board of Directors evaluate the reasonableness and the economic rationale of major strategic shareholdings on an annual basis. With respect to exercising voting rights for such strategic shareholdings, the Company shall examine the proposal from the viewpoint of whether it will lead to enhancing not only the corporate value of the relevant issuing company, but also that of the Company.

### **Related Party Transactions**

The Board of Directors shall supervise transactions between the Company and any of its Directors, Audit & Supervisory Board Members, major shareholders, etc. (i.e., related party transactions) appropriately in light of the importance of such transactions, and in accordance with the Company's relevant procedures such as the requirement of approval at the meeting of the Board of Directors at which Independent Outside Directors are present, in order to ensure that such transactions are fair and reasonable from the viewpoint of enhancing the corporate value.

### 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 group company management rules in place to ensure Group companies implement appropriate business operations. Each of the Sumitomo Dainippon Pharma 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 group corporate governance structure, enhancement of global compliance system, and promotion of social contribution efforts.

### Efforts to Facilitate the Exercise of Voting Rights

Sumitomo Dainippon Pharma takes the appropriate measures so that the rights of shareholders are actually ensured, sending 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 and other rights of shareholders and posting the materials on the Company's website the day before the convocation notices are sent out. For foreign shareholders, Sumitomo Dainippon Pharma posts an English translation of the convocation notice and other materials on the Company's website at the same time as the Japanese version. Methods of voting include the Electronic Voting Platform and other digital methods in addition to conventional voting in writing.

In addition, 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 shall strive to facilitate purposeful dialogues with shareholders, investors, etc., in accordance with "Basic Policy for Promoting Constructive Dialogues with Shareholders, Investors, etc."

Sumitomo Dainippon Pharma regularly holds meetings with analysts and institutional investors from Japan and from abroad. 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. 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 arranged by securities firms 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, Fact Books and notices of convocation for the annual shareholders' meeting among others.

### Information Disclosure

### Timely, Appropriate and Fair Disclosure of Information

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. We also disclose information appropriately in English to the extent reasonably possible.

With regard to information for which timely disclosure is not required, we actively disclose information needed for stakeholders, including shareholders, to understand Sumitomo Dainippon Pharma properly through such means as press releases and our corporate website.

### Policy on Publication of Business Strategies and Business Plans

In releasing its business strategies and business plans, Sumitomo Dainippon Pharma shall strive to provide sufficient information in an easily understandable manner, by presenting its basic principles for the earnings and capital policy and the financial targets, including those for profitability and capital efficiency.

### Development and Implementation of Internal Control System

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

### Internal Control over Financial Reporting

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.

### [Compliance and Risk Management]

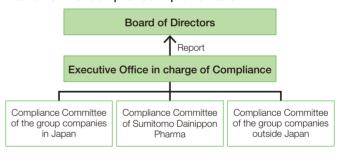
### Compliance

Sumitomo Dainippon Pharma has declared in our publicly announced Declaration of Conduct our commitment to "abide by relevant laws and regulations, and conduct our business 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. We have also established internal and external compliance hotlines to serve as contact points for reporting and inquiries about compliance.

In fiscal 2015, we reorganized the compliance promotion system that we have established to date in order to further strengthen the DSP Group framework for promoting compliance. We created a compliance promotion system with three committees: the Sumitomo Dainippon Pharma Compliance Committee, the Japanese Group Companies Compliance Committee, and the Overseas Group Companies Compliance Committee, presided over by the executive officer in charge of compliance. Based on this compliance promotion system, each compliance committee met regularly and discussed the status of compliance in light of reports from individual group companies. The DSP Group's compliance status and the activities of the individual compliance committees were reported to the Board of Directors.

### Framework for compliance implementation



### 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.

Moreover, we have formulated the Emergency Response Rules to keep to a minimum the impact of emergencies that could pose a serious obstacle to management or business activities and to ensure management and business continuity.

At present, under the Basic Policy for Developing the Internal Control System, we are promoting a review into the reorganization of our risk management system in order to enhance the DSP Group's risk management system.

### Product Recall Training in Corporate Regulatory Compliance & Quality Assurance Division

Sumitomo Dainippon Pharma holds regular simulated recall drills for the relevant departments, primarily in the Corporate Regulatory Compliance & Quality Assurance Division, as training in the recall operations stipulated in our Quality Control Operating Procedures for Manufacture and Sale based on Article 6 of the GQP Ministerial Ordinance. We conduct the drills in accordance with actual circumstances with the objectives of affirming our organizational systems, spreading awareness of and continually improving recall procedures, and managing risk.

### **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-scale disaster and an infectious disease pandemic, such as new strains of influenza.

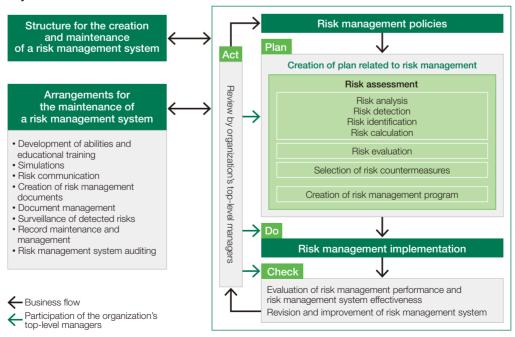
For example, in the outbreak of a pandemic, we respond with reference to the epidemic phase of WHO and Japan's Ministry of Health, Labour and Welfare to establish our own epidemic danger period phases, implement countermeasures, and prepare manuals for the set up and operational procedures of a headquarters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

### Information Management

Sumitomo Dainippon Pharma performs appropriate, fair and timely disclosure of information to society. We also manage information appropriately, having established a global policy for management of recording and information and various regulations on information security. In addition, we properly protect and manage personal information and customer information obtained through our business activities, having established a policy and rules on the protection of personal information. We manage insider information appropriately, having established rules on internal information.

Furthermore, since the operation of our global network, we have been striving to align the level of rules on information security in our group companies in Japan, the U.S., and Europe and strengthen operational aspects. In parallel with this, we are working to develop and operate controls that comply with ISO 27001, the international standard on information security.

### Risk Management System



#### **Directors**



Masayo Tada Representative Director, President and Chief Executive Officer

1968: Joined Sumitomo Chemical Co., Ltd.

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

2005: Director and Managing Executive Officer of the former Sumitomo Pharmaceuticals Co., Itd.

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 (to the present)



### Hiroshi Nomura Member, Board of Directors, **Executive Vice President**

External Affairs; Corporate Secretariat & Industry Affairs; Finance & Accounting; Drug Development (Division); Special Assignments

1981: Joined Sumitomo Chemical Co., Ltd.

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

2016: Member of the Board of Directors and Executive Vice President of the Company (to the present)



Hiroshi Noguchi Representative Director, Senior Executive Vice President

Drug Research; Drug Development; Technology Research & Development; Regenerative & Cellular Medicine; Global Oncology

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 (to the present)



Masaru Ishidahara

Member, Board of Directors, Senior Executive Officer Corporate Governance; Personnel

1976: Joined The Sumitomo Bank, Limited

(presently, 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

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

Nobuo Takeda **Audit & Supervisory Board Member** 

Yasuji 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**

### Nobuhiko Tamura

Senior Executive Officer Chair and President, Sunovion Pharmaceuticals

Yoshinori Oh-e Senior Executive Officer Executive Director, Corporate Regulatory Compliance & Quality Assurance (Division); Regulatory Affairs

### Yoshiharu Ikeda

Senior Executive Officer

Executive Director, Manufacturing (Division); Executive Director, Technology Research & Development (Division)

### Kazuo Koshiya

Senior Executive Officer

President, Boston Biomedical Pharma, Inc.; Global Oncology Office; Oncology Clinical Development Unit; Oncology Strategy Unit; Head of Global Oncology Office



Hitoshi Odagiri Member, Board of Directors, Senior Executive Officer Executive Director, Sales & Marketing (Division) 1979: Joined Inabata & Co., Ltd.

1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd. 2012: Executive Officer of the Company 2016: Senior Executive Officer of the Company Member of the Board of Directors and Senior Executive Officer of the Company



### 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: Outside Audit & Supervisory Board Member of the Company

2011: Outside Director of JS Group Corporation (currently, LIXIL Group Corporation) (to the present)

2013: Outside Member of the Board of Directors of the Company (to the present)
2014: Outside Director of Resona Bank, Ltd.

2015: Outside Director of Resona Holdings, Inc. (to the present)



Toru Kimura Member, Board of Directors, **Executive Officer** 

Senior Director, Global Corporate Planning; Regenerative & Cellular Medicine Office

1989: Joined Sumitomo Chemical Co., Ltd. 1992: Joined the former Sumitomo Pharmaceuticals Co., Ltd. 2015: Executive Officer of the Company
2016: Member of the Board of Directors and
Executive Officer of the Company

(to the present)



### 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,

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. 2014: Outside Member of the Board of Directors

of the Company (to the present) 2016: Senior Adviser of Kobe Steel, Ltd.

(to the present)

### Nobuyuki Hara **Executive Officer** Executive Director, Drug Development (Division)

### Hiroyuki Baba **Executive Officer**

Global Business Development; Legal Affairs; Intellectual Property; Corporate IT Management; International Business Management; Head of Global Business Development for Sumitomo Dainippon Pharma Group

### Hajime Kinuta

**Executive Officer** 

Senior Director, Corporate Governance; Corporate Service Center

### Hideyuki Harada

**Executive Officer** 

Executive Director, Drug Research (Division)

### **Antony Loebel**

**Executive Officer** 

Executive Vice President, 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

### Approach on CSR-Based Management and Principal Activities

Sumitomo Dainippon Pharma defines the practice of its Corporate Mission, "To contribute broadly to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide," as CSR-based management. 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 the content of our Mission in more concrete terms, and serves as our basic 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.

In promoting CSR-based management, we actively utilize the core subjects framework of ISO 26000 to assist in practice in addition to valuing dialogue with stakeholders. We work to enhance our approach appropriately to meet the changes in the globalization of business and society with a focus on

organizational governance, human rights, labour practices, the environment, fair operating practices (transparency and compliance), consumer issues, and community involvement and development.

In this report, we introduce initiatives on which we are placing importance. Detailed information about other CSR activities is posted on our website.

Masaru Ishidahara

Masaru Ishidahara
Member, Board of Directors, Senior Executive Officer

ISO26000 Core Subjects	Applicable item of the "Declaration of Conduct"	Principal A	ctivities	Page
Organizational Governance	Declaration of Conduct 1234567	Corporate Governance     Compliance		P41
Human Rights	Declaration of Conduct	Clinical Studies Put the Human Rights of Subjects First     Initiatives to Prevent Harassment	Respect for Freedom of Association and Right to Collective Bargaining     Respect for Human Rights in the Supply Chain	P24 P50
Labour Practices	Declaration of Conduct  Declaration of Conduct  Declaration of Conduct  Declaration of Conduct	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	Promoting Employment of Persons with Disabilities Diversification Work-Life Balance Establishing Consultation Desks	P43
Environment	Declaration of Conduct Declaration Declaration of Conduct Declaration Declaration Declaration Declaration	Basic Environmental Policies     Environmental Accounting     Development of Environmental Conservation Systems     Overview of Environmental Impact     Mid-term Environmental Plan     Fostering Environmental Awareness	Initiatives Aimed at Energy Conservation and Prevention of Global Warming     Initiatives to Save Resources     Biodiversity Initiatives     Promotion of Communication     Initiatives on Water Resources	P56
Fair Operating Practices	Declaration of Conduct  Declaration of Conduct	Appropriate Information Disclosure and Management     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	P52
Consumer Issues	Declaration of Conduct Declaration of Conduct Declaration of Conduct Declaration of Conduct	Activities to Secure Product Safety     Encouragement of Proper Use of related to Safety     Running a Medical Information Website and a Health Information Website     Initiatives for Access to Health	Running An Exclusive Commitment to Handling Inquiries: Product Information Center Recognizing and understanding the needs of our customers Approach to Human Tissue Research Ethical Considerations in Animal Experimentation	P53
Community Involvement and Development	Declaration of Conduct Declaration	Our Policy on Social Contribution Activities Supporting through Officer and Employee Participation Supporting with Donations Social Support	10th Anniversary Social Contribution Activities     Activities of Global Group Companies	P54

<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 stakeholders involved with the Company, and in its "Declaration of Conduct" and "Compliance Standards" 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.

### **Initiatives to Prevent Harassment**

In our in-house training, we provide regular and ongoing 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. We also make exhaustive efforts to raise awareness about preventing harassment in our grade-specific training and training for managers.

Moreover, we have set up consultation desks at our main business sites, including head office, creating an organization that can respond promptly and considerately to inquiries from employees.

