

Securities Code 4506

Annual Report 2017

# Innovation today, healthier tomorrows



Sumitomo Dainippon Pharma Co., Ltd.

### Profile

**Company Overview** Sumitomo Dainippon Pharma Co., Ltd. was established in October 2005 through the merger of Dainippon Pharmaceutical Co., Ltd. and Sumitomo Pharmaceuticals Co., Ltd. with the aim of broadly contributing to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide. The spirit of these two companies has been passed on to Sumitomo Dainippon Pharma. While striving to be a cutting-edge pharmaceutical company with a strong market presence, we will continue to provide innovative and effective pharmaceutical solutions to people not only in Japan, but also around the world.

# Corporate MissionTo broadly contribute to society through value creation based on<br/>innovative research and development activities for the betterment<br/>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

55.3% **Ratio of Overseas Sales** 11 countries **Countries with Business Operations** (Own sales channel) **Research and Development Costs** billion 416

Net Sales

Late-Stage Development Products

No. of Participants in Social Contribution Activities billion

# Snapshot 2016

We achieved record-high net sales and operating income.

Additionally, acquisition activities enhanced our pipeline in the areas of Psychiatry & Neurology, as well as Oncology, while we made strategic growth investments for when the exclusivity period of LATUDA<sup>®</sup> expires.



From April 2015, we started a ONE TEAM operating structure for the Global Clinical Development (GCD) organization, which unifies Sumitomo Dainippon Pharma and Sunovion Pharmaceuticals Inc. Under this cooperative structure, we are pursuing GCD that allows simultaneous new drug application submission in Japan and the U.S., while accelerating development of late-stage development products.





Tolero Pharmaceuticals CEO David J. Bearss explaining the hematologic malignancies treatment pipeline at an R&D meeting

### Enhanced pipeline from acquisitions and in-licensing

The acquisition of Cynapsus Therapeutics Inc. (Canada) added to our pipeline sublingual apomorphine hydrochloride, under development as a treatment for OFF episodes associated with Parkinson's disease, and the acquisition of Tolero Pharmaceuticals, Inc. (U.S.) added alvocidib, under development as a hematologic malignancies treatment. We aim to bring these compounds to market in fiscal 2018-2019.

Additionally, Sunovion Pharmaceuticals Inc. entered into an exclusive license agreement with Novartis for the U.S. commercialization rights to three treatments for chronic obstructive pulmonary disease (COPD).

#### LATUDA® sets a new record for North American sales

LATUDA®, which grew into a blockbuster drug surpassing annual sales of US\$ 1 billion in North America in fiscal 2015, continued to post strong results in fiscal 2016, recording sales of US\$ 1.25 billion. This was a new record high for sales.

E Latuda

20 mg



### Snapshot 2016

# Contributing to global health

We participate in "Access Accelerated", the first global partnership activity among global pharmaceutical companies to improve access to healthcare in developing countries. The partnership is focused on improving access to prevention, treatment, and care of non-communicable diseases (NCDs), such as cancers and cardiovascular diseases, in low- and middle-income countries where nearly 80% of NCD-related deaths occur.



http://www.accessaccelerated.org/

## WE BELIEVE THAT A LIFE NOT DEFINED BY DISEASE IS A LIFE OF POSSIBILITY

Moving NCD Care Forward

### WE BELIEVE THAT A LIFE **NOT DEFINED BY DISEASE** IS A LIFE OF **POSSIBILITY**

Moving NCD Care



### Enhancing programs supporting work-life balance

In October 2015, we introduced a Paternity and Child Care Leave System for men (dubbed "Good Daddy Leave"). In order to encourage men to participate in child care, the new system allows male employees to take up to five days of leave during the period up until their child turns one. The system, which is easy to use and allows non-contiguous days off, has a 100% utilization rate among eligible employees (during the period from October 2015 to the end of March 2017).





### Achieved

### record-high net sales and operating income

North American income for LATUDA®, BROVANA®, and APTIOM® all made strong gains. In Japan, the strategic products AIMIX®, TRERIEF®, and Trulicity® showed steady results and we achieved record highs for Group net sales and operating income in fiscal 2016.

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### P.27 *Focus* Enhanced Pipeline from In-licensing and Acquisitions

We strive to enhance our pipeline, which sustains our future business, through new in-licensing, acquisitions, and reevaluating in-house projects.

#### P.29 Production and Quality Control



#### Editorial Policy

#### Applicable Period

This report is based on the results for fiscal 2016 (April 1, 2016 to March 31, 2017). Some of the activities described were conducted in fiscal 2017.

#### 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.

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

The Sumitomo Dainippon Pharma Group's active initiatives on issues, including development of a governance system, responses to environmental problems, and initiatives toward social problems have been highly evaluated. We have been selected for indices for socially responsible investment that include the FTSE4Good Index Series, the MSCI Global Sustainable Indexes, and the Morningstar Socially Responsible Investment Index. Please see p. 100 for related details. (As of July 2017)

- FTSE4Good Index Series
- FTSE Blossom Japan Index
- MSCI Global Sustainability Indexes
- MSCI Japan ESG Select Leaders Index
- MSCI Japan Empowering Women Index (WIN)
- Morningstar Socially Responsible Investment Index
- SNAM Sustainability index

#### Business Model — Value Creation Process

# **Business Model for Value Creation**

Sumitomo Dainippon Pharma will continue to organically integrate our capital resources, pursue innovative processes in all of our businesses, and create value.

At the same time, we spell out the social responsibilities that each process needs to fulfill as we address CSR.

#### Social issues

#### Value creation process

#### Unmet medical needs

There are unmet medical needs, including diseases for which no therapeutics exist as well as diseases for which therapeutics are not fully satisfactory.

### Issues related to healthcare access

There are regions and countries where residents do not have equal access to necessary healthcare for reasons including poverty and inadequate healthcare systems.

### Sources of value creation

#### 🔐 Financial capital

• Stable and robust financial base, primarily from Japan and North America

### Manufactured capital

- Production bases able to engage in stable manufacturing
- Research laboratories with leading-edge technology
- Global supply chain

#### 😥 Intellectual capital

- Patents, licenses, and other intellectual property
- Research and development capabilities for discovering new pharmaceuticals

#### Human capital

- Fostering human resources to take on the challenges of the future (DSP Academy)
- Promoting diversification targeting active participation by a varied work force
- Striving to improve employee satisfaction (DSP Opinion)

### Social and relationship capital

- Trust from patients and general public
- Trust from medical institutions and business partners

#### A Natural capital

- Environmental resources related to our business activities
- Initiatives to minimize environmental burdens from our business activities

#### **Business activities**

#### Research & development for details

- Focus therapeutic areas: Psychiatry & Neurology and Oncology. Also focus on disease fields where no approved drugs exist, in addition to the Regenerative Medicine and Cell Therapy field
- Research activity striving to discover innovative pharmaceuticals through our research laboratories (with their leading-edge technology) and through active collaboration with research institutions inside and outside Japan
- Under our ONE TEAM operating structure for Global Clinical Development linking our Japan and U.S. units, conduct efficient development focused on late-stage clinical development products

#### Marketing



- Japan: Further strengthen sales capacity in focus areas, and build a highly efficient sales organization that can flexibly respond to changing local healthcare
- North America: further growth for antipsychotic agent LATUDA® and antiepileptic APTIOM®, and expand sales in the Chronic Obstructive Pulmonary Disease (COPD) area by launching new products
- China: maximize profits from existing products and establish a highly efficient business foundation



CSR Management See p. 51 for details

#### Value provided to society



Corporate regulatory See p. 31 for details.

- Quality assurance system for delivering safety worldwide
- Prompt responses to inquiries using unique Quality Information System
- Promoting global safety management and proper usage of products



Corporate Governance



Social and relationship

Countries selling LATUDA<sup>®</sup> (own sales channel)

capital

11

#### Delivering pharmaceutical products in the Psychiatry & Neurology area and Oncology area

Delivering pharmaceutical products that contribute to the treatment of various diseases in the Psychiatry & Neurology area and in the Oncology area, where unmet medical needs are high

### Stably supplying high quality pharmaceuticals

Delivering high quality products and information that are generated in collaboration with the Manufacturing, Quality Assurance and Safety Management departments

# Contributing to the development of medical science through research and development activities

Generating further innovation through coordination with academia, venture companies, and other partners

### Contributing to Global Health

Striving to improve access to healthcare through coordination with government, international organizations, and research institutions, as well as with society and through in-house product R&D

### Financial and Non-Financial Highlights

# Financial and Non-Financial Highlights

**Financial Highlights** 









**Non-Financial Highlights** 

Number of Employees







Shareholders' Equity Ratio











Message from the President

## Aiming for medium- to long-term business growth, always looking one step ahead of the times

In fiscal 2016 (ended March 31, 2017), we achieved record-high net sales and profits, driven by steady increases in sales of our mainstay products such as the atypical antipsychotic LATUDA<sup>®</sup>, which posted sales of more than US\$1.2 billion in North America.

Going forward, we will continue to invest substantial effort into research and development of new drugs, focusing on the areas of Psychiatry & Neurology and Oncology. Concurrently, we will work on organizational reforms, strengthening human resources, making progress on fortifying our business foundation, including corporate governance, and aiming for medium- to long-term growth.

### Masayo Tada

Representative Director, President and Chief Executive Officer

#### Looking back over fiscal 2016 (ended March 31, 2017), how would you rate the Group's business performance?

#### We saw new records set in both sales and profit, thanks to steady growth in our North America business.

The consolidated financial results for fiscal 2016, which posted new records in sales and profit, recorded ¥411.6 billion in net sales, which was a 2.1% improvement year on year, ¥52.8 billion in operating income, up 42.9%, and ¥29.0 billion in net income attributable to owners of the parent. That represented a 17.4% improvement on the previous year's result. Regarding returns to shareholders, since we achieved our Mid-term Business Plan's ¥50 billion target for operating income a year ahead of schedule, we were able to add a ¥2 special dividend onto our ordinary dividend, for a total dividend per share of ¥20.

In fiscal 2016, LATUDA<sup>®</sup> surpassed US\$1.2 billion in North American sales, and we also saw strong sales gains for our antiepileptic drug APTIOM<sup>®</sup> and the long-acting beta-agonist BROVANA<sup>®</sup>. Not only did sales of these products rise, but selling costs shrank due to the impact of exchange rates, leading to a substantial increase of ¥18.1 billion in segment profit. In Japan, sales expanded for strategic and new products, including AIMIX<sup>®</sup>, a therapeutic agent for hypertension, TRERIEF<sup>®</sup>, a therapeutic agent for Parkinson's disease, and Trulicity, a GLP-1 receptor agonist. As a result, overall domestic performance surpassed that for the previous fiscal year on a volume basis; however, on a value basis, segment income declined ¥3.2 billion as a result of the impact of NHI price revisions. In China, although sales of our mainstay product MEROPEN<sup>®</sup>, a carbapenem antibiotic, grew and revenue improved on a yuan basis, exchange rate impacts led to lower revenue on a yen basis and segment income contracted by ¥1.2 billion.

In terms of R&D expenditure, higher development costs for napabucasin in Oncology, and higher development costs for late-stage development products accompanying acquisitions, led to material increases, though the effect of exchange rates resulted in an overall ¥1.2 billion decrease.

Consequently, whereas fiscal 2016 presented difficult circumstances in Japan and China due to NHI price revisions and the impact of exchange rates, solid growth in our North America business allowed us to achieve results in excess of our initial plans. I believe that this was due to the tireless efforts made by all of our Group directors and employees.

That said, within our industry, we still have not achieved a sufficiently high operating margin and we also face the so-called "LATUDA cliff," which is a decline in business performance due to the impending expiry in 2019 of the exclusivity period for LATUDA<sup>®</sup>. Hence, we will continue to focus serious attention on developing an effective "post-LATUDA" strategy and working hard to further strengthen our business foundation.

	1		1	(Billions of yen)
	FY2015	FY2016	Year o	on year
	result	result	Change	Rate of change (%)
Net sales	403.2	411.6	8.4	2.1
Operating income	36.9	52.8	15.8	42.9
Net income attributable to owners of the parent	24.7	29.0	4.3	17.4

#### What is your evaluation of activities 2 on the R&D front?

#### We made substantial progress on late-stage development products and significantly expanded our product pipeline through in-licensing and acquisitions.

In terms of clinical development, in Psychiatry & Neurology, we completed a pivotal study in the U.S. of dasotraline in attention-deficit hyperactivity disorder (ADHD) and we plan to submit an NDA in the second guarter of fiscal 2017 for adult and pediatric ADHD. Also with regard to dasotraline, we are moving ahead with our second pivotal study, again in the U.S., which is investigating binge eating disorder (BED) in adults. Our October 2016 acquisition of Cynapsus Therapeutics Inc. added to our pipeline APL-130277, which is currently undergoing, in the U.S., a Phase 3 study for management of OFF episodes associated with Parkinson's disease. We aim to submit an NDA in the second half of fiscal 2017. In Japan, since a primary endpoint was met in a Phase 3 study evaluating the effects of TRERIEF<sup>®</sup> in patients with parkinsonism in dementia with Lewy bodies (DLB), we plan to submit an sNDA in the first half of fiscal 2017. And, with regard to lurasidone, we are aiming to submit an NDA in Japan in fiscal 2019 for schizophrenia and bipolar disorder (depression/bipolar maintenance).

In Oncology, we initiated a new R&D framework in April 2017. Considering that the January 2017 acquisition of Tolero Pharmaceuticals, Inc. expanded the scope of our oncology business and increased the depth of human resources in

Oncology, we determined that we had reached the stage for transitioning to a new management framework focused on the Group's overall oncology business. Under the leadership of our newly established Global Head of Oncology, we are developing our Oncology-related business through collaboration among our divisions that focus on oncology, as well as Boston Biomedical, Inc. and Tolero Pharmaceuticals. As regards personnel, Kazuo Koshiya, who has experience managing businesses in Oncology, has been appointed Global Head of Oncology, while Patricia Andrews, who has management experience in oncology with major U.S. pharmaceutical manufacturers, has been appointed as the new CEO of Boston Biomedical. Former Boston Biomedical CEO Chiang Li will continue to provide R&D support in Oncology as Senior Special Oncology Advisor.

With regard to progress on research and development in Oncology, we decided in June 2017 to unblind our Phase 3 study of gastric and gastro-esophageal junction adenocarcinoma based on a recommendation by the study's independent Data and Safety Monitoring Board, which determined that the study was unlikely to reach its primary endpoint of superior overall survival. As the unexpected outcome does not directly negate the efficacy of napabucasin, other Phase 3 studies are ongoing, including colorectal cancer (Japan and U.S. NDAs targeted for FY2020) and pancreatic cancer (Japan and U.S. NDA targeted for FY2021). For alvocidib, which was added to our pipeline with the acquisition of Tolero Pharmaceuticals, we are carrying out a Phase 2 study in acute myeloid leukemia (AML) and aim to submit an NDA in the U.S. in fiscal 2018.