### Respect for Freedom of Association and the Right to Collective Bargaining

In Japan, we have concluded a labor agreement with the Dainippon Sumitomo Pharma Labor Union and conduct regular discussions about working conditions and various systems, including the human resources system to promote proposals and exchange of opinions from the perspectives of each party.

### Respect for Human Rights in the Supply Chain

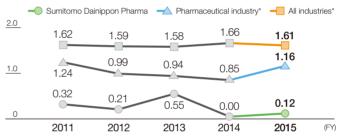
We promote CSR procurement based upon Sumitomo Dainippon Pharma's Ethics in Procurement and continuously strive to establish criteria for the selection of suppliers that take account of respect for human rights in such ways as prohibiting forced labor and child labor and prohibiting non-humane and discriminatory treatment. For details, see Production and Quality Control on page 29.

### **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, taking countermeasures in order of priority of the risks, and then implementing PDCA cycles. In particular, with regard to risk factors that lead to fires, explosions, or other major work-related accidents, Sumitomo Dainippon Pharma has actively 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 operational rules to minimize any potential impact.

### Frequency rate of industrial accident

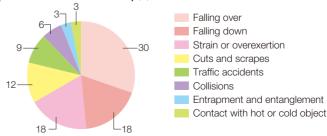


\* Ministry of Health, Labour and Welfare, Survey on industrial accidents http://www.mhlw.go.jp/toukei/list/44-23b.html (Japanese only)

### **Analysis of Work-Related Accidents**

As a result of classifying the types of work-related accidents that occurred in the five years from fiscal 2011 to fiscal 2015 (excluding accidents involving business vehicles), we found that falls accounted for 48% of the total. Therefore, Sumitomo Dainippon Pharma has made the prevention of accidents involving falling over and falling down into the priority challenges for fiscal 2016 and is promoting awareness raising activities, including Japanese National Safety Week, with reference to the content of the initiatives under the STOP! Industrial Fall Accidents Project organized by the Ministry of Health, Labour and Welfare.

### Classification of work-related accidents by type (fiscal 2011 – fiscal 2015) (%)



\* Classification of work-related accidents during five-year period from fiscal 2011 and fiscal 2015 (excluding accidents involving business vehicles).

### **Promoting Health Management**

In fiscal 2015, 100% of our employees underwent the checkups. The health insurance association and occupational physicians collaborate to provide specific health guidance and encourage consultations to prevent exacerbation as needed, and to support health promotion such as counselling on smoking cessation, lifestyle improvement as a measure to address metabolic syndrome, and early treatment of disease. Counselling on smoking cessation is particularly noteworthy, and, in fiscal 2015, smoking during working hours was completely prohibited at all of our workplaces.

Moreover, our health insurance association subsidizes the costs of various vaccinations for employees and their family members.

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

In addition to fostering an environment in which employees can develop their own skills independently, Sumitomo Dainippon Pharma actively supports employee growth and puts efforts into the establishment of an environment that 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 conjunction with job rotation. In particular, starting in fiscal 2016, we will develop a company-wide education and training system focused on developing human resources who take the initiative in business in efforts aimed at active human resource development.

In addition, we have introduced a self-reporting system in order to encourage employees to take on work challenges based on their own independence. Supervisors conduct individual interviews with subordinates based on the self-assessment reports with the primary purpose of identifying individual situations, circumstances and ambitions through consideration of the long-term training and skill development of each employee.

This system provides an opportunity for employees to reevaluate their resolve, interests, and aspirations with the aim of enhancing their future with the company, and supports individual growth as supervisors reflect on training policies and day-to-day duties and link them to OJT and Off-JT.

### Work-Life Balance

With the aim of achieving work-life balance, Sumitomo Dainippon Pharma rigorously enforces no overtime days and takes measures to encourage employees to take their paid leave. In addition, we have held the DSP WLB Labour-Management Meeting 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.

#### **Diversification**

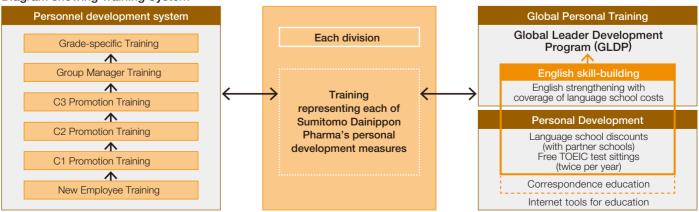
Sumitomo Dainippon Pharma is also actively supporting diversification. We believe that it is important to remove obstacles that inhibit the participation of all people with the desire to fully exercise their capabilities and provide opportunities for equal participation irrespective of employee attributes.

Specifically, we are implementing such measures as raising the awareness of managers and developing systems to facilitate the selection of diverse work styles, and we have newly established and revised our systems as described below since fiscal 2015.

### **Details of Specific Initiatives**

- Introduction of a Paternity Leave (Dubbed "Good Daddy Leave") System (October 2015)
  - We established a new system to allow male employees to take leave during the period up until their child turns one in order to encourage men to participate in child care.
- Extension of Eligible Parental Period for Shorter Working Hours and Flexible Arrival/Leave Hours (October 2015)
  - We made it possible for employees with a child who has a physical or mental disability who require the continuation of shorter working hours or staggered working hours to extend the period of applicability (until end of third year of elementary school) → until end of third year of junior high school)
- MR area selection system (April 2016)
   For the MRs who are raising children, we established a new system which enables them to select their responsible area on their request.
- Working from home system (June 2016)
   To allow employees involved in child care or nursing care, we established a new system which enables them to work from home up to five times a month.

### Diagram showing Training System



### Supporting Women's Active Participation

Sumitomo Dainippon Pharma has actively strived for active participation by women in particular in recent years as one of the focuses of our efforts on diversification. Specifically, we are promoting company-wide reforms from the three perspectives of awareness, systems, and culture with the aim of increasing the number of female employees who continue to work despite life events such as marriage and child birth and promoting career development.

We have always promoted human resources with skills and motivation into management positions irrespective of whether they are men or women, and women accounted for approximately 7% of managerial staff as of April 2016. We have formulated a General Business Owner Action Plan as required under the Act on Promotion Women's Participation and Advancement in the Workplace which came into force in April 2016 and have set a goal of at least 10% for the percentage of female managerial staff in 2020.

### **Details of Specific Initiatives**

- 1. Provision of training for managerial staff on the retention and development of female employees
- 2. Provision of training for female employees aimed at the development of managerial staff
- 3. Creation of environment in which both men and women can achieve work-life balance and job satisfaction
- 4. Implementation of measures to support return to work and career development after child care leave

### **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. In addition to arranging a number of ways in which inquiries can be received, including by telephone, fax, e-mail, and letter, and giving consideration to a reassuring environment that facilitates consultation, we also provide feedback on how the company responded to the substance of an inquiry to the employees who made it.

#### List of Consultation Desks

- Compliance Hotline
- Harassment Consultation Desk
- Mental Health Consultation Desk (Outside)
- General Consultation Desk

### **Fair Operating Practices**

### **Fair and Transparent Corporate Activities**

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, at all stages from drug discovery to postmarketing information provision activities that ensure the proper use of pharmaceuticals.

Representatives of patient groups are sitting on an increasing number of government committees and investigative commissions as governments and the medical community put greater emphasis on the "voice of the patient."

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

The Japan Pharmaceutical Manufacturers Association (JPMA) 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 Groups in April 2013. In accordance with these guidelines, we publicly disclose information on our corporate website on 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 established the DSP Promotion Code for Prescription Drugs to specify the standards of conduct with which the MRs have to comply when promoting our products with the aim of engaging in fair promotion activities. For details, see Marketing on page 36.

### **CSR Procurement**

We consistently promote "untainted transactions that are balanced, fair and transparent" based upon Sumitomo Dainippon Pharma's Ethics in Procurement and strive for CSR procurement on the basis of evaluation criteria for CSR activities in areas that include respect for human rights and environmental protection and consideration. For details, see Production and Quality Control on page 29.

### **Consumer Issues**

### Recognizing and Understanding the Needs of Our Customers

### To Address Unmet Medical Needs

At Sumitomo Dainippon Pharma, the safety of the patients who use our products is our top priority. To ensure safety of drug compliance, we have been committed to making our products

more distinguishable and publishing safety notices to prevent errors. To enhance our expertise and raise the reliability of our data we are continuously collaborating with our overseas subsidiaries and suppliers to meet wide range of unmet medical needs.

While packaging and labeling designs are subject to many restrictions, displaying certain product information is mandatory, as well. Given these limitations, the design of more than one company's product packaging and labels may happen to look alike, and this confusion has become a contributing factor in pharmaceutical product mix-ups. At Sumitomo Dainippon Pharma, the packaging and labeling team of the Manufacturing Division heads our efforts to respond to the needs of both medical professionals and patients by improving packaging and label designs to prevent medical errors. We focus particularly closely on making sure that our packaging and labels are easily distinguished from other products since serious problems can arise when pharmaceuticals are taken incorrectly.

We take immediate action to rectify the situation when, by any chance, our products are mistaken for others even after launch. We work with the company relevant to the marketing of the product to modify product names and designs so that they are easily distinguishable from one another.

### Launched a Medical Information Website and a Health Information Website

Through the Medical Information Website, we provide medical professionals with information, including basic product information, notices of various revisions to product information and information about the seminars we hold.

Through the Health Information Website, we provide the general public with information, including data on causes of diseases, tips on healthy living and warnings about the use of our products.

### 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 FY2015 (Approximately 56,000)



### **Initiatives for Access to Health**

### Responding to demands for development of unapproved or off-label drugs

Japan's Ministry of Health, Labour and Welfare (MHLW) invites requests for development of unapproved or off-label drugs that

have been approved for use in Europe and the United States but have yet to be approved in Japan. Upon receipt of such a request, MHLW, through a meeting of the Evaluation Committee on Unapproved or Off-Label Drugs with High Medical Needs, evaluates the medical need for the drug concerned and ascertains the validity of clinical studies required to support an application for approval and the drug's eligibility for an Application Based on Public Knowledge, thus promoting the development of such drugs by pharmaceutical manufacturers. Sumitomo Dainippon Pharma endorses this initiative and has implemented the programs below in order to meet unmet medical needs of patients.

Product name	Indication(s)	Development status
Thiotepa (generic name)	Pretreatment for autologous or allogeneic hematopoietic stem cell transplantation (adults) Pretreatment for autologous or allogeneic hematopoietic stem cell transplantation (pediatric)	Planning
Amlodin®	Additional indication of hypertension in pediatric patients	Approved on June 22, 2012
Metgluco®	Additional indication of type 2 diabetes in pediatric patients	Approved on August 29, 2014

### Participation in the Global Health Innovative Technology Fund (GHIT Fund)

Sumitomo Dainippon Pharma participates in the Global Health Innovative Technology Fund (GHIT-Fund).

Through our participation, we are seeking to explore how we can utilize our innovative drug discovery technologies for neglected tropical diseases (NTDs), malaria, and other disease fields in which there are significant unmet medical needs, thereby aiming to enhance Access to Health.

### **Preventing Counterfeit Pharmaceuticals**

The threat of illegally manufactured or distributed pharmaceuticals (counterfeit pharmaceuticals) is expanding throughout the world in terms of both quantity and the targeted area. The problem of counterfeit pharmaceuticals has another international dimension; their trading could be a lucrative business for organized crime and international terrorist organizations.

To ensure safety of and trust in our products, we together with peer pharmaceuticals companies join in the initiatives of industrial associations and international organizations and collect and exchange up-to-date information in the fight against counterfeit pharmaceuticals. Specific actions are detailed below.

### Membership in PSI: Pharmaceutical Security Institute

As a member of PSI (Pharmaceutical Security Institute), Sumitomo Dainippon Pharma shares information, including case studies of action, with other global pharmaceutical manufacturers in Japan and overseas in information gathering and initiating enforcement through appropriate authorities.

Working with INTERPOL to Combat Counterfeit Pharmaceuticals Crimes Sumitomo Dainippon Pharma is one of 29 global pharmaceutical companies (including eight companies in Japan) 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.

### **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 with the hope that "every patient we serve and the families can lead a healthier and more fulfilling life tomorrow, even if the improvement might be gradual" in the spirit of "Innovation today, healthier tomorrows."

Specifically, we take initiatives based on the basic thoughts below with our social activities centered on supporting activities by employees, supporting by donations, and social supports.

- 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.



### Community Service at Social Welfare Facilities

Supporting Activities by Employees

As members of a life science company, Sumitomo Dainippon Pharma actively supports social welfare facilities and organizations through our officers and employees participation.

In fiscal 2015, a total of 304 of our officers and employees supported 33 welfare facilities and organizations for people with disabilities, senior citizens, and children. We provided assistance to help in the daily activities of the people using the facilities and to help with special events planned and run by the facilities.