In the fields of Regenerative Medicine and Cell Therapy, we are advancing five projects: chronic stroke (allogeneic mesenchymal stem cells), age-related macular degeneration (allogeneic iPS cells), Parkinson's disease (allogeneic iPS cells),



New global oncology organization (changed April 2017)



retinitis pigmentosa (allogeneic iPS cells), and spinal cord injury (allogeneic iPS cells). Our Parkinson's disease project was designated as a "Sakigake Designation System" product by the Ministry of Health, Labour and Welfare in February 2017. We also started building a cell production and processing facility and we are proceeding to establish a manufacturing framework for full-fledged practical use and commercialization at an early date.

While aiming to bring "post-LATUDA" candidates to market, we are continuing with proactive research and development. With ¥88 billion budgeted for investment in R&D in fiscal 2017, our concerted efforts will be focused on late-stage development products. Also, with regard to acquisitions and new in-licensing in order to expand and enhance our pipeline, we estimate total investment of up to ¥150–200 billion. Whereas we focused these activities on North America in fiscal 2016, we plan to consider and implement them mainly in Japan in fiscal 2017.

#### Could you give us any details on key strategies for fiscal 2017 and the structure of the next Mid-term Business Plan?

Along with further strengthening our North America business and raising operational efficiency in Japan,we are continuing to review our long-term vision as we work toward formulating our next Mid-term Business Plan.

In fiscal 2017, we will dedicate our efforts to further growth in LATUDA<sup>®</sup> sales in North America, while also expanding sales of strategic products such as APTIOM<sup>®</sup> and BROVANA<sup>®</sup>. In addition, we intend to focus on growing sales of treatments for chronic obstructive pulmonary disease (COPD), including SUN-101, which is planned for launch during fiscal 2017, and three treatments in-licensed from Novartis: UTIBRON<sup>™</sup> NEOHALER<sup>®</sup>, SEEBRI<sup>™</sup> NEOHALER<sup>®</sup>, and ARCAPTA<sup>®</sup> NEOHALER<sup>®</sup>. We are continuing to leverage an efficient sales organization with a view to long-term growth. Meanwhile, within Japan, we will work to grow sales of promoted products while boosting productivity by in-licensing new products, collaborating with partners, and reforming work styles. We will also strive for increased operational efficiency through ongoing cost reductions and other measures.

With regard to our next Mid-term Business Plan, we have started discussing a five-year plan to cover fiscal years 2018 through 2022. We want to start by reaching a consensus as to the kind of company we want to be 15 years from now; then, we will incorporate into our next Mid-term Business Plan our first five-year strategy for achieving that shared vision.

#### Submission target Area Development FY2020-2022 FY2017 FY2018 FY2019 SEP-225289 (Adult, Pediatric ADHD) U.S <dasotraline> APL-130277 <apomorphine> (Parkinson's disease) U.S. **TRERIEF®** <zonisamide> (Parkinsonism in Dementia with Lewy Bodies) Japar Psychiatry SEP-225289 <dasotraline> (BED) U.S. Neurology LONASEN® <blonanserin> (Schizophrenia / Transdermal patch) Japan (Schizophrenia / Bipolar I depression / Bipolar maintenance) SM-13496 <lurasidone> **BBI608** <napabucasin> (Colorectal cancer / Combination therapy) U.S./ Japan Oncology **BBI608** (Pancreatic cancer / Combination therapy) U.S./ Japan <napabucasin>

#### Submission Target of Key Late-stage Pipeline (as of July 2017)

#### Q4 Could you give us some insight into your thinking and concrete initiatives for strengthening corporate governance and the business foundation?

For targeting increased medium- to long-term corporate value, we are building out our business foundation by strengthening our corporate governance system, promoting organizational reforms, and bolstering our human resources.

Also for targeting increased medium- to long-term corporate value, we are constantly working to fortify our corporate governance systems. In October 2015, we formulated the Basic Policy on Corporate Governance and, in April 2016, we established the Corporate Governance Department to effectively deploy that policy. In 2017, we added one Outside Director with the objective of facilitating sustainable growth and enhanced medium- to long-term corporate value by making our Board of Directors more diversified and by strengthening governance. We also formulated the DSP Group Risk Management Policy, in January 2017, in order to further coordinate our risk management system as a corporate group. We reorganized our risk management systems so that, according to the particularities of each risk, risks are divided into those requiring a horizontal, group-wide approach, and those requiring specific approaches by each company.



At the same time, in order to further fortify our business foundation, we are continually working both within and outside of Japan to bolster our organization and our human resources. In Japan, where the business environment is particularly difficult, we offered early retirement to employees and implemented measures to streamline our sales organization in fiscal 2016. In April 2017, we created the position of Global Head of Oncology as one step toward establishing a framework to strengthen our global oncology business. With regard to integrating our domestic production sites, we brought our initial plans forward and now expect to implement them by the end of fiscal 2018.

To strengthen our corporate foundation, we also introduced a new personnel system, effective April 2016. This system emphasizes employees' abilities to produce results and is a new measure for further developing our human resources. In addition to our existing managerial positions, we established a new career path for promotion of employees with a strong ability to produce results by leveraging their advanced expertise.

In terms of fostering human resources, we also created the DSP Academy, which is a career grade-specific training system. From young employees to mid-career employees and managers, personnel in four grades are selected for their ambition and potential, and then provided with training using case methods, action learning, and various other types of instruction.

#### Please tell us about your basic approach to CSR-based management and the initiatives that you have focused on in recent years.

Toward achieving our Corporate Mission, we are dedicating efforts to promoting employee "work style innovations" and contributing to global health.

Sumitomo Dainippon Pharma believes that the very objective of our CSR-based management is implementing our Corporate Mission to "broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." In April 2017, we revised our Declaration of Conduct, which is a set of guidelines to help each and every director and employee implement our mission. We are also working to enhance awareness throughout the Group about environmental changes in society and in our industry, and further reinforcing business ethics.

As one component of CSR-based management, we are

engaging in active dialogue with employees, who are also important stakeholders. For example, in fiscal 2016, we again conducted an opinion poll (DSP Opinion) of all employees with the aim of encouraging communication between management and employees. Following the survey, executives visited each division and created opportunities for direct dialogue with employees, including discussing opinions, etc. expressed in the survey. Going forward, we will continue to promote dialogue with employees and will work to energize our organization and personnel, while further disseminating our Corporate Mission and strategies.

We have positioned 2017 as "Year One for Work Style Innovations" and are promoting a variety of initiatives in this regard. In March 2017, we brought in an expert authority and held a seminar for all employees in order to deepen their understanding of work style innovations. Then, in April and May, we ran training sessions for all management rank employees in order to promote work style innovations at each work site.

In the case of Sumitomo Dainippon Pharma, our MRs mainly work outside of the office, while employees in our plants work according to the particular hours of operation for each production line. This creates large differences in both content and style of work depending on the job category. As a result, while we are promoting group-wide measures, such as no overtime days (aimed at addressing the issue of excessive working hours) and greater utilization of paid leave, specific approaches at each work site are also necessary, as are considerations of new work styles that can yield the greatest results within limited working hours. As a company, we are providing institutional support by establishing systems, etc. for these work site-specific approaches. For example, in June 2016, we launched a work-from-home system to support employees who are engaged in childcare or nursing care. We have plans to make more employees eligible for the system and to leverage it as a way to achieve higher employee productivity. Sumitomo Dainippon Pharma aims to maximize corporate value by promoting future work style innovations and achieving a virtuous cycle of work-life balance and greater productivity for employees.

Furthermore, we are committed to contributing to Global Health as part of our social responsibility as a pharmaceutical company. Since January 2017, we have participated in a program with 23 of the world's pharmaceutical companies collaborating to improve access to healthcare in developing countries. In September 2016, we began collaborating with the local government and NGOs in Cambodia with the objective of improving health for mothers and children through safe childbirth and proper child development.

#### **Do you have a message for** 6 **stakeholders?**

Constantly looking one step ahead of the times, we will challenge ourselves to develop new treatments that deliver value, and we will achieve sustainable growth as a pharmaceutical company with a distinctive global presence.

In fiscal 2017 (year ending March 31, 2018), led by continued strong performance by our North America business, we expect to exceed Mid-term Business Plan targets with ¥450.0 billion in net sales (plan target: ¥440.0 billion) and ¥55.0 billion in operating income (plan target: ¥50.0 billion), which would bring about record high results for a second consecutive year. With regard to our dividend, we plan to pay an annual dividend on par with that for fiscal 2016, or ¥20 per share, including a ¥2 special dividend.

Currently, Sumitomo Dainippon Pharma is working to create innovative new drugs by focusing research and development in the areas of Psychiatry & Neurology and Oncology. Through accelerating these efforts, and fostering our next generation of mainstay products, we will reduce the impact of the "LATUDA cliff" and pursue sustainable growth.

Under our new Mid-term Business Plan, which starts in fiscal 2018, we will continue to look one step ahead of the times, challenge ourselves to discover new treatments that deliver value, and achieve sustainable growth as a research and development-oriented pharmaceutical company with a distinctive global presence. We look forward to the ongoing support of all stakeholders.

July 2017

Representative Director, President and Chief Executive Officer

#### **Research & Development**

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

#### **Basic Strategy**

### Seeking rapid development and approval for our late-stage pipeline

• Accelerating late-stage clinical development products Under our ONE TEAM operating structure for the Global Clinical Development linking our Japan and U.S. units, we are conducting efficient development focused on late-stage clinical development products to obtain fast approval.

### Boost drug discovery research activity to create novel differentiated drug candidates

 Allocate research resources to the focus therapeutic areas (Psychiatry & Neurology, and Oncology) and new therapeutic areas

We are focusing our research activities in areas of significant unmet medical needs, Psychiatry & Neurology and Oncology. We are also dedicating our research effort to new areas such as the Regenerative Medicine and Cell Therapy field, and disease fields where no approved drugs exist.

### • Ensuring "POC\* First" to quickly confirm drug concepts in humans

We are applying translational research to bridge basic research to clinical studies. One such activity is to evaluate the same biomarkers in non-clinical and clinical studies, in order to predict clinically effective dose ranges and demonstrate clear POC at earlier clinical phases. Additionally, we are making efforts in repositioning/repurposing the drugs or drug candidates whose safety has been confirmed in humans, to other therapeutic indications.

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

### • Drug discovery leveraging our strengths; Accelerating external collaborations

We are applying leading-edge technologies in drug discovery, such as using in-silico methods for drug design, using iPS cells to confirm efficacy/safety, and using disease-specific iPS derived cells to clarify the mechanisms of disease. We are working further to incorporate leading-edge technologies from external collaborations and strengthen our drug discovery activities.

#### R&D Sites (including Alliances) Hub & Spoke, Central & Satellite System



DSK: Kyoto University and Sumitomo Dainippon Pharma Joint Research Project DRD: Drug Research Division RACMO: Regenerative & Cellular Medicine Office

#### Actively collaborating with external research institutions

Engaged in drug discovery research to continuously create innovative drug candidates based on cutting-edge technologies, we are not limiting our research activities to internal technologies and talents but are aggressively promoting external collaborations with academic institutions and biotech companies having innovative technologies.

In April 2016, we started the second phase of the Kyoto University and Sumitomo Dainippon Pharma Joint Research Project (DSK Project), aiming to discover innovative anti-cancer drugs. Additionally, we signed several contracts for joint research collaborations under the "PRISM" framework, our open innovation program, which we ran again in fiscal 2016.

#### R&D organizational structure supporting active drug discovery research

In order to strengthen our drug discovery activities, we are operating early/late research stages with different management philosophies and processes.

Early-stage research mimics start-up biotech-style approach, to maximize individual talents and creativity. Late-stage research emphasizes organizational and team strengths, and collaboration across multiple functions such as clinical research, CMC\*, and regulatory affairs to proceed toward early approvals.

Additionally, from April 2016 we established a PC (Professional Contributor) job title as part of our emphasis on individual specialization and career paths for employees aspiring to make a difference.

\* CMC: An abbreviation of Chemistry (characteristics analysis) of active ingredients/formulations, Manufacturing, and Controls (quality control). CMC refers to parts of the company involved with pharmaceutical manufacturing and quality during the process of applications for approval.

#### Product Launch Plan (as of July 28, 2017)



Candidates for delivering sustainable growth - Striving for a quick recovery from the "LATUDA cliff" -

#### LATUDA<sup>®</sup> (lurasidone hydrochloride) Atypical antipsychotic Developed in-house

LATUDA<sup>®</sup> (lurasidone hydrochloride) is an atypical antipsychotic agent that is believed to have an affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2A</sub> and serotonin 5-HT<sub>7</sub> receptors where it has antagonist effects. In addition, LATUDA<sup>®</sup> is a partial agonist at the serotonin 5-HT<sub>1A</sub> receptor and has no appreciable affinity for histamine H<sub>1</sub> or muscarinic M<sub>1</sub> receptors.

#### Dasotraline (SEP-225289)

### Attention-deficit hyperactivity disorder (ADHD), Binge eating disorder (BED) Developed in-house (Sunovion Pharmaceuticals Inc.)

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 a continuous therapeutic effect by dosing at 24-hour intervals.

#### Apomorphine hydrochloride (APL-130277)

**Parkinson's disease** Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics)

APL-130277 is a sublingual film formulation of apomorphine, a dopamine agonist, which is the only molecule approved in the U.S. for acute intermittent treatment of OFF episodes associated with Parkinson's disease. It is designed to rapidly, safely and reliably convert a Parkinson's disease patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine.

#### Napabucasin (BBI608)

#### Cancer Developed in-house (Boston Biomedical, Inc.)

BBI608 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways by targeting STAT3. By inhibiting pathways involved in the maintenance of

cancer stemness, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis.

#### Amcasertib (BBI503)

#### Cancer Developed in-house (Boston Biomedical, Inc.)

BBI503 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways, including Nanog, by targeting stemness kinases. By inhibiting pathways involved in the maintenance of cancer stemness, 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 cancer cells. By adding a helper T cell-inducing peptide, improved efficacy over that observed with a killer peptide alone may be achieved.

#### Alvocidib

#### Cancer In-licensed from Sanofi S.A.

Alvocidib targets cyclin-dependent kinase (CDK) 9, a member of cyclin-dependent kinase family, which activates transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anti-cancer activity observed with alvocidib.

#### **Drug Discovery**

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

Taking on the challenge to discover new, fundamental treatments for neurodegenerative disorders, at the intersection of psychiatric and neurologic research The Psychiatry & Neurology area is one in which Sumitomo Dainippon Pharma has had longstanding expertise, with eight products/compounds launched in the last quarter of century since the 1990s. We are making progress in research and development aiming to discover fundamental disease modifying drugs in neurodegenerative disorders which could improve motor activities and cognitive functions.

Furthermore, with regard to psychiatric disorders, we have directed resources to diseases and symptoms insufficiently treated by current regimens, and will expand our focus of drug discovery to "treatment-resistant depression and schizophrenia" and "symptoms associated with neurodegenerative disorders". The latter includes behavioral and psychological symptoms of dementia (BPSD), and Parkinson disease with psychosis (PDP). This can also be described as the merging of research on psychiatric and neurodegenerative disorders. At present, we have multiple compounds at the stage of clinical development targeting BPSD and PDP.