The President of Sumitomo Dainippon Pharma supporting a special event

### Forest Conservation Activities by Officers and Employees

Supporting Activities by Employees

Sumitomo Dainippon Pharma works on biodiversity initiatives through forest conservation activities as part of our environmental communication program in which officers and employees take part.

In fiscal 2015, a total of 241of our officers and employees took part in thinning and weeding of forests and bamboo forests, primarily in areas close to our business sites (Kishiwada City, Osaka Prefecture, Suzuka City, Mie Prefecture, Niihama City, Ehime Prefecture, etc.)



Activity to create a Satoyama for children to play in at Fukadani Park in Suzuka City, Mie Prefecture

### **Donations Activities**

Supporting by Donations

In the spirit of "Innovation today, healthier tomorrows," Sumitomo Dainippon Pharma matches donations from our officers and employees with a corresponding company donation to organizations that work to foster the future generation of people and extend assistance to patients and their families, which are what we focus on.

In fiscal 2015, Sumitomo Dainippon Pharma provided donations in the form of funds to assist with activities to the Japan Mental Health Peer Support Specialists Training Organization, the Japan Association of Certified Child Life Specialists, and the Japan Association of Medical Translation for Cancer.



Presentation ceremony for donation to Japan Mental Health Peer Support Specialists Training Organization

### The Japan Epilepsy Research Foundation (JERF)

Social Supports

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.

In fiscal 2015, we provided 12 research grants, two overseas study grants, and two Japan Epilepsy Research Grants for Inviting Overseas Researchers to Japan.

### Support for Establishment of Funded Laboratory

**Social Supports** 

In April 2015, Sumitomo Dainippon Pharma made a donation to support the establishment of the Department of Drug Discovery Medicine, a funded laboratory established by the Graduate School of Medicine, Kyoto University with the aim of developing human resources to undertake drug discovery in industry and academia.

### Great East Japan Earthquake Reconstruction Support

Donations with Officer and Employee Participation

Sumitomo Dainippon Pharma has continued to work on activities to support the people affected by the Great East Japan Earthquake that took place in March 2011 in accordance with changes in needs. Moreover, we have continued to make donations through ASHINAGA in support of children who lost parents and caregivers in the earthquake.

In fiscal 2015, we supported sports days at kindergartens, elementary and junior high schools in Ofunato City, Iwate Prefecture and Okuma town, Fukushima Prefecture. It was the fifth year for this activity in Okuma town and the third year in Ofunato City.

In addition, we held Michinoku marché (marché is the French word for market) in support of areas affected by the Great East Japan Earthquake at our head offices in Osaka and Tokyo with sales of specialty products from affected areas and panel displays of the reconstruction support activities we have implemented to date, and many of our employees took part.

### **International Contribution Activities**

Supporting by Donations

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 health.

### **Promoting the Vaccine Business**

Sumitomo Dainippon Pharma has been involved in the new tuberculosis vaccine business utilizing a human parainfluenza type 2 virus vector 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

Sumitomo Dainippon Pharma supports Future Code, an NGO involved in tuberculosis checkups and human resource training in developing countries, including Haiti.

### Supporting Activities to Eradicate Malaria

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,. We supports insecticide-treated mosquito net, rapid diagnostic test kits for malaria, and educational activities

### Social Contribution by Overseas Subsidiaries

Supporting Activities by Employees

In the spirit of "Innovation today, healthier tomorrows", the Sumitomo Dainippon Pharma Group works on social contribution activities that include assistance for patients and children and assistance for local communities, including forest conservation, in partnership with overseas subsidiaries.

### Sunovion Pharmaceuticals Inc. Implementing "Hands On!" Community Service Activities

Sunovion in the U.S. has been working on its "Hands On!" community service activities since 2012, running volunteer activities that contribute to the local community with a cumulative total of more than 18,000 hours spent up to 2015.

In fiscal 2015, 330 employees took part in programs in 14 areas to implement activities that included removal of weeds from a YMCA campground, improvement of part of a nature trail, harvesting in a vegetable garden, and support for skills training in a learning facility for adults with developmental disorders. Sunivion's MRs all over the country also implemented various activities in the areas they have responsibility for.



Sunovion employees involved in "Hands On!"

### Sumitomo Pharmaceutical (Suzhou) Co., Ltd. Assistance for Rongshui Orphanage, Jiangxi Province

Sumitomo Pharmaceutical (Suzhou) Co., Ltd. has been providing assistance an orphanage in Rongshui, Jiangxi Province since 2013.

In fiscal 2015, 15 employees took part in deepening interaction with the children with barbecues and other events and served as instructors to run Karate classes, sand-picture classes, and science experiments. In addition to clothes and stationary donated by employees, the company presented a gatekeeper's office at the front entrance of the orphanage.



Employees of Sumitomo Pharmaceutical (Suzhou) Co., Ltd. visiting the orphanage

### **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.

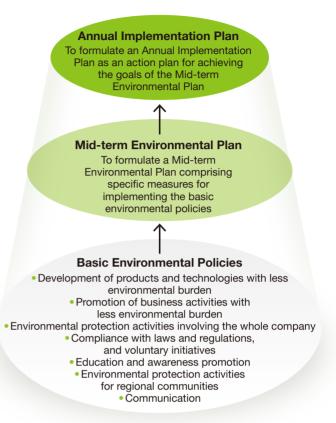
The Basic Environmental Policies, established in fiscal 2005, express our objectives and initiatives to realize them and have been placed as a pillar for promoting all our environmental activities since they were established. Under the Basic Environmental Policies, we formulated a Mid-term Environmental Plan that specifies goals of special importance and objectives for three years (from fiscal 2015 to fiscal 2017).

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

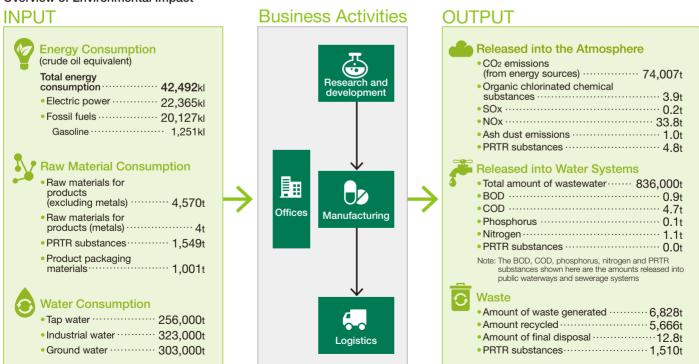
Sumitomo Dainippon Pharma has acquired ISO 14001 certification at its three plants (Suzuka Plant, Ibaraki Plant, and Oita Plant).

### **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.



### Overview of Environmental Impact



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 2015 -2017)

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 2015, 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: ©

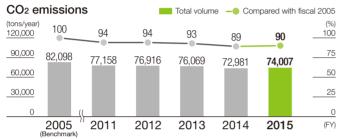
Degree of progress: ⊚Goal achieved ○ Steady progress made toward objective △ Progress somewhat behind schedule

Goals of Special Importance	Objectives	Progress in FY2015	Degree of Progress
Reduce emissions of chemical substances	Properly manage chemical substances, and continually strive to reduce emissions of chemical substances (PRTR substances, etc.) into the environment	With increase in the volume of PRTR substances handled, atmospheric emissions of these substances increased approximately 4.7% over the previous fiscal year, but emission rates (emission volume/amount handled) decreased compared to the previous fiscal year.	0
	[1] Numerical targets:	[1] Numerical targets:	
	Reduce CO <sub>2</sub> emissions for the whole Company to 23% of FY2005 levels by FY2020	Company-wide CO <sub>2</sub> emissions in FY2015 stood at 90.1% of the level in FY2005 and 101.4% of the previous fiscal year	0
	Improve per-unit energy consumption and CO <sub>2</sub> emissions for the whole Company by 1% or	Per-unit energy consumption: 103.2% of FY2014	Δ
	more per year, respectively	Per-unit CO <sub>2</sub> emissions: 102.4% of FY2014	Δ
2. Promote energy	[2] Activity targets:	[2] Activity targets:	
savings and address climate change	Promote the introduction of energy-efficient equipment and machinery at the Company's work sites	Invested in energy saving equipment, such as updating boilers and air conditioning equipment at the Suzuka Plant	0
	Promote the use of renewable energy at the Company's work sites	Currently operating solar power generation equipment at the Central Research Laboratories and the Osaka Research Center	0
	Promote energy saving at the Company's work sites	Implemented across the whole Company and at each work site	0
	Promote visualization of energy consumption at the Company's work sites	Considered various measures at each work site	0
Avert power shortages	Consider and implement measures to reduce energy use in summer and winter	Each work site sets unique targets and implemented measures to reduce energy use	0
	Maintain final landfill disposal by the whole Company at less than 1% of waste generated	Maintained at less than 1% (FY2015 result 0.2%)	0
4. Reduce waste	Plants and research laboratories: Maintain final landfill disposal of industrial waste at less than 1% of amount generated	Zero emissions goal achieved at four plants and two research laboratory	0
	Other sites: Continue complete recycling of recyclable waste	Other sites made progress in recycling recyclable waste	0
5. Promote communication with Group companies	Support environmental and safety activities of Group companies	Conducted environmental and safety audits at two Group companies in Japan, and held meeting in September 2015 to exchange information on the environmental management of domestic Group companies	0
6. Promote	Understand environmental risks that corporate activities can present to the local community	Gained understanding of most risks and implemented countermeasures	0
communication with local communities	Disclose information to the local community in an appropriate way	Implemented appropriately	0
	Participate actively in local environmental activities	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 and considering details of activities	0
8. Enhance environmental	Establish and implement environmental education system for employees	Formulated environmental education plan at each work site and implemented education in accordance with plans	0
education	Train key persons in environmental management	Formulated training plans at each work site and implementing training in accordance with plans	0

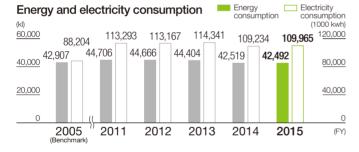
### Activities to Conserve Energy and Address Climate Change

In addition to the active introduction of equipment with outstanding energy conservation performance that emits 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 addressing CO<sub>2</sub> emissions reduction.

In fiscal 2015, we continued our initiatives already in place to introduce various kinds of energy-saving equipment to operations and hybrid vehicles to our leased sales fleet as well as measures to conserve energy in both the summer and winter months. However, CO<sub>2</sub> emissions rose slightly compared to the previous fiscal year as production increased.



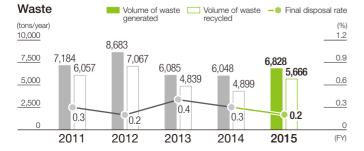
Note: We use a fixed value determined in-house for CO<sub>2</sub> conversion factor. This is to exclude the impact from external factors such as operations at nuclear power stations to clarify the outcomes of our initiatives. Therefore, these values differ from values reported under the Act on Promotion of Global Warming Countermeasures.



### **Waste Reduction**

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

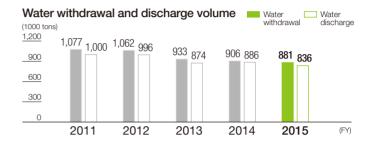
In fiscal 2015, as a result of improvements in the recycling rate at our plants and research laboratories, the corporate percentage of landfill waste (landfill waste as a percentage of total waste generated) was approximately 0.2%, and we successfully achieved the corporate target for less than 1% landfill waste as we did in the previous fiscal year.



### **Efficient Utilization of Water Resources**

In order to utilize water resources that are essential for our effective business activities and to reduce environmental impact, we manage water usage and wastewater volume at all business sites as we strive to reduce water consumption.

Water consumption in fiscal 2015 fell 3% from the previous fiscal year and has declined steadily since fiscal 2009.



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

In order to reduce the environmental impact of chemical substances, we strive to reduce the discharge of such substances into the environment.

As for measures to prevent air pollution, we work to reduce the discharge of these substances into the atmosphere through such means as installing chemical substance recovery equipment. As for measures to prevent water pollution, we conduct appropriate wastewater management through regular monitoring of compliance with wastewater standards.

### **Biodiversity Initiatives**

Sumitomo Dainippon Pharma promotes biodiversity initiatives of forest conservation activities through our employees' participation in environment communication program. Since October 2015, we have been working on the Owls Forest Restoration Project, which is an environmental conservation activity promoted by Kishiwada City, Osaka Prefecture.

Under the project, we are taking responsibility for the appropriate development of 0.45 hectares of satoyama woodland in Sangayamacho, Kishiwada City as the Sumitomo Dainippon Pharma Forest based on a five-year plan. The goal is

to restore and maintain a rich natural environment to enable the owl, which is at the top of the area's ecological pyramid, to survive through the creation of an excellent woodland environment.



Activities at Sumitomo Dainippon Pharma's forest

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

In fiscal 2015, there were no incidents that had a serious impact on the environment just the same as last year.