#### Exercising unique research methods

We are dedicating efforts to utilize our unique phenotypic drug screening systems to produce original drug candidates. Using characteristic cells grown from iPS cells derived from patients with various diseases, we are measuring phenotypic readouts possibly related to clinical symptoms.



#### Research Strategies in the Psychiatry & Neurology Area

#### **Oncology Area**

In the Oncology area, we are committed to contribute to treatments for patients with cancer, and are driving research and development forward under the four core strategies below. Our aim is to deliver unique products that have not been available to date.

- Cancer Stemness Inhibitor
- Cancer Peptide Vaccine
- Kinase Inhibitor
- aiRNA therapeutic

We are aiming for a fiscal 2019 launch of the cyclin-dependent kinase (CDK) 9 inhibitor alvocidib. Additionally, we are making progress with development of the cancer stemness inhibitor napabucasin and cancer peptide vaccine DSP-7888 as we steadily push forward R&D aiming for on-going approvals and product launches in the Oncology area.

Newly acquired Tolero Pharmaceuticals is utilizing evaluation systems that assess disease relevance and in-silico drug discovery platforms, while striving to discover drugs targeting kinases that are highly related to diseases.



Research Strategies in the Oncology Area

BBI-801a (preclinical)



#### **Intellectual Property**

Sumitomo Dainippon Pharma recognizes that intellectual property is an essential part of the business development of a pharmaceutical company. In filing patent applications, we are building up a patent portfolio including not only substance patent applications but also patent applications that encompass uses, manufacturing processes and formulations to comprehensively protect 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.

#### Consideration in clinical studies

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

We conduct human clinical studies required for new drug applications in accordance 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 etc.) 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.

#### Ethical Approach to Human Tissue Research

The Research Ethical Review Committee, part of the Corporate Regulatory Compliance & Quality Assurance Division, 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).

### **Development Pipeline**

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

Brand name / Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
	a a li a a sha ma a si a a	(New indication) Epilepsy- Monotherapy	Canada				
<b>APTIOM®</b>	eslicarbazepine acetate	(New usage :pediatric) Epilepsy- Monotherapy / adjunctive therapy	U.S.				
		Schizophrenia	China				
LATUDA®	lurasidone	(New usage :pediatric) Bipolar I depression	U.S. / Canada				
(SM-13496)	hydrochloride	Schizophrenia	Japan			1	
		Bipolar I depression, Bipolar maintenance	Japan				
LONASEN®	blonanserin	(New usage :pediatric) Schizophrenia	Japan				
LONAGEN	Dionansenn	(New formulation: Transdermal patch) Schizophrenia	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan		1		*1
SEP-225289 0	dasotraline	Adult, Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Binge eating disorder (BED)	U.S.				
APL-130277	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
EPI-589	TBD	Parkinson's disease	U.S.				
EF1-309	IBD	Amyotrophic lateral sclerosis (ALS)	U.S.				
		Schizophrenia	U.S.				
SEP-363856	TBD	Parkinson's disease psychosis	U.S.				
		Schizophrenia	Japan				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S. / Japan				
DSP-1200	TBD	Treatment-resistant depression	U.S.				
DSP-6745	TBD	Parkinson's disease psychosis	U.S.				
SEP-378608	TBD	Bipolar disorder	U.S.				

(As of July 28, 2017)

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

#### Dasotraline (SEP-225289)

In the U.S., a Phase 2/3 study and Phase 3 study were conducted evaluating the drug in pediatric attention-deficit hyperactivity disorder (ADHD). The studies met their primary endpoints. Based on the results of these studies and prior adult studies, we intend to submit a New Drug Application in the U.S. in fiscal 2017 for ADHD in adult and pediatric populations.

Dasotraline also met the primary endpoint of a Phase 2/3 study for binge eating disorder (BED) and we have started a Phase 3 study. We will continue to develop dasotraline for BED in adults in the U.S.

#### **TRERIEF**®

In order to obtain approval for a new indication of TRERIEF<sup>®</sup> in Japan, a Phase 3 study was conducted evaluating its effects in patients with Parkinsonism in dementia with Lewy bodies. The study produced encouraging analytical results.

Based on these results, we intend to submit a supplemental New Drug Application for the new indication in Japan in fiscal 2017.

#### Apomorphine hydrochloride (APL-130277)

Currently undergoing a Phase 3 study on OFF episodes associated with Parkinson's disease in the U.S. We are aiming to submit a New Drug Application in the U.S. in fiscal 2017.

#### **Oncology Area**

Brand name / Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
		Colorectal cancer (Combination therapy) (Global clinical study)	U.S. / Canada / Japan, etc.				
		Pancreatic cancer (Combination therapy) (Global clinical study)	U.S. / Japan				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
BBI608	napabucasin	Solid tumors (Ovarian cancer, Breast cancer, Melanoma, Glioblastoma, etc.) (Combination therapy) $^{\rm *3}$	U.S. / Canada			*1	
		Malignant pleural mesothelioma (Combination therapy)	Japan			*1	
		Solid tumors (Combination therapy) <sup>*4</sup> Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada *5				
		Hepatocellular carcinoma (Combination therapy)	Japan				
		Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			*1	
		Solid tumors (Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy)	Canada				
BBI503 a	amcasertib	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	napabucasin amcasertib	Solid tumors (Combination therapy)	U.S.				
		Myelodysplastic syndromes (Monotherapy)	Japan			*1	
DSP-7888	adegramotide/	Pediatric malignant glioma (Monotherapy)	Japan			*1	
201-7000	nelatimotide	Glioblastoma (Combination therapy)	U.S. / Canada / Japan, etc.				
		Solid tumors, Hematologic malignancies (Monotherapy)	U.S. / Canada				
alvocidib	alvocidib	Acute myeloid leukemia (AML) (Combination therapy / Biomarker-driven)	U.S. / Canada				
WT4869	TBD	Myelodysplastic syndromes (Monotherapy)	Japan		*2		
W14009 IBD		Solid tumors (Monotherapy)	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies (Monotherapy)	U.S.				
		Solid tumors (Monotherapy)	Japan				
TP-0903	TBD	Solid tumors (Monotherapy)	U.S.				
DSP-1958 *6	thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT) (Monotherapy)	Japan				

(As of July 28, 2017)

\*1 Phase 2 of Phase 1/2 study \*2 Phase 1 of Phase 1/2 study \*3 Glioblastoma's development is only Canada \*4 Multiple studies for different tumor types (Gastrointestinal cancer, Hepatocellular carcinoma, Pancreatic cancer)

\*5 Clinical study for gastrointestinal cancer is conducted only in Canada \*6 Development for the use of unapproved or off-labeled drugs

#### Napabucasin (BBI608)

Patients are being enrolled in a Phase 3 study for colorectal cancer (combination therapy / CanStem303 study) and a Phase 3 study for pancreatic cancer (combination therapy / CanStem111P study). Meanwhile, we unblinded a Phase 3 study for gastric and gastro-esophageal junction cancer (combination therapy / BRIGHTER study) based on a recommendation by the study's independent Data and Safety Monitoring Board (DSMB). The DSMB determined that the study was unlikely to reach its primary endpoint of superior overall survival for the napabucasin arm compared to the control arm.

#### Application objectives

Colorectal cancer	FY2020
(combination therapy with FLOFIRI and bevacizumab)	(U.S. & Japan)
Pancreatic cancer	FY2021
(combination therapy with gemcitabine and nab-Paclitaxel)	(U.S. & Japan)

#### Alvocidib

We are conducting an open-label, randomized Phase 2 study for MCL-1-high relapsed and refractory acute myeloid leukemia (AML) in two stages, to evaluate the efficacy of the ACM regimen compared to CM treatment. We aim to complete Stage 1 in the first half of fiscal 2017, then initiate Stage 2 in the second half of the year. We are aiming to submit an NDA for AML in fiscal 2018 in the U.S. based on the results of this study.



#### **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 28, 2017)

#### Glycopyrronium bromide (SUN-101)

SUN-101 is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the proprietary investigational eFlow<sup>®</sup> closed system nebulizer. A New Drug Application was submitted to the U.S. Food and Drug Administration (FDA) for the long-term, maintenance treatment of chronic obstructive pulmonary disease (COPD). In May 2017, we received a Complete Response Letter from the FDA, and we resubmitted the NDA to address the requests indicated in the letter in June. We are preparing for product launch during fiscal 2017.

#### **Regenerative Medicine / Cell Therapy Field**

In the regenerative medicine and cell therapy field, we are pursuing multiple R&D projects aiming for early commercialization.

Furthermore, establishing manufacturing capability for regenerative medicines is one of the highest priority issues ahead of practical use. Consequently, we started construction of a cell production and processing facility at our Central Research Laboratories (Suita, Osaka), with the objective of commencing operations during fiscal 2017.

	Dentroping	Region	0-11-1-1-1		Schedule for pr	actical use (Calendar ye	ear)
	Partnering	Region (planned)	ned) Cell type	2017	2018	2019	2020-2022
Chronic Stroke	SanBio	North	Allo	Pha	ise 2b		Approval Target
Chilonic Stroke	Sandio	America	MSC			Phase 3	
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell	Clinical research * Investig	ator or corporate init	iated clinical study	Approval Target
Parkinson's disease (Designated as a "SAKIGAKE" Product in Feb. 2017)	Kyoto Univ CiRA	Global	Allo iPS cell		Inv	estigator-initiated clinica	Istudy
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell			Clinical research	
Spinal Cord Injury	Keio Univ Osaka National Hospital	Global	Allo iPS cell			Clinical research	

Regenerative Medicine / Cell Therapy Business Plan

(As of July 28, 2017)

\* Start of clinical studies originally scheduled in 2017 may be delayed due to changes in non-clinical study plans.

#### Chronic Stroke (SB623)

In-licensed from SanBio

SB623 is an allogeneic cell product, derived from mesenchymal stem cells isolated from bone marrow of healthy donors. Unlike autologous cell therapy, which requires individualized cell preparation at a medical 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 commercialization rights in North America. Currently, a Phase 2b study is being conducted in the U.S. with SanBio, Inc. to evaluate the effects of SB623 on chronic stroke.

#### 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. Aiming to commercialize the world's first products using iPS cells, we are pursuing joint development with Healios K.K. and promoting examinations for manufacturing to take place at Sighregen K.K.



RPE cells (iPS cell-derived)

#### Parkinson's disease

Dopaminergic neural progenitor cells (iPS cell-derived) In February 2017, allogeneic iPS cell-derived dopaminergic neural progenitor cells, which we are working to use in practice in collaboration with the Center for iPS Cell Research and Application (CiRA) at Kyoto University, were designated as a "SAKIGAKE Designation System" product for regenerative medicine & cell therapy by the Ministry of Health, Labour and Welfare.

Kyoto University is planning an investigator-initiated clinical study in regenerative medicine for Parkinson's disease using dopaminergic neural progenitor cells derived from iPS cells of healthy (allogeneic) donors. Based on the results of the investigator-initiated clinical study, we are aiming to acquire manufacturing and marketing approval for the cells as a regenerative medicine product.

#### **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. Carrying this research forward, we are applying the results to human iPS cells and are working with RIKEN on R&D to bring about regenerative medicine addressing retinitis pigmentosa.

#### **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 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.

# Enhanced Pipeline from In-licensing and Acquisitions

### We strive to enhance our pipeline, which sustains our future business, through new in-licensing, acquisitions, and reevaluating in-house projects.

In addition to aggressive research and development, we are pursuing opportunities for new in-licensing and acquisitions in the Psychiatry & Neurology and Specialty areas up to a maximum scale of ¥150 – ¥200 billion from fiscal 2016, in order to expand our pipeline. What follows is an introduction of the Global Business Development Department's initiatives at the heart of this focus.

#### ${ m Q1.}\,$ What type of role does your department play?

# A1. Our department handles partnerships and acquisitions in order to expand our product pipeline, in addition to out-licensing to other companies.

The Global Business Development Department handles new in-licensed products, acquisitions in order to expand our product pipeline, and out-licensing our products to other companies.

Specifically, we start our evaluations with the voluminous amounts of information obtained from surveys and referrals through our unique network, then, if a product is judged to hold value for the Company, we collaborate with internal divisions to

#### Shigeyuki Nishinaka

Executive Officer Senior Director, Global Business Development; International Business Management

After working at other companies before joining DSP in 2009, Nishinaka planned and proposed product strategies in the Strategic Planning & Business Development Division and established partnerships in 2010 that led to signing future license agreements (including the option agreement for SB623).

After that, he was involved in numerous acquisitions and in-licensing projects. He gained experience at our U.S. subsidiary, then became Head of Global Business Development Department in April 2016. Nishinaka was also involved in the acquisition of Tolero Pharmaceuticals, Inc. and Cynapsus Therapeutics Inc carefully examine the product. This may include working with the Research Division to see if the mechanism of action of the compound is valid, working with the Sales & Marketing Department on market forecasts, and working with the Manufacturing Department on production issues. Proposals with concrete ideas for partnerships or acquisitions are then made to management.

Generally, new drug discovery has an extremely low success rate of approximately 1 in 30,000 and development spans a long period of time. Though Sumitomo Dainippon Pharma is actively engaged in in-house development, expanding the pipeline through new product in-licensing and acquisitions is also important, so I feel that the role of our department is growing with each day.

### Q2. What do you emphasize when considering acquisitions and partnerships?

# A2. We emphasize the three standpoints of science, business, and finance, and proceed with considerations in a broad range of fields.

If there are late-stage development products that can be brought to market at an early date, other companies also show strong interest and competition for the acquisition becomes fierce. So, we try to have a broad focus spanning many fields in order to evaluate products in the first stages of drug discovery research to those that have progressed into clinical studies.

When assessing these, I put my greatest emphasis on the three perspectives of science, business, and finance. This is because scientific knowledge is needed when assessing the mechanism of action of early-stage development products, an overall pharmaceutical business perspective is needed when considering commercial viability post-approval, and financial knowledge is needed when judging business value. Additionally, it is also important to have direct dialogue with partner companies during these assessments. Meeting in person allows us to discover many things that cannot be seen from data alone.



#### $Q_3$ . What are you currently putting effort into?

# A3. Primarily inside Japan, we are focusing on partnerships and acquisitions, in addition to re-evaluating previous development products.

Development products added with the fiscal 2016 acquisitions of Tolero Pharmaceuticals, Inc. and Cynapsus Therapeutics Inc. will have a substantial contribution to expanding our pipeline ahead of the expiry of the exclusivity period for LATUDA® in 2019. One of the factors allowing us to carry out these valuable acquisitions is our stance toward respecting the corporate culture of acquired companies. This is evident in our previous acquisitions of Sunovion Pharmaceutical Inc. and Boston Biomedical, Inc., where we followed a policy of allowing the companies to continue to exist as partners that we stand shoulder to shoulder with. This stance is arguably also an attractive feature for venture companies that get acquired.

We would like to leverage this characteristic strength of Sumitomo Dainippon Pharma as we direct our next initiatives at the extremely competitive domestic market. To that end, we are simultaneously evaluating other companies' compounds while reevaluating in-house projects. Even development projects that were previously discontinued could yield new value at a different point in time. Furthermore, awareness of symptomology not previously recognized as a disease means it is possible that the need for new pharmaceutical products will emerge. It is important to quickly notice such developments.