### Eleven-Year Summary of Selected Financial Data

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

-	2006	2007	2008	2009	2010	
RESULTS OF OPERATIONS:						
Net sales	¥245,784	¥261,213	¥263,993	¥264,037	¥296,262	
Overseas sales revenue	9,696	22,032	24,521	22,051	53,015	
Ratio of overseas sales revenue	3.9%	8.4%	9.3%	8.4%	17.9%	
Cost of sales	130,437	99,346	99,385	103,741	112,263	
Selling, general and administrative expenses	86,461	116,312	124,794	129,130	148,374	
(Research and development costs	29,636	40,870	47,266	52,819	51,371	
(Ratio of net sales)	12.1%	15.6%	17.9%	20.0%	17.3%	
Operating income	28,886	45,555	39,814	31,166	35,625	
Operating margin	11.8%	17.4%	15.1%	11.8%	12.0%	
Income before income taxes	25,687	38,415	41,457	32,168	31,423	
Net income	15,377	22,605	25,592	19,988	20,958	
Comprehensive income (loss)	_	_	_	_	27,148	
FINANCIAL POSITION:						
Current assets	¥249,733	¥234,313	¥251,063	¥263,540	¥287,555	
Net property, plant and equipment	68,336	65,241	70,280	69,105	74,084	
Total assets	392,966	382,535	399,791	391,295	626,743	
Current liabilities	80,071	56,039	67,915	53,350	265,000	
Long-term liabilities	24,262	20,484	13,598	13,449	18,260	
Net assets	288,633	306,012	318,278	324,496	343,483	
OTHER STATISTICS:						
Capital expenditures	¥ 6,616	¥ 9,543	¥ 15,491	¥ 10,569	¥ 6,471	
Depreciation and amortization	8,901	12,008	11,870	11,455	18,650	
EBITDA	36,179	54,875	48,802	41,970	56,448	
PER SHARE OF COMMON STOCK:						
Basic net income	¥ 54.57	¥ 56.86	¥ 64.39	¥ 50.30	¥ 52.75	
Net assets	723.63	767.52	800.63	816.49	864.51	
Cash dividends applicable to the year	12.00	14.00	18.00	18.00	18.00	
FINANCIAL INDICATORS:						
ROE	7.3%	7.6%	8.2%	6.2%	6.3%	
ROA	5.2%	5.8%	6.5%	5.1%	4.1%	
Equity ratio	73.2%	79.8%	79.6%	82.9%	54.8%	
Dividend payout ratio	22.0%	24.6%	28.0%	35.8%	34.1%	
				()///01 11001 05 ::		_

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 ¥113 to US\$1.00, the approximate rate of exchange at March 31, 2016.

<sup>2</sup> On June 19,2014, Dainippon Sumitomo Pharma Co., Ltd. changed its name 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 as of March 31, 2006 have been reclassified.

A STATE OF THE STA	Thousands of U.S. dollars
Millions of yen Percent change	(Note 1)

2016	2016/2015	2016	2015	2014	2013	2012	2011
3,568,195	8.6%	¥403,206	¥371,371	¥387,693	¥347,724	¥350,396	¥379,513
1,903,142	23.0%	215,055	174,911	174,286	133,125	130,243	152,226
		53.3%	47.1%	45.0%	38.3%	37.2%	40.1%
924,522	3.2%	104,471	101,228	104,100	101,686	98,857	110,030
2,316,859	6.1%	261,805	246,868	241,450	220,994	231,137	238,531
725,965	15.0%	82,034	71,304	69,804	59,844	56,891	68,160
		20.3%	19.2%	18.0%	17.2%	16.2%	18.0%
326,814	58.7%	36,930	23,275	42,143	25,044	20,402	30,952
		9.2%	6.3%	10.9%	7.2%	5.8%	8.2%
350,097	17.2%	39,561	33,755	34,709	18,158	16,328	25,050
218,557	59.9%	24,697	15,448	20,061	10,044	8,630	16,796
49,371	(90.7%)	5,579	60,108	45,165	37,174	2,396	(12,066)
3,730,840	5.0%	¥421,585	¥401,699	¥359,612	¥333,439	¥334,251	¥333,000
547,124	(5.1%)	61,825	65,160	72,689	69,862	66,697	69,794
6,262,982	(0.5%)	707,717	711,584	659,033	607,219	559,410	589,868
1,590,469	14.6%	179,723	156,844	131,208	124,831	105,966	157,204
721,425	(21.4%)	81,521	103,719	129,285	133,140	134,217	108,681
3,951,088	(1.0%)	446,473	451,021	398,540	349,248	319,227	323,983
86,593	(8.3%)	¥ 9,785	¥ 10,676	¥ 23,421	¥ 12,384	¥ 8,742	¥ 8,663
179,354	5.4%	20,267	19,226	26,777	35,085	40,232	44,628
493,628	29.4%	55,780	43,095	68,101	60,333	59,880	77,971
U.S. dollars	Percent change						Yen
0.55	59.9%	¥ 62.16	¥ 38.88	¥ 50.49	¥ 25.28	¥ 21.72	¥ 42.27
9.94	(1.0%)	1,123.76	1,135.21	1,003.11	879.03	803.47	815.44
0.16	0.0%	18.00	18.00	18.00	18.00	18.00	18.00
		5.5%	3.6%	5.4%	3.0%	2.7%	5.0%
		3.5%	2.3%	3.2%	1.7%	1.5%	2.8%
		63.1%	63.4%	60.5%	57.5%	57.1%	54.9%
		29.0%	46.3%	35.7%	71.2%	82.9%	42.6%

<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).

5. Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries adopted the new accounting standard for presentation of comprehensive income and the

revised accounting standard for consolidated financial statements. In accordance with the adoption of the new accounting standards, comprehensive income (loss) has been presented in the results of operations from 2010 to 2016.

<sup>6.</sup> EBITDA = income before income tax + interest expenses - interest income +depreciation and amortization + amortization of goodwill - extraordinary income (loss)

### Operating Results and Financial Condition

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

During the fiscal year ended March 31, 2016, the Japanese economy continued on a mild recovery path, overall, with corporate earnings remaining at high levels but exports and manufacturing output weakening somewhat, primarily due to slowdowns in emerging economies. The U.S. economy also continued to expand, driven chiefly by increased consumer spending under a stable employment environment. The Chinese economy, on the other hand, experienced a gradual slowdown. Overall, the outlook for the global economy is growing more uncertain in light of downside risks in emerging economies, including China, and falling oil prices.

In the pharmaceutical sector, businesses are obliged to run high risks, as visibility lowers owing primarily to the increasing difficulty of developing new drugs, the rise in R&D costs, and intensifying international competition in line with the price curb on brand-name drugs and accelerated use of generic drugs in a bid to put the brakes on expansion of social security benefits expenditures worldwide.

Against this background, the Group focused on providing scientific information in Japan in an effort to further boost sales of its strategic products, such as AIMIX® (therapeutic agent for hypertension), TRERIEF® (therapeutic agent for Parkinson's disease), and LONASEN® (atypical antipsychotic).

In North America, the Company's U.S. subsidiary Sunovion Pharmaceuticals Inc. poured its resources into expanding sales of the atypical antipsychotic LATUDA® (generic name: lurasidone hydrochloride), with the result that this global strategic product for the group became a blockbuster drug with North American sales topping 1.0 billion US dollar. In the Oncology area, Boston Biomedical, Inc., another U.S. subsidiary of the Company, concentrated its efforts on the ongoing development of napabucasin (product code: BBI608), placing top priority on an early launch of this drug in the U.S.A.

In Europe, all development and commercialization rights with respect to LATUDA® in that region have been transferred back to the Company from Takeda Pharmaceutical Company Limited out of market and business considerations at Takeda Pharmaceutical Company Limited.

### **Operating Results**

### **Net Sales**

Sales in Japan fell sharply, primarily due to the decline in sales of long-listed brands as the government encourages the use of generic drugs. However, North America saw sales increase substantially on the back of steady growth for LATUDA® and the antiepileptic agent APTIOM®, which has recently been approved for an additional indication as monotherapy, and the benefits of the weaker yen. On a consolidated basis, net sales increased by 8.6% year-on-year to reach 403,206 million yen.

### **Selling, General and Administrative Expenses**

Selling, general, and administrative expenses increased due to the Group's series of strategic investments, including aggressive R&D activities in North America, and the additional impact of yen depreciation.

### **Operating Income**

As a result of the above, operating income increased by 58.7% year-on-year to 36,930 million yen.

### Other income (expenses) and net income attributable to owners of the parent

Net income attributable to owners of the parent increased by 59.9% to 24,697 million yen as a result of recording gain on sales of investment securities and foreign exchange losses, etc. as other income (expenses).

### **Financial Condition**

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

Current assets increased by 19,886 million yen from the previous fiscal year-end as the increase in cash and time deposits and deferred tax assets more than offset the decrease in marketable securities. Fixed assets decreased substantially by 23,753 million yen from the previous fiscal year-end owing to depreciation, amortization and appreciation of the yen, despite the increase in investment securities. As a result, total assets decreased by 3,867 million yen from the previous fiscal year-end to 707,717 million yen.

#### -Liabilities

Despite the decrease in interest-bearing debts (bonds and long-term loans payable), liabilities increased by 681 million yen from the previous fiscal year-end to 261,244 million yen as income tax payable rose and the reserve for rebates of sales increased due to greater sales in North America.

### -Net assets

Net assets declined by 4,548 million yen from the previous fiscal year-end to 446,473 million yen, as retained earnings and unrealized gains on available-for-sale securities increased while foreign currency translation adjustments decreased significantly due to the stronger yen. The shareholders' equity ratio as of the end of the fiscal year under review was 63.1%.

### Status of cash flows

### -Net cash provided by operating activities

Cash flows provided by operating activities rose by 19,164 million yen from the previous fiscal year to 49,415 million yen, owing primarily to the increase in income before income taxes and the decrease in income taxes paid.

### -Net cash provided by investing activities

Cash flows provided by investing activities decreased by 7,561 million yen from the previous fiscal year to 15,887 million yen due to a significant decline in proceeds from sales of property, plants and equipment, although proceeds from sales of investment securities increased.

### -Net cash used in financing activities

Cash flows used in financial activities increased by 26,880 million yen from the previous fiscal year to 42,605 million due to the Company's redemption of bonds during the fiscal year under review, in addition to repayment of debts and payment of dividends.

### -Cash and cash equivalents

After adding the impact of foreign currency translations applied to cash and cash equivalents and the adjustments in cash and cash equivalents associated with fiscal year-end changes of subsidiaries, the balance of cash and cash equivalents as of March 31, 2016 amounted to 135,576 million yen, an increase of 12,782 million yen from the end of the previous fiscal year.

### 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, 2017

Net sales in Japan, the Company will attempt to maximize sales of its strategic products, such as AIMIX® and LONASEN® as well as its new offerings of REMITCH®, pruritus treatment, and Trulicity®,GLP-1 receptor agonist. Nonetheless, net sales in Japan are expected to decline as the negative impact of NHI price revisions and falling sales of long-listed drugs are forecast to continue. In North America, on the other hand, net sales are expected to increase as sales of LATUDA®, BROVANA®, and APTIOM® appear set to rise. All things considered, net sales are expected to reach 410.0 billion yen, up 6.8 billion yen from the previous year.

Selling, general and administrative expenses less R&D expenses will likely to increase in the sales expense in North America despite the impact of strong yen. Research and development cost is expected to rise because of the clinical development costs for late-stage development products.

As a result, the Company expects operating income of 40.0 billion yen, up by 3.1 billion yen year-on-year and net income attributable to owners of the parent company of 25.0 billion yen, up by 0.3 billion yen.

Note: Foreign currency exchange rate used for the forecasts 1 USD = 110 yen, 1 RMB = 17.0 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, 2016.

### 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 because of the growing difficulty of development of new drug. 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 by price restraint of branded prescription drug and promotion of generic drug use, 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, labor issues, fair trade, etc., relating to the business activities of the Group. Depending on the development thereof, such cases could have a significant and negative impact on the Group's operating results and financial position.