#### Major recent acquisitions

Company coquired	Date acquired	Major development products					
Company acquired	Date acquired	Product code	Development stage	Development location	Category		
	January 2017	alvocidib (Generic name)	Phase 2	U.S., Canada	Anticancer drug		
Tolero Pharmaceuticals, Inc.		TP-0903	Phase 1	U.S.	Anticancer drug		
(U.S.)		TP-1287	Preclinical	U.S.	-		
		TP-0184	Preclinical	U.S.	-		
Cynapsus Therapeutics Inc. (Canada) (currently Sunovion CNS Development Canada ULC)	October 2016	APL-130277	Phase 3	U.S.	Therapeutic agent for Parkinson's disease		

#### Major recent in-licensed products

Brand name / Generic name / Product code	Indication / Proposed indication	Licensed from	Date of licensing	Development stage	Territory
UTIBRON <sup>™</sup> NEOHALER®					
SEEBRI™ NEOHALER®	Chronic obstructive pulmonary disease (COPD)	Novartis (Switzerland)	December 2016	Approved	U.S.
ARCAPTA® NEOHALER®					
SB623	Chronic stroke (cellular medicine)	SanBio, Inc. (U.S.)	September 2014	Phase 2	U.S., Canada
vatiquinone (EPI-743)	Mitochondrial disease	BioElectron Technology		completed Phase 2/3	Japan
EPI-589	Neurodegenerative diseases	Corporation (formerly Edison Pharmaceuticals, Inc.) (U.S.)	March 2013	Phase 2	Japan, U.S., Canada (U.S., Canada: adults only)
obeticholic acid (DSP-1747)	Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals, Inc. (U.S.)	March 2011	Phase 2	Japan, China, Korea

#### 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. We have worked hard to increase the precision of our production plans by strengthening collaboration between the Manufacturing Division, Sales & Marketing Division, overseas subsidiaries, and business partners. We have also made proactive efforts such as double sourcing of active pharmaceutical ingredients and optimizing 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.

In fiscal 2016, 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, we work to preempt problems before they occur 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. This network allows us, fundamentally, to deliver products to our pharmaceuticals wholesalers within 48 hours of receiving an order (or within 24 hours for neighboring regions). Additionally, in order to maintain stable supply during emergency situations such as natural disasters, we have been working to enhance our business continuity plan (BCP).

Furthermore, in fiscal 2016, we continued initiatives aimed at developing a Good Distribution Practice (GDP)<sup>\*2</sup> system based on our company-wide GDP guidelines formulated in fiscal 2015 as a response to our global expansion. \*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.

When partnering with companies for the first time, we make selections according to the standards outlined in our 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, we provide internal lectures on the 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 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, Sumitomo Dainippon Pharma is 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.

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, and printing the product name on tablets of our major products.

### Initiatives for environment conservation and industrial safety and health

The three plants 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 thorough 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

### From development to post-marketing services, assuring the global quality of products and information.

### Quality Assurance System for making people worldwide feel reassured and safe

The Sumitomo Dainippon Pharma Group is developing new drugs in Japan, the U.S., Europe, China, and other countries, while also receiving approval from regulatory authorities in each country and delivering products to patients and healthcare professionals around the world. In order to provide products that patients and healthcare professionals can use with a sense of safety and reassurance, the Group has established global policies for quality and safety management. Under a Global Regulatory Compliance System that unites us with our subsidiaries outside Japan, we are collectively striving to provide high quality products.

We provide guidance and perform audits for all manufacturing and packaging subcontractors in each country, since it is necessary to assure quality across the entire supply chain for pharmaceutical products. This approach to quality assurance activities, from development to post-marketing services, is implemented under a global framework.

### Prompt Responses to Inquiries Using a Unique Quality Information System

Inside Japan, 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 under the Good Quality Practice (GQP)<sup>\*1</sup> 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 retained 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, our MRs (medical representatives) carry tablet terminals that have answers to many expected inquires, which facilitates 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).

### Promoting Global Safety Management and Proper Usage of Products

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 the proper use of pharmaceuticals by collecting and evaluating a wide range of information on safety and efficacy and assessing their benefit and risk in the post-marketing period. It is also important to

#### Flowcharts : Safety Information

PMDA : Pharmaceuticals and Medical Devices Agency FDA : U.S. Food and Drug Administration EMA : European Medicines Agency



promptly provide necessary information to physicians and pharmacists 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 ordinance (GVP)\*<sup>2</sup>.

Moreover, we have a system that helps us to manage and evaluate all safety information on products developed and marketed in multiple countries and to take 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 healthcare professionals with updated information on the proper use of pharmaceuticals in order to ensure that the benefits of each pharmaceutical can be utilized more safely. For example, when new adverse reactions are added to precautions on package inserts, "Notice of Revisions to Precautions" are promptly provided to healthcare professionals by MRs and via our website, and we communicate what kind of adverse reactions should be taken into consideration in the use of pharmaceuticals. Furthermore, the tablet terminals carried by MRs are equipped with information for explaining the "Notice of Revisions to Precautions" in more detail, making it possible for them to communicate to healthcare professionals accurately.

We also provide documents such as "Kusuri-no-shiori" and "Instructional Leaflets" which are used by healthcare professionals in explaining to patients about dosing schedules, precautions for use, possible adverse reactions, and so on. Illustrations are used in the "Instructional Leaflet" so that the elderly and children can easily understand them.

### $\operatorname{CSR}$ Activities in Corporate Regulatory Compliance & Quality Assurance

#### Medical communication and provision of medical information based on robust scientific evidence in order to address current unmet medical needs

Sumitomo Dainippon Pharma's Medical Science framework, composed of Medical Information and Medical Affairs Departments, has been newly established in order to strengthen our capability to accurately grasp the unmet needs of healthcare professionals and to execute medical communication and provision of medical information to address those needs in a scientifically objective, unbiased, reliable, and evidence-based manner. The Medical Information and Medical Affairs Departments are both corporate departments reporting to the same executive officer and carry out their activities with closer collaboration as a Medical Science framework.

Medical Information supports MRs' provision of safety and quality information and ensures the provision of accurate promotional information by reviewing promotional materials and slides presented at lecture meetings.

Medical Affairs, in order to have the efficacy and safety of our pharmaceuticals meet the needs of patients and healthcare professionals, will continue to communicate the true value of our products by explaining their medical information from a scientific standpoint. Furthermore, we assigned a medical science liaison (MSL) in the therapeutic field of neurology working to grasp unmet medical needs through scientific communication with healthcare professionals, which will lead to new evidence generation, additional dosage formulation, and additional indications. An MSL also serves as a contact person for clinical research and provides medical information with informed scientific knowledge in response to requests from healthcare professionals.

We are contributing to the healthy lives of patients and their

families by leveraging our new Medical Science framework to enhance activities for providing high quality medical information and fulfill unmet medical needs that take into account the needs of healthcare professionals.

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

Sumitomo Dainippon Pharma established the Pharmaceuticals Information Center as a customer support contact center for inquiries about our products from patients and their families, in addition to healthcare professionals. To contribute to the health of patients, we will continue swiftly and politely providing accurate information on the proper use of pharmaceuticals.

The Pharmaceuticals Information Center is integrated with the Medical Information Department. Consequently, by carrying out inquiry responses, knowledge sharing, FAQ updates, and so on within the same department, we expect to more promptly and efficiently provide information with a robust scientific background. We also encourage appropriate internal feedback on content learned from external requests, which leads to further improvements of our products and materials.