### 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, 2016 and 2015

Thousands of U.S. dollars (Note 1) Millions of yen

		*	, ,
ASSETS	2016	2015	2016
CURRENT ASSETS:			
Cash and time deposits (Notes 3 and 5)	¥ 54,923	¥ 30,553	\$ 486,044
Marketable securities (Notes 3, 5 and 6)	81,039	111,293	717,159
Receivables:			
Trade notes (Note 5)	2,512	2,311	22,230
Trade accounts (Note 5)	105,316	101,525	931,999
Due from parent company, unconsolidated subsidiaries and			
affiliates (Notes 5 and 13)	48,513	49,131	429,319
Allowance for doubtful receivables	(4)	(126)	(35)
Total	156,337	152,841	1,383,513
Inventories (Note 4)	59,589	62,388	527,336
Deferred tax assets (Note 9)	63,992	38,867	566,301
Other current assets	5,705	5,757	50,487
Total current assets	421,585	401,699	3,730,840

### PROPERTY, PLANT AND EQUIPMENT:

Land	6,269	6,298	55,478
Buildings and structures	95,280	94,185	843,186
Machinery and equipment	113,233	111,705	1,002,062
Construction in progress	1,497	1,245	13,248
Total	216,279	213,433	1,913,974
Accumulated depreciation	(154,454)	(148,273)	(1,366,850)
Net property, plant and equipment	61,825	65,160	547,124

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

Investment in unconsolidated subsidiaries and affiliates (Notes 5)	1,819	1,709	16,097
Investment securities (Notes 5 and 6)	58,613	56,485	518,699
Goodwill	76,950	88,075	680,973
In-process research and development	60,145	64,456	532,257
Other intangible assets	19,486	21,332	172,442
Asset for retirement benefits (Note 10)	67	1,935	593
Deferred tax assets (Note 9)	2,314	4,794	20,478
Other assets	4,913	5,939	43,479
Total investments and other assets	224,307	244,725	1,985,018
TOTAL	¥ 707,717	¥ 711,584	\$ 6,262,982

Thousands of U.S. dollars (Note 1)

Millions o	of yen
------------	--------

LIABILITIES AND NET ASSETS	2016	2015	2016
CURRENT LIABILITIES:			_
Short-term loans payable (Note 5 and 8)	¥ 1,010	¥ –	\$ 8,938
Current portion of long-term debt (Notes 5 and 8)	22,000	36,522	194,690
Payables:			
Trade notes (Note 5)	93	87	823
Trade accounts (Notes 5, 6 and 7)	42,436	42,835	375,540
Due to parent company, unconsolidated subsidiaries and affiliates (Notes 5 and 13)	1,111	1,964	9,832
Total	43,640	44,886	386,195
Income taxes payable (Note 5)	26,358	3,289	233,257
		65,400	701,743
Accrued expenses	79,297		-
Other current liabilities  Total current liabilities	7,418 179,723	6,747 156,844	65,646 1,590,469
Total current liabilities	179,723	130,044	1,590,409
LONG-TERM LIABILITIES:			
Long-term debt (Notes 5 and 8)	28,000	50,000	247,788
Liability for retirement benefits (Note 10)	16,159	15,274	143,000
Deferred tax liabilities (Note9)	16,209	17,355	143,442
Other liabilities (Note 8)	21,153	21,090	187,195
Total long-term liabilities	81,521	103,719	721,425
NET ASSETS:			
Shareholders' equity (Note 11)			
Common stock: authorized — 1,500,000,000 shares in the years ended March 31, 2016 and 2015; issued — 397,900,154 shares in the years ended March 31, 2016 and 2015	22,400	22,400	198,230
Capital surplus	15,861	15,860	140,363
Retained earnings	341,402	326,686	3,021,257
Treasury stock, at cost: 598,599 shares in the year ended March 31, 2016	·		
and 596,335 shares in the year ended March 31, 2015	(663)	(660)	(5,868)
Total shareholders' equity	379,000	364,286	3,353,982
Accumulated other comprehensive income (loss)	05 000	22.000	202 022
Unrealized gains (losses) on available-for-sale securities	25,293	23,099	223,832
Deferred gains (losses) on hedges	(13)		(115)
Foreign currency translation adjustments	48,025	68,171	425,000
Remeasurements of defined benefit plans  Total accumulated other comprehensive income (loss)	(5,832) 67,473	(4,537) 86,735	(51,611)
Total accumulated other comprehensive income (loss)  Total net assets	446,473	451,021	597,106 3,951,088
	¥ 707,717		
TOTAL	¥ /U/,/ 1/	¥711,584	\$6,262,982

See Notes to Consolidated Financial Statements.

### Consolidated Statements of Income

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

	Millions	Millions of yen		
	2016	2015	2016	
NET SALES (Notes 12 and 13)	¥ 403,206	¥ 371,371	\$ 3,568,195	
COST OF SALES (Notes 12 and 13)	104,471	101,228	924,522	
Gross profit	298,735	270,143	2,643,673	
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Notes 2 and 13)	261,805	246,868	2,316,859	
Operating income	36,930	23,275	326,814	
OTHER INCOME (EXPENSES):				
Interest and dividend income (Note 13)	1,657	1,574	14,664	
Interest expense	(920)	(937)	(8,142)	
Foreign exchange losses	(2,993)	(996)	(26,487)	
Gain on investments in partnership	1,296	1,990	11,469	
Gain on sales of investment securities (Note 6)	6,107	36	54,044	
Gain on sales of property, plant and equipment	10	15,984	88	
Compensation income for damage	_	1,711	_	
Restructuring (Note 17)	(613)	(1,961)	(5,425)	
Impairment loss (Notes 2 (h) and 16)	(553)	(5,310)	(4,894)	
Other — net	(1,360)	(1,611)	(12,034)	
Other income (expenses) — net	2,631	10,480	23,283	
INCOME BEFORE INCOME TAXES	39,561	33,755	350,097	
INCOME TAXES (Note 9):				
Current	39,587	14,034	350,327	
Deferred	(24,723)	4,273	(218,787)	
Total income taxes	14,864	18,307	131,540	
NET INCOME	¥ 24,697	¥ 15,448	\$ 218,557	
NET INCOME ATTRIBUTABLE TO				
NET INCOME ATTRIBUTABLE TO:	V 04 007	V 15 440	¢ 040 557	
Owners of the parent	¥ 24,697	¥ 15,448	\$ 218,557	
Non-controlling interests	_		_	
PER SHARE OF COMMON STOCK:	Ye	n	U.S. dollars (Note 1)	
Basic net income				
Cash dividends applicable to the year	¥ 62.16	¥ 38.88	\$ 0.55	
	18.00	18.00	0.16	
See Notes to Consolidated Financial Statements.				

### Consolidated Statements of Comprehensive Income (Loss)

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries

Thousands of U.S. dollars of yen (Note 1)

Years Ended March 31, 2016 and 2015	Millions o	Millions of yen				
	2016	2015	2016			
NET INCOME	¥ 24,697	¥ 15,448	\$ 218,557			
OTHER COMPREHENSIVE INCOME (LOSS):						
Unrealized gains (losses) on available-for-sale securities (Note 18)	2,194	5,851	19,416			
Deferred gains (losses) on hedges (Note 18)	(15)	3	(132)			
Foreign currency translation adjustments (Note 18)	(20,002)	41,379	(177,009)			
Remeasurements of defined benefit plans (Note 18)	(1,295)	(2,573)	(11,461)			
Total other comprehensive income (loss) (Note 18)	(19,118)	44,660	(169,186)			
COMPREHENSIVE INCOME (LOSS)	5,579	60,108	49,371			
COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO:						
Owners of the parent	5,579	60,108	49,371			

Non-controlling interests
See Notes to Consolidated Financial Statements.

# Consolidated Statements of Changes in Net Assets Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

	Thousands	of shares						Millions of ye	n				
				Sha	areholders' ec	uity		Accur	nulated oth	ner comprehe	nsive incom	ne (loss)	
	Issued number of shares of common stock	Number of treasury stocks	Common	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, 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 attributable to owners of the parent					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
BALANCE, APRIL 1, 2015	397,900	(596)	¥ 22,400	¥ 15,860	¥ 326,686	¥ (660)	¥ 364,286	¥ 23,099	¥2	¥ 68,171	¥ (4,537)	¥ 86,735	¥ 451,021
Cash dividends, ¥18.00 per share					(7,152)		(7,152)						(7,152)
Net income attributable to owners of the parent					24,697		24,697						24,697
Purchases of treasury stock		(3)		1		(3)	(3)						(3)
Sales of treasury stock		0				0	1						1
Change of scope of equity method					(5)		(5)						(5)
Decrease due to change													
in fiscal period of consolidated													
subsidiaries					(2,824)		(2,824)						(2,824)
Net change in items other than shareholders' equity								2,194	(15)	(20,146)	(1,295)	(19,262)	(19,262)
BALANCE, MARCH 31, 2016	397,900	(599)	¥22,400	¥15,861	¥341,402	¥(663)	¥379,000	¥ 25,293	¥ (13)	¥ 48,025	¥(5,832)	¥67,473	¥446,473

					Thousand	ds of U.S. doll	ars (Note 1	)			
		Sh	areholders' e	quity		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, 2015	\$ 198,230	\$140,354	\$ 2,891,027	\$ (5,841)	\$3,223,770	\$204,416	\$17	\$ 603,283	\$ (40,150)	\$767,566	\$3,991,336
Cash dividends, U.S.\$ 0.16 per share			(63,292)		(63,292)						(63,292)
Net income attributable to owners of the parent			218,557		218,557						218,557
Purchases of treasury stock				(27)	(27)						(27)
Sales of treasury stock		9		0	9						9
Change of scope of equity method			(44)		(44)						(44)
Decrease due to change											
in fiscal period of consolidated											
subsidiaries			(24,991)		(24,991)						(24,991)
Net change in items other than shareholders' equity						19,416	(132)	(178,283)	(11,461)	(170,460)	(170,460)
BALANCE, MARCH 31, 2016	\$198,230	\$140,363	\$3,021,257	\$(5,868)	\$3,353,982	\$223,832	\$(115)	\$425,000	\$(51,611)	\$597,106	\$3,951,088

See Notes to Consolidated Financial Statements.

### Consolidated Statements of Cash Flows

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

Thousands of U.S. dollars (Note 1)

	Millions	Millions of yen		
	2016	2015	2016	
OPERATING ACTIVITIES:				
Income before income taxes	¥ 39,561	¥ 33,755	\$ 350,097	
Adjustments for:			•	
Depreciation and amortization	14,287	13,780	126,434	
Impairment loss	553	5,310	4,894	
Amortization of goodwill	5,980	5,446	52,920	
Increase (decrease) in liability for retirement benefit	1,045	181	9,248	
Provision for other liabilities	18,787	3,772	166,257	
Interest and dividend income	(1,657)	(1,574)	(14,664)	
Loss (gain) on investments in partnership	(1,296)	(1,930)	(11,469)	
Interest expense	920	937	8,142	
Loss (gain) on sales of property, plant and equipment	(1)	(15,982)	(9)	
Loss (gain) on sales of investment securities	(6,107)	(36)	(54,044)	
Restructuring	613	1,961	5,425	
Changes in assets and liabilities:				
Increase (decrease) in receivables	(6,879)	13,075	(60,876)	
Decrease (increase) in inventories	(3,026)	(790)	(26,779)	
Increase (decrease) in payables	3,171	(2,269)	28,062	
Other — net	(1,120)	(3,357)	(9,913)	
Subtotal	64,831	52,279	573,725	
Interest and dividend received	1,744	1,824	15,434	
Interest paid	(644)	(887)	(5,699)	
Payment for restructuring	(585)	(1,589)	(5,177)	
Income taxes paid	(15,931)	(21,376)	(140,982)	
Net cash provided (used) by operating activities	49,415	30,251	437,301	
INVESTING ACTIVITIES:				
Purchases of property, plant and equipment	(5,383)	(8,662)	(47,637)	
Purchases of intangible assets	(4,358)	(3,705)	(38,566)	
Proceeds from sales of property, plant and equipment	22	20,014	195	
Net decrease (increase) in marketable securities	18,499	15,261	163,708	
Proceeds from sales of investment securities	6,383	1,202	56,487	
Purchases of investment securities	(297)	(1,667)	(2,628)	
Proceeds from redemption of investment securities	3,072	2,273	27,186	
Payment of loan receivable	(2,089)	(546)	(18,487)	
Other — net	38	(722)	335	
Net cash provided (used) by investing activities	15,887	23,448	140,593	
FINANCING ACTIVITIES:				
	(C E20)	(10.240)	(EZ 700)	
Repayment of long-term borrowings  Redemption of bonds	(6,530)	(10,349)	(57,788)	
Dividends paid	(30,000)	(7.150)	(265,487)	
Other — net	(7,152)	(7,152) 1,776	(63,292)	
Net cash provided (used) in financing activities	1,077		9,532 (377,035)	
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(42,605)	(15,725)		
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(8,224) 14,473	10,703 48,677	(72,779) 128,080	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	122,794	73,919	1,086,673	
Increase (decrease) in cash and cash equivalents resulting from	122,194	10,313	1,000,073	
change of scope of consolidation	_	198	_	
Increase (decrease) in cash and cash equivalents resulting from				
change in the fiscal period of subsidiaries	(1,691)		(14,965)	
CASH AND CASH EQUIVALENTS, END OF YEAR (Note3)	¥ 135,576	¥ 122,794	\$1,199,788	

See Notes to Consolidated Financial Statements.

### Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd., and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

### 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 four 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 ¥113 to U.S.\$1.00, the approximate rate of exchange on March 31, 2016. 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 2015 consolidated financial statements to conform to the classifications applied in 2016. 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 13 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 Canada Holdings Inc. and other 2 subsidiaries have been excluded from the scope of consolidation since the beginning of this fiscal year because of the merger and liquidation.

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 3 significant affiliates. Investments in the unconsolidated subsidiaries and affiliates other than 3 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 10 consolidated overseas subsidiaries. Among the consolidated subsidiaries, Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., has a fiscal accounting year-end date of December 31. In the preparation of the consolidated financial statements, Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. prepared a set of financial statements based on a provisional statement of accounts at March 31 for consolidation purpose.

For the year ended March 31, 2016, in order to achieve a more appropriate disclosure of consolidated financial information, Boston Biomedical, Inc. ("BBI") changed its fiscal year-end from December 31 to March 31. The Company included the BBI's operating results for the twelve-months period from April 1, 2015, to March 31, 2016 in the consolidated statement of income for the year ended March 31, 2016, and presented its operating results for the three-months period from January 1, 2015 to March 31, 2015 in the consolidated statement of changes in net assets for the year ended March 31, 2016, as a charge to retained earnings as "Decrease due to change in fiscal period of consolidated subsidiaries". The Company presented the decrease of cash and cash equivalents for the three-months period in the consolidated statement of cash flows for the year ended March 31, 2016 as "Increase (decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries".

### Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

### 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 14 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 14 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.

### i. 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, 2016 and 2015 were ¥82,034 million (\$725,965 thousand) and ¥71,304 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 ven 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 risk exposure 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.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

#### 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 397,303 thousand and 397,305 thousand for the years ended March 31, 2016 and 2015, 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 and its domestic subsidiaries adopted "Revised Accounting Standard for Business Combinations" (ASBJ Statement No.21, September 13, 2013 (hereinafter, "Statement No.21")), "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No.22, September 13, 2013 (hereinafter, "Statement No.22")) and "Revised Accounting Standard for Business Divestitures" (ASBJ Statement No.7, September 13, 2013 (hereinafter, "Statement No.7")) (together, the "Business Combination Accounting Standards"), from the current fiscal year. As a result, the Company changed its accounting policies to recognize in capital surplus the differences arising from the changes in the Company's ownership interest of subsidiaries over which the Company continues to maintain control and to record acquisition related costs as expenses in the fiscal year in which the costs are incurred. In addition, the Company changed its accounting policy for the reallocation of acquisition costs due to the completion following provisional accounting to reflect such reallocation in the consolidated financial statements for the fiscal year in which the business combination took place. The Company also changed the presentation of net income and the term "non-controlling interests" is used instead of "minority interests". Certain amounts in the prior year comparative information were reclassified to conform to such changes in the current year presentation.

With regard to the application of the Business Combination Accounting Standards, the Company followed the provisional treatments in article 58-2 (4) of Statement No.21, article 44-5 (4) of Statement No.22 and article 57-4 (4) of Statement No.7 where the changes are applied prospectively from the beginning of the current fiscal year onwards.

In the consolidated statement of cash flows, cash flows from acquisition or disposal of shares of subsidiaries with no changes in the scope of consolidation are included in "Cash flows from financing activities" and cash flows from acquisition related costs for shares of subsidiaries with changes in the scope of consolidation or costs related to acquisition or disposal of shares of subsidiaries with no changes in the scope of consolidation are included in "Cash flows from operating activities".

As a result, there was no impact on consolidated financial statement for the current fiscal year.

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

"Revised Implementation Guidance on Recoverability of Deferred Tax Assets" (ASBJ Guidance No. 26, March 28, 2016 (hereinafter, "Guidance No.26")

### (1) Overview

Following the framework in Auditing Committee Report No. 66 "Audit Treatment regarding the Judgment of Recoverability of Deferred Tax Assets", which prescribes estimation of deferred tax assets according to the classification of the entity by one of five types, the following treatments were changed as necessary.

(i) Treatment for an entity that does not meet any of the criteria in types 1 to 5

- (ii) Criteria for types 2 and 3
- (iii) Treatment for deductible temporary differences which an entity classified as type 2 is unable to schedule
- (iv) Treatment for the period which an entity classified as type 3 is able to reasonably estimate with respect to future taxable income before consideration of taxable or deductible temporary differences that exist at the end of the current fiscal year; and
- (v) Treatment when an entity classified as type 4 also meets the criteria for types 2 or 3

### (2) Effective date

Effective from the beginning of the fiscal year ending March 31, 2017

### (3) Effects of application of the Guidance

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. Change of accounting estimates

When accounting for retirement benefits, actuarial gains and losses and past service costs were previously amortized over 15 years but are now amortized over 14 years, effective from the year ended March 31, 2016, due to a decrease in the employees' average remaining years of service. As a result, operating income, ordinary income and income before income taxes for the year ended March 31, 2016 decreased by ¥411 million (\$3,637 thousand). The impact of this change on segment information is noted in the corresponding section.

### s. Reclassifications

Certain reclassifications of the financial statements and accompanying footnotes for the year ended March 31, 2015 have been made to conform the presentation for the year ended March 31, 2016.

### 3. SUPPLEMENTARY **CASH FLOW INFORMATION**

Cash and cash equivalents as at March 31, 2016 and 2015 for purposes of the consolidated statements of cash flows consisted of the following:

	Millions	U.S. dollars	
	2016	2015	2016
Cash and time deposits	¥ 54,923	¥ 30,553	\$ 486,044
Time deposits with maturities over three months	(386)	(511)	(3,415)
Marketable securities with a maturity of three months or less when purchased	81,039	92,752	717,159
Cash and cash equivalents	¥ 135,576	¥ 122,794	\$ 1,199,788

As at March 31, 2016 and 2015, a time deposit of ¥386 million (\$3,415 thousand) and ¥511 million is pledged as collateral for a letter of credit issued by a bank, respectively.

### 4. INVENTORIES

Inventories at March 31, 2016 and 2015 consisted of the following:

	Millions	U.S. dollars	
	2016	2015	2016
Finished goods and semi-finished goods	¥ 48,101	¥ 50,750	\$ 425,673
Work-in-process	3,207	1,626	28,381
Raw materials and supplies	8,281	10,012	73,282
Total	¥ 59,589	¥ 62,388	\$ 527,336

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

# 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 three years from March 31, 2016. 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, 2016 and 2015 were as follows:

	Millions of yen				
		2016			
	Book values	Fair values	Difference		
(1) Cash and time deposits	¥ 54,923	¥ 54,923	¥ —		
(2) Trade notes	2,512	2,512	_		
(3) Trade accounts	105,316	105,316	_		
(4) Due from parent company, unconsolidated subsidiaries and affiliates	48,513	48,513	_		
(5) Marketable securities and investment securities	132,683	132,683	_		
Total assets	¥ 343,947	¥ 343,947	¥ —		
(1) Trade notes	93	93	_		
(2) Trade accounts	42,436	42,436	_		
(3) Due to parent company, unconsolidated subsidiaries and affiliates	1,111	1,111	_		
(4) Short-term loans payable	1,010	1,010	_		
(5) Income taxes payable	26,358	26,358	_		
(6) Bonds payable (*1)	30,000	30,390	390		
(7) Long-term loans payable (*2)	20,000	20,075	75		
Total liabilities	¥ 121,008	¥ 121,473	¥ 465		
Derivative transactions	¥ 181	¥ 181	¥ —		

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

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

_	Millions of yen				
	2015				
	Book values	Fair values	Difference		
(1) Cash and time deposits	¥ 30,553	¥ 30,553	¥ —		
(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 loans payable (*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 loans payable include the amount of current portion of long-term loans payable.

(1) Cash and time deposits

subsidiaries and affiliates

subsidiaries and affiliates

(7) Long-term loans payable (\*2)

(4) Short-term loans payable

(5) Income taxes payable

(6) Bonds payable (\*1)

Total liabilities

(4) Due from parent company, unconsolidated

(3) Due to parent company, unconsolidated

(5) Marketable securities and investment securities

(2) Trade notes

(3) Trade accounts

Total assets

(2) Trade accounts

(1) Trade notes

Sumitomo Dainippon Pharma Co., Ltd., and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

	2016					
	Book values		Fair values	Diffe	erence	_
	486,044	\$	486,044	\$	_	
	22,230		22,230		_	Ī
	931,999		931,999		_	
	429,319		429,319		_	
1	1,174,186		1,174,186		_	
3	3,043,778	\$ :	3,043,778	\$	_	Ī

823

375.540

9,832

8,938

233,257

268,938

177,655

1,602

\$ 1,074,983

\$

3.451

\$4,115

\$

664

Thousands of U.S. dollars

\$ 3,043

823

375.540

9,832

8.938

233,257

265,487

176,991

\$ 1,070,868

\$

Derivative transactions	Ψ	1,002
(*1) Bonds payable include the amount of current portion of long-terr	n bonds	payable.

<sup>(\*2)</sup> Long-term loans payable include the amount of current portion of long-term loans 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)Short-term loans payable, (5) Income taxes payable
  - The fair value of these liabilities due within a year is approximately equal to book value.
- (6) Bonds payable
  - The fair value of corporate bonds is calculated according to market price
- (7) Long-term loans payable

The fair value of long-term loans payable 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."

(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			
	Millions	Millions of yen		
	2016	2015	2016	
Unlisted shares	¥ 6,355	¥ 8,319	\$ 56,239	
Investment in unconsolidated subsidiaries and affiliates	1,819	1,709	16,097	
Investment in limited partnership	614	1,830	5,433	

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

	ivillions of yen			
	2016			
	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years
Cash and time deposits	¥ 54,923	¥ —	¥ —	¥ —
Trade notes	2,512	_	_	_
Trade accounts	105,316	_	_	_
Due from parent company, unconsolidated subsidiaries and affiliates	48,513	_	_	_
Marketable securities and investment securities:				
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)	11,100	_	_	_
Total	¥ 222,364	¥ —	¥ —	¥ —

	Millions of yen 2015			
	Within 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	¥ 229,028	¥ —	¥ —	¥ 49

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

	Thousands of U.S. dollars				
	2016				
	\	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years
Cash and time deposits	\$	486,044	\$ —	\$ <b>-</b>	\$ -
Trade notes		22,230	_	_	_
Trade accounts		931,999	_	_	_
Due from parent company, unconsolidated subsidiaries and affiliates		429,319	_	_	_
Marketable securities and investment securities:					
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)		98,230	_	_	_
Total	\$ -	1,967,822	\$ —	\$ —	\$ —

### 6. MARKETABLE SECURITIES AND INVESTMENT SECURITIES

Marketable securities and investment securities as of March 31, 2016 and 2015 consisted of the following:

	Millions	Thousands of U.S. dollars	
	2016	2015	2016
Current:			
Government / local government bonds	¥ –	¥ 6,268	\$ -
Corporate bonds	_	11,817	_
Negotiable certificates of deposits	11,100	27,424	98,230
MMF	69,939	65,784	618,929
Total	¥ 81,039	¥111,293	\$ 717,159
Noncurrent:			
Equity securities	¥ 51,644	¥ 46,287	\$ 457,027
Trust fund investments and other	_	49	_
Total	¥ 51,644	¥ 46,336	\$ 457,027

The carrying amount and aggregate fair value of marketable securities and investment securities as at March 31, 2016 and 2015 were as follows:

		Millions of yen				
		2016				
	Cost	Unrealized gains	Unrealized losses	Fair value		
Available-for-sale securities:						
Equity securities	¥ 15,811	¥ 36,017	¥ 184	¥ 51,644		
Government / local government bonds	_	_	_	_		
Corporate bonds	_	_	-	_		
Other securities	_	_	_	_		

		Millions of yen					
		2015					
	Cost	Unrealized gains	Unrealized losses	Fair value			
Available-for-sale securities:							
Equity securities	¥ 14,444	¥ 31,844	¥ 1	¥ 46,287			
Government / local government bonds	6,268	_	0	6,268			
Corporate bonds	11,820	0	3	11,817			
Other securities	31	18	0	49			

	Thousands of U.S. dollars					
	2016					
	Cost	Unrealized gains	Unrealized losses	Fair value		
Available-for-sale securities:				_		
Equity securities	\$ 139,920	\$ 318,735	\$ 1,628	\$ 457,027		
Government / local government bonds	_	_	_	_		
Corporate bonds	_	_	_	_		
Other securities	_	_	_	_		

Proceeds from sales of available-for-sale securities were ¥6,383 million (\$56,487 thousand) and ¥2,908 million for the years ended March 31, 2016 and 2015, respectively. Realized gains from sales of available-for-sale securities were ¥6,107 million (\$54,044 thousand) and ¥36 million for the years ended March 31, 2016 and 2015, and costs on sales of available-for-sale securities were ¥276 million (\$2,442 thousand) and ¥2,872 million for the years ended March 31, 2016 and 2015, respectively. The cost of securities sold when computing realized gains was determined using the moving average method.

On March 31, 2016, investment securities of ¥52 million (\$460 thousand) were pledged as collateral for accounts payable of ¥77 million (\$681 thousand). On March 31, 2015, investment securities of ¥67 million were pledged as collateral for accounts payable of ¥82 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.

Derivative transactions as of March 31, 2016 were as follows:

1) Currency related derivative transactions for which hedge accounting is not applied

	Millions of yen			Thousands of U.S. dollars					
		Contract	amounts			Contract a	Contract amounts		
Tra	ansaction type	Total	Portion over 1 year	Fair value	Valuation difference	Total	Portion over 1 year	Fair value	Valuation difference
Foreign ex forward co	•								
S	Sell contracts								
	USD	¥ 15,692	¥ —	¥ 201	¥ 201	\$138,867	\$ <i>—</i>	\$ 1,779	\$ 1,779
	Γotal	¥ 15,692	¥ —	¥ 201	¥ 201	\$138,867	\$ <i>—</i>	\$ 1,779	\$ 1,779

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

2) Currency related derivative transactions to which hedge accounting is applied

Main items hedged by foreign forward exchange forward contracts are trade accounts payable.

	Millions of yen				Thousands of U.S. dollars			
		Contract	amounts		Contract amounts			
Trans	saction type	Total	Portion over 1 year	Fair value	Total	Portion over 1 year	Fair value	
	eign exchange vard contracts Buy contracts							
	USD	¥ 2,321	_	¥ (22)	\$ 20,540	_	\$ (195)	
	EUR	481	_	2	4,257	_	18	
-	THB	139	_	(0)	1,230	_	(0)	
	Total	¥ 2,941	_	¥ (20)	\$ 26,027	_	\$ (177)	

The following foreign exchange forward contracts meet certain conditions and their corresponding hedged items are stated by the forward exchange contract rates. Main items hedged by foreign exchange forward contracts are trade accounts payable, and their fair values are included in those of their hedged items in the notes of "5.Financial instruments".

		Millions of yen Thousands of U.S. dollars			ars		
		Contract	amounts		Contract amounts		
Trans	saction type	Total	Portion over 1 year	Fair value	Total	Portion over 1 year	Fair value
	eign exchange vard contracts Buy contracts						
	USD	¥ 491	_	_	\$ 4,345	_	_
	EUR	55	_	_	487	_	_
	GBP	5	_	_	44	_	_
	THB	10	_	_	89	_	_
	Total	¥ 561	_	_	\$ 4,965	_	_

Derivative transactions as of March 31, 2015 were as follows:

- 1) Currency related derivative transactions to which hedge accounting is not applied Not applicable.
- 2) Currency related derivative transactions to which hedge accounting is applied Main items hedged by foreign exchange forward contracts are trade accounts payable.

	Millions of yen				
	Contract				
Transaction type	Total Portion over 1 year		Fair value		
Foreign exchange forward contracts					
Buy contracts					
USD	¥ 2,014	_	¥ 12		
EUR	250	_	(10)		
THB	150	_	0		
Total	¥ 2,414	_	¥ 2		

The following foreign exchange forward contracts meet certain conditions and their corresponding hedged items are stated at the forward exchange contract rates. Main items hedged by foreign exchange forward contracts are trade accounts payable, and their fair values are included in those of their hedged items in the notes of "5. Financial instruments".

Millions of yen				
Contract	amounts			
Total	Portion over 1 year	Fair value		
¥ 639	_	_		
75	_	_		
2	_	_		
17	_	_		
¥ 733	_	_		
	¥ 639 75 2 17	Contract amounts		

### 8. SHORT-TERM **LOANS PAYABLE AND LONG-TERM DEBT**

Short-term loans payable consisted of unsecured loans from banks bearing interest at a rate of 1.2% at March 31, 2016.

Long-term debt at March 31, 2016 and 2015 were as follows:

	Millions	s of yen	U.S. dollars
	2016	2015	2016
Unsecured loans from banks and financial institutions, due 2015 to 2017 with average interest rate of 0.4–1.2%	¥ 20,000	¥ 26,522	\$ 176,990
Unsecured bonds due 2016 with average interest rate of 0.78%	_	30,000	_
Unsecured bonds due 2016 with average interest rate of 0.54%	10,000	10,000	88,496
Unsecured bonds due 2017 with average interest rate of 1.11%	10,000	10,000	88,496
Unsecured bonds due 2018 with average interest rate of 0.82%	10,000	10,000	88,496
Total	¥ 50,000	¥ 86,522	\$ 442,478
Less current portion	(22,000)	(36,522)	(194,690)
Long-term debt, less current portion	¥ 28,000	¥ 50,000	\$ 247,788

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

Year Ending March 31	Millions of yen	Thousands of U.S. dollars
2017	¥ 22,000	\$ 194,690
2018	18,000	159,292
2019	10,000	88,496
Total	¥ 50,000	\$ 442,478

Other liabilities include deposits received from customers in the amount of ¥5,991 million (\$53,018 thousand) as of March 31, 2016, bearing interest at an average rate of 4.86%, and ¥5,756 million as of March 31, 2015, bearing interest at an average rate of 4.29%.

Thousands of

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

### 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 33.0% and 35.6% for the years ended March 31, 2016 and 2015 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, 2016 and 2015 were as follows:

Thousands of

	Millions	of yen	Thousands of U.S. dollars
	2016	2015	2016
Deferred tax assets:			
Accrued bonuses to employees	¥ 3,539	¥ 2,216	\$ 31,319
Reserve for sales rebates	16,579	13,270	146,717
Accrued enterprise taxes	1,874	252	16,584
Liability for retirement benefits	4,966	4,315	43,947
Loss on devaluation of investment securities	626	587	5,540
Research and development costs	8,171	9,546	72,310
Inventories	4,813	2,698	42,593
Net operating loss carried forward	6,964	3,003	61,628
Amortization of intangible assets	12,686	14,388	112,265
Tax credit for research and development costs of overseas subsidiaries	3,107	6,298	27,496
Unrealized gain on inventories	25,024	2,826	221,451
Other	11,237	13,921	99,442
Gross deferred tax assets	99,586	73,320	881,292
Valuation allowance	(11,904)	(7,586)	(105,345)
Total deferred tax assets	¥ 87,682	¥ 65,734	\$ 775,947
Deferred tax liabilities:			
Unrealized gains on available-for-sale securities	¥ (10,980)	¥ (10,246)	\$ (97,168)
Deferred gain on sales of fixed assets	(697)	(766)	(6,168)
Tax effect of intangible assets related to business combination	(24,735)	(26,966)	(218,894)
Refund of capital surplus of a subsidiary	(405)	(426)	(3,584)
Undistributed earnings of foreign subsidiaries	(311)	(381)	(2,752)
Other	(457)	(643)	(4,044)
Total deferred tax liabilities	¥ (37,585)	¥ (39,428)	\$ (332,610)
Net deferred tax assets	¥ 50,097	¥ 26,306	\$ 443,337

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, 2016 and 2015 was as follows:

	2016	2015
Normal statutory tax rate	33.0%	35.6%
Increase (decrease) in taxes due to:		
Expenses not deductible for tax purposes	4.8	6.6
Non-taxable dividend income	(0.4)	(0.9)
Tax credits for research and development costs	(14.9)	(8.8)
Amortization of goodwill	5.0	5.7
Change in valuation allowance	8.8	5.2
Effect of revised corporate tax rate	3.0	6.4
Tax effects attributable to investments in subsidiaries	(0.2)	0.5
Other	(1.5)	3.9
Effective tax rate	37.6%	54.2%

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

The liability for retirement benefits as at March 31, 2016 and 2015 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	U.S. dollars
	2016	2015	2016
Balance at the beginning of the fiscal year	¥ 92,042	¥ 83,703	\$ 814,531
Cumulative effects of changes in accounting policies	_	308	_
Restated balance	92,042	84,011	814,531
Service cost	3,408	3,145	30,159
Interest cost	920	1,260	8,142
Actuarial gain	144	7,218	1,274
Benefits paid	(3,632)	(3,602)	(32,142)
Other	30	10	266
Balance at the end of fiscal year	¥ 92,912	¥ 92,042	\$ 822,230

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

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Balance at the beginning of the fiscal year	¥ 78,529	¥ 74,485	\$ 694,947
Expected return on plan assets	1,443	1,377	12,770
Actuarial gain	(2,786)	3,074	(24,655)
Contributions paid by the employer	2,296	2,403	20,319
Benefits paid	(2,729)	(2,810)	(24,151)
Balance at the end of the fiscal year	¥ 76,753	¥ 78,529	\$ 679,230

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

	Millions	Millions of yen	
	2016	2015	2016
Balance at the beginning of the fiscal year	¥ (174)	¥ (12)	\$ (1,540)
Retirement benefit costs	172	(128)	1,522
Benefits paid	(37)	(2)	(327)
Contributions paid by the employer	(44)	(41)	(389)
Other	16	9	141
Balance at the end of the fiscal year	¥ (67)	¥ (174)	\$ (593)

Thousands of

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

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

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Funded retirement benefit obligations Plan assets	¥ 79,348 (78,323)	¥ 78,150 (80,085)	\$ 702,195 (693,124)
	1,025	(1,935)	9,071
Unfunded retirement benefit obligations	15,067	15,274	133,336
Total Net liability (asset) for retirement benefits at the end of the fiscal year	16,092	13,339	142,407
Liability for retirement benefits Asset for retirement benefits	16,159 (67)	15,274 (1,935)	143,000 (593)
Total Net liability (asset) for retirement benefits at the end of fiscal year	¥ 16,092	¥ 13,339	\$ 142,407

Note: Includes plan applied simplified method.

### 5) Retirement benefit costs

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Service cost	¥ 3,408	¥ 3,145	\$ 30,159
Interest cost	920	1,260	8,142
Expected return on plan assets	(1,443)	(1,377)	(12,770)
Net actuarial loss amortization	1,587	836	14,044
Past service costs amortization	(366)	(336)	(3,239)
Retirement benefit costs applied simplified method	172	(128)	1,522
Other	468	_	4,142
Total retirement benefit costs for the fiscal year	¥ 4,746	¥ 3,400	\$ 42,000

Other than those above, the Company recorded ¥613 million (\$5,425 thousand) and ¥1,551 million of special retirement benefit for the years ended March 31, 2016 and 2015 respectively.

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

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Past service costs	¥ (366)	¥ (336)	\$ (3,239)
Actuarial gains and losses	(1,342)	(3,308)	(11,876)
Total	¥ (1,708)	¥ (3,644)	\$ (15,115)

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

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Unrecognized past service costs	¥ (1,420)	¥ (1,786)	\$ (12,566)
Unrecognized actuarial gains and losses	9,821	8,479	86,911
Total	¥ 8,401	¥ 6,693	\$ 74,345

### 8) Plan assets

i) Plan assets comprise:

I) FIAN ASSELS COMPINSE.		
, rial accord complice.	2016	2015
Bonds	54.3%	45.5%
Equity securities	14.0%	15.2%
Cash and cash equivalents	5.1%	14.5%
General account	10.5%	11.4%
Other	16.1%	13.4%
Total	100.0%	100.0%

Millions of yen

Note: "Other" mainly consists of investment trust.

Retirement benefit trusts set up for corporate pension plans account for 6.6 percent and 8.2 percent of total plan assets at March 31, 2016 and 2015, 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, 2016 and 2015 (expressed as weighted averages) were as follows:

	2016	2015
Discount rate	1.0%	1.0%
Long-term expected rate of return	2.0%	2.0%
Estimated salary increase rate	3.8 ~ 5.8%	3.8 ~ 5.8%

### 2. Defined contribution plans

The amount of required contributions to the defined contribution plans of the Company and consolidated subsidiaries was ¥2,992 million (\$26,478 thousand) and ¥2,624million for the years ended March 31, 2016 and 2015, 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.

At the annual shareholders' meeting held on June 23, 2016, the shareholders approved year-end cash dividends of ¥9.00 (\$0.08) per share, amounting to ¥3,576 million (\$31,646 thousand). These appropriations have not been accrued in the consolidated financial statements as of March 31, 2016. 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 (\$0.16) per share.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

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, 2016 and 2015 were as follows:

	Millions of yen		U.S. dollars
	2016	2015	2016
Sales	¥ 268	¥ 258	\$ 2,372
Purchases	7,633	8,210	67,549

# 13. RELATED PARTY TRANSACTIONS

Major transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., for the years ended March 31, 2016 and 2015 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Purchases of products	¥ 3,673	¥ 3,902	\$ 32,504
Payment of other expenses	1,138	1,209	10,071
Loans	2,089	546	18,487
Interest income	292	204	2,584

The balances due to or from the parent company, Sumitomo Chemical Co., Ltd., as at March 31, 2016 and 2015 were as follows:

	Millions of yen		U.S. dollars
	2016	2015	2016
Receivables	¥ 48,553	¥ 49,154	\$429,673
Payables	666	1,034	5,894

### 14. LEASES

The minimum lease payments under non-cancelable operating leases as of March 31, 2016 and 2015 were as follows:

	Millions of yen		U.S. dollars
	2016	2015	2016
Due within one year	¥ 1,010	¥ 924	\$ 8,938
Due after one year	6,656	8,273	58,903
Total	¥ 7,666	¥ 9,197	\$ 67,841

Thousands of

# 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.

As described in Note 2 (r), the Group changed the accounting estimates for retirement benefits. When accounting for retirement benefits, actuarial gains and losses and past service costs were previously amortized over 15 years but are now amortized over 14 years, effective from the year ended March 31, 2016, due to a decrease in the employees' average remaining years of service. As a result, the effects of the change of accounting estimates decreased the "Income of segment" of "Japan" by ¥301 million (\$2,664 thousand), "North America" by ¥6 million (\$53 thousand), "China" by ¥2 million (\$18 thousand), and "Other regions" by ¥4 million (\$35 thousand) respectively.

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

Segment information for the Group for the years ended March 31, 2016 and 2015 were as follows:

		Millions of yen									
				2016							
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total				
Net sales											
Sales to customers	¥ 146,492	¥ 184,869	¥ 18,374	¥ 11,189	¥ 360,924	¥ 42,282	¥ 403,206				
Intersegment sales and transfers	142	_	_	_	142	77	219				
Total	146,634	184,869	18,374	11,189	361,066	42,359	403,425				
Income of segment	41,535	65,155	7,992	2,446	117,128	1,821	118,949				
Others											
Depreciation and amortization	4,353	3,735	421	422	8,931	152	9,083				
Amortization of Goodwill	_	5,980	_	_	5,980	_	5,980				

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						
	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			
Amortization of Goodwill	_	5,446	_	_	5,446	_	5,446			

		Thousands of U.S. dollars									
				2016							
	Japan	Japan North America China Other Regions Subtotal Other Business Tota									
Net sales											
Sales to customers	\$ 1,296,389	\$ 1,636,009	\$ 162,602	\$ 99,018	\$ 3,194,018	\$ 374,177	\$ 3,568,195				
Intersegment sales and transfers	1,256	_	_	_	1,256	682	1,938				
Total	1,297,645	1,636,009	162,602	99,018	3,195,274	374,859	3,570,133				
Income of segment	367,566	576,593	70,726	21,646	1,036,531	16,115	1,052,646				
Others											
Depreciation and amortization	38,522	33,053	3,726	3,734	79,035	1,346	80,381				
Amortization of Goodwill		52,920	_	_	52,920	_	52,920				

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

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

in the consolidated financial statements			Thousands of
	Millions	s of yen	U.S. dollars
Net sales	2016	2015	2016
Reportable segments total	¥ 361,066	¥ 330,805	\$ 3,195,274
Net sales of "Other Business" category	42,359	40,760	374,859
Elimination of intersegment transactions	(219)	(194)	(1,938)
Net sales in the consolidated statements of income	¥ 403,206	¥ 371,371	\$ 3,568,195
	Millions	s of yen	Thousands of U.S. dollars
Income	2016	2015	2016
Reportable segments total	¥117,128	¥ 92,372	\$ 1,036,531
Income of "Other Business" category	1,821	2,207	16,115
Research and development costs	(82,034)	(71,304)	(725,965)
Elimination of intersegment transactions	15	0	133
Operating income in the consolidated			
statements of income	¥ 36,930	¥ 23,275	\$ 326,814
	Millions	s of yen	Thousands of U.S. dollars
Other items	2016	2015	2016
Depreciation and amortization			
Reportable segments total	¥ 8,931	¥ 8,312	\$ 79,035
Other Business	152	202	1,346
Adjustment	3,561	3,332	31,513
The amount in the consolidated financial statements	¥ 12,644	¥ 11,846	\$ 111,894
Amortization of goodwill			
Reportable segments total	¥ 5,980	¥ 5,446	\$ 52,920
Other Business	_	_	_
Adjustment	_	_	_
The amount in the consolidated financial statements	¥ 5.980	¥ 5.446	\$ 52.920

### 5) Other information

Sales information by product or service for the Group for the years ended March 31, 2016 and 2015 were as follows:

	Millions	U.S. dollars	
Sales to customers	2016	2015	2016
Pharmaceuticals	¥ 360,924	¥ 330,673	\$ 3,194,018
Other products	42,282	40,698	374,177
Total	¥ 403,206	¥ 371,371	\$ 3,568,195

Geographical segment information for the Group for the years ended March 31, 2016 and 2015 were as follows:  $_{\text{Thousands of}}$ 

	Millions of yen				
Net sales	2016	2015	2016		
Japan	¥ 190,156	¥ 198,560	\$ 1,682,796		
U.S.	181,085	144,792	1,602,522		
Other regions	31,965	28,019	282,877		
Total	¥ 403,206	¥ 371,371	\$ 3,568,195		

Duran out a relevat and a suring so eat	Millions	Thousands of U.S. dollars		
Property, plant and equipment	2016	2015	2016	
Japan	¥ 51,852	¥ 54,151	\$ 458,867	
U.S.	8,513	9,176	75,336	
Other regions	1,460	1,833	12,921	
Total	¥ 61,825	¥ 65,160	\$ 547,124	

lateraile accets	Millions	U.S. dollars		
Intangible assets	2016	2015	2016	
Japan	¥ 8,792	¥ 9,583	\$ 77,805	
U.S.	147,241	163,302	1,303,018	
Other regions	548	978	4,849	
Total	¥ 156,581	¥ 173,863	\$ 1,385,672	

Sales information by major customer for the Group for the years ended March 31, 2016 and 2015 were as follows:

Net sales	Millions	U.S. dollars	
Name of major customer and related segment	2016	2015	2016
McKesson Corporation / North America	¥ 62,474	¥ 46,561	\$ 552,867
Cardinal Health Inc. / North America	47,778	36,024	422,814
AmerisourceBergen Corporation / North America	42,168	34,573	373,168

### 6) Information on impairment loss of non-current assets, amortization and unamortized balance of goodwill by reportable segment.

					Millions of yen					
					2016					
	Japan	Nor	th America	China	Other Regions	Su	btotal	Other Busine	SS	Total
Impairment loss	¥ 33	¥	263	¥ —	¥ —	¥	296	¥ 257	¥	553
Amortization of goodwill	_		5,980	_	-		5,980	_		5,980
Balance of goodwill	_		76,950	_	_	7	6,950	_		76,950
					Millions of yen					
					2015					

		2015										
	Japan	Nort	h 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	_	8	38,075	_	_	88,075	_	88,075				

		Thousands of U.S. dollars										
		2016										
	Japan	Japan North America China Other Regions Subtotal Other Business Total										
Impairment loss	\$ 292	2 \$	2,328	\$ <b>—</b>	\$ —	\$ 2,620	\$ 2,274	\$ 4,894				
Amortization of goodwill	_		52,920	_	_	52,920	_	52,920				
Balance of goodwill	_	- 6	80,973	_	_	680,973	_	680,973				

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2016 and 2015

### 16. IMPAIRMENT LOSS

Impairment loss of tangible assets and intangible assets for the years ended March 31, 2016 was as follows:

			Millions of yen	Thousands of U.S. dollars
Usage for	Item	Location	2016	2016
Production facilities	Buildings and structures, etc.	Japan	¥ 257	\$ 2,274
Research and development with respect to compound in development	In-process research and development	U.S.A	152	1,345
Sales facilities	Construction in progress for software	U.S.A	111	983
Idle assets	Machinery, equipment and carriers etc.	Japan	33	292

One of the subsidiaries impaired the book value of its production facilities after measuring the recoverable amount based on value-in-use since the subsidiary has booked operating losses continuously.

In addition, the Company and its consolidated subsidiaries impaired the book value of idle tangible assets, as well as in-process research and development costs and intangible assets (Construction in progress for software) of which future economic benefits were expected to be less than the recoverable amount.

The recoverable amount of intangible assets (Construction in progress for software) and idle tangible assets was measured based on value-in-use, which was determined as zero.

The recoverable amount of in-process research and development costs was 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, 2015 was as follows:

			Millions of yen
Usage for	Item	Location	2015
Production facilities	Buildings and structures, Machinery, equipment and carriers, Construction in progress and Others	Japan	¥ 5,128
Research and development with respect to compound in development	In-process research and development	U.S.A	116
Idle assets	Land, Machinery, equipment and carriers	Japan	66

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%.

### 17. RESTRUCTURING

Restructuring carried out in the year ended March 31, 2016 was for the purpose of improving the business structure and organization in the Company.

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.

### **18. OTHER COMPREHENSIVE INCOME (LOSS)**

Components of other comprehensive income (loss) for the years ended March 31, 2016 and 2015 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Unrealized gains on available-for-sale securities			
Amount arising during the period under review	¥ 10,358	¥ 9,687	\$ 91,664
Reclassification adjustment for gains (losses) included in net income	(7,430)	(1,966)	(65,752)
Before income tax effect adjustment	2,928	7,721	25,912
Amount of income tax effect	(734)	(1,870)	(6,496)
Unrealized gains on available-for-sale securities, net of tax	¥ 2,194	¥ 5,851	\$ 19,416
Deferred gains or losses on hedges			
Amount arising during the period under review	¥ (22)	¥ 3	\$ (194)
Amount of income tax effect	7	0	62
Deferred gains or losses on hedges	¥ (15)	¥ 3	\$ (132)
Foreign currency translation adjustment			
Amount arising during the period under review	¥ (20,002)	¥ 41,379	\$ (177,009)
Foreign currency translation adjustment	(20,002)	41,379	(177,009)
Remeasurements of defined benefit plans			
Amount arising during the period under review	¥ (2,929)	¥ (4,144)	\$ (25,920)
Reclassification adjustment for gains (losses) included in net income	1,221	500	10,805
Before income tax effect adjustment	(1,708)	(3,644)	(15,115)
Amount of income tax effect	413	1,071	3,654
	¥ (1,295)		
Remeasurements of defined benefit plans  Total other comprehensive income (loss)	. , ,	¥ (2,573)	+ (,,
Total other comprehensive income (ioss)	¥ (19,118)	¥ 44,660	\$ (169,186)

### 19. CONTINGENT LIABILITIES

Contingent liabilities for guarantees as of March 31, 2016 and 2015 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Guarantees of indebtedness — Bank loans guaranteed for an affiliate	¥ _	¥ 3	\$ _
Loans guaranteed — Employee's housing loans guaranteed	101	109	894

# 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, 2016 and 2015, 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, 2016 and 2015, 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, 2016 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.

June 23, 2016 Osaka, Japan

KPMG AZSALLC

# Shareholder Data

### **Principal Shareholders**

(As of March 31, 2016)

Name	No. of Shares Held (Thousands of Shares)	
Sumitomo Chemical Co., Ltd.	199,434	50.20
Inabata & Co., Ltd.	27,282	6.87
The Master Trust Bank of Japan, Ltd. (Trust account)	16,373	4.12
Japan Trustee Services Bank, Ltd. (Trust account)	10,018	2.52
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
NORTHERN TRUST CO. (AVFC) RE U.S. TAX EXEMPTED PENSION FUNDS	4,310	1.08
Sumitomo Dainippon Pharma Employee shareholders' association	4,248	1.07

Securities Companies
1.23%

Individuals and Others
8.20%

Foreign Corporations
10.52%

Financial Institutions
20.12%

Other Domestic Corporations

59.78%

**Composition of Shareholders** 

(As of March 31, 2016)

Note: Percentage of shareholding is calculated excluding treasury stock (598,599 shares).

### **Share Price Range and Trading Volume**

(Thousands of shares) 2,000 Share Price Trading Volume 90,000 75,000 1,500 60,000 1,000 45,000 30,000 500 15,000 0 Aug. Dec. Feb. Aug. Oct. Dec. Feb. Mar. Apr. Jun. Oct. Apr. Jun. 2014 2015 2016



Corporate Data	As of April 1.	2016

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: +81-3-5159-2948
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), 15 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)



IR Site

http://www.ds-pharma.co.jp/ir/



**CSR Site** 

http://www.ds-pharma.co.jp/csr/





MSCI (2016 Constituent MSCI Global Sustainability Indexes