Inquiries during FY2016 (Approximately 48,500)										
Drug formulation Safety Clinical usage     Requests for materials Law / Healthcare systems / Prescriptions     Discontinuation / Distribution Other										
30.8%		17.2%		7.7% 8.4%						
	17.4%		15.7%	2.8%						

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

#### Japanese Market

About target

disease

- Further strengthen sales capacity in focus areas
- Build a highly efficient sales organization that can flexibly respond to changing local healthcare



#### **TRERIEF**®



Parkinson's disease

Features

Parkinson's disease drug with levodopa-enhancing effect

 Approx. 160,000 patients in Japan. Onset often affects those aged 50-65, with the rate of incidence increasing with age.

 Since no treatment currently exists for stopping the progression of the disease, appropriate pharmaceutical treatment or surgery is selected according to the severity of conditions.



#### LONASEN<sup>®</sup>



Schizophrenia

Fe

Dopamine D2 receptors and serotonin 5-HT2A receptors blocker

Approx. 770,000 patients in Japan

About target disease • On-going treatment to prevent recurrence is important since the disease tends to be chronic. Progress in new drug development and psychosocial care has raised the prospects of full and long-term recovery for nearly half of first-time patients.



About target - Approx. 10,100,000 patients in Japan, with deaths due to hypertensive disease exceeding 6,000 people a year.

 The basic approach to treatment is lifestyle changes (exercise therapy, diet therapy) and pharmaceutical treatment. If the disease progresses, the strength and elasticity of vascular walls are lost and arteriosclerosis is accelerated.







Vorth

#### North American Market

- Further growth in sales of atypical antipsychotic agent LATUDA® and antiepileptic APTIOM®
- Expand sales in the Chronic Obstructive Pulmonary Disease (COPD) area by launching new products

#### **LATUDA®**



Schizophrenia, bipolar I depression

#### Features

An atypical antipsychotic with affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonist effects

• Schizophrenia is a chronic, serious and often severely disabling brain disorder. Symptoms such as hallucinations and delusions usually start between ages 16 and 30. It affects approximately About target 2.4 million adults in the United States. disease

 Bipolar disorder is a mental health condition that is characterized by potentially debilitating mood swings, including periods of depression and mania. It affects approximately 12.6 million adults in the United States





Indications Partial-onset seizures

(Monotherapy / Combination therapy)

#### Features

APTIOM is the only exclusively once-daily, AED FDA-approved for use as monotherapy or adjunctive therapy for partial-onset seizures in adults.

• Epilepsy is the fourth most common neurological condition. In the U.S., approximately 2.9 million About target people are living with active epilepsy, including approximately 460,000 children aged 0 to 17 years. disease

Indications

Features

**BROVANA®** 



A long-acting beta-agonist, which is indicated for the long-term, twice-daily maintenance treatment of patients with COPD, including chronic bronchitis and emphysema.

Chronic obstructive pulmonary disease (COPD)

• COPD is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or lung abnormalities usually caused by significant exposure to toxic particles or gases. About target • Approximately 15.7 million adults in the U.S. report that they have been diagnosed with COPD. COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the U.S.

#### **Chinese Market Net Sales**



#### **Chinese Market**

disease

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



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

General infections, febrile neutropenia

#### Features

Indications

Standard therapy for severe infections, used in many countries

### Japanese Market



#### Net sales / Income of segment



#### **Key Measures**

- Further strengthen sales capacity in focus areas
- Build a highly efficient sales organization that can flexibly respond to changing local healthcare

#### Focus areas

Psychiatry & Neurology, Cardiovascular/Diabetes, and Specialty Areas (areas with high unmet medical needs where intensive specialization is required)

#### **Promoted Products**

TRERIEF®, LONASEN®, AIMIX®, AVAPRO®, Trulicity®, SUREPOST®, METGLUCO®, REPLAGAL®, AmBisome®, REMITCH®

#### Number of MRs (Fiscal 2016)

\* MR: Medical Representative



#### Fiscal 2016 Main Initiatives and Business Results

Since April 2016, Sumitomo Dainippon Pharma has progressively dissolved our region-based sub-division structure and transferred functions such as strategy planning to each respective branch. By increasing the authority of each branch, this new regionally focused system allows a structure that enables a flexible response to changing local healthcare.

The result has been significant growth for strategic and new products, including AIMIX<sup>®</sup>, TRERIEF<sup>®</sup>, and Trulicity<sup>®</sup>, a GLP-1 receptor agonist. On a volume basis, performance was nearly the same as the prior fiscal year; however, on a value basis, sales declined as a result of the impact of NHI drug price revisions.

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

Brand Name	Therapeutic Indication	FY 2015	FY 2016	Rate of change (%)	FY 2017 (forecast)
AIMIX®	Therapeutic agent for hypertension	14.9	17.1	14.5	17.5
TRERIEF®	Therapeutic agent for Parkinson's disease	13.1	15.1	15.3	16.0
LONASEN®	Atypical antipsychotic	12.6	12.8	1.6	13.2
METGLUCO®	Biguanide oral hypoglycemic	14.7	11.2	(23.9)	11.3
REPLAGAL®	Anderson-Fabry disease drug	10.2	10.7	4.7	11.3
AVAPRO®	Therapeutic agent for hypertension	10.8	10.3	(4.6)	8.0
Trulicity®*	GLP-1 receptor agonist	0.7	6.8	812.3	11.0
AmBisome®	Therapeutic agent for systemic fungal infection	4.3	4.4	0.8	4.5
SUREPOST®	Rapid-acting insulin secretagogue	3.6	4.3	21.8	5.3
AMLODIN®	Therapeutic agent for hypertension and angina pectoris	16.4	13.0	(20.8)	10.6

\* Trulicity® is shown on NHI price basis.

#### **Overview of Promoted Products**

As for AIMIX<sup>®</sup>, the HD tablet with 10 mg of amlodipine, one of its formulations continued its solid performance. Going forward, we will propose hypotensive treatments in accordance with patients' conditions as we promote further sales growth.

Trulicity®, a once-weekly dosage indicated for type 2 diabetes and launched in September 2015, has been growing steadily in prescription numbers since the lifting of the limit on the prescription period in September 2016, and the product contributes as a new option in diabetes treatment.

Additionally, REMITCH<sup>®</sup>, which was approved in May 2015 for a new indication for "improvement of pruritus in chronic liver disease patients," was approved in March 2017 in OD tablets as an additional dosage formulation, which has put it in a position to deliver new value.

In the Psychiatry & Neurology area, dedicated CNS MRs focusing on LONASEN® and TRERIEF® have been able to
promote the value of these two pharmaceuticals by providing very specialized information. With REPLAGAL® as well, 20 dedicated MRs have been newly added and posted at each branch.

#### Aiming to Build a Highly Efficient Sales Organization

Following the dissolution of our region-based sub-division structure and downsizing of the number of branches in April 2016, early retirements in December 2016 brought our employee numbers down and our sales offices nationwide shrank from 152 to 131 locations. While continuing to increase the authority of each branch and sales office, we have aimed for an efficient sales structure that enables a flexible response to changing local healthcare.

#### Fiscal 2017 Business Plan and Outlook

With the anticipated launch of generic drugs for AVAPRO<sup>®</sup> in December 2017, we forecast its sales to fall.

In the schizophrenia area, we forecast the severe market environment to continue due to the impact of the government's rule on reducing polymedication, and we expect this to blunt the growth of LONASEN<sup>®</sup>. At the same time, the number of patients being prescribed TRERIEF® has been steadily increasing and we aim for it to be ranked number one in fiscal 2017 in patient prescriptions as an adjunctive drug in the treatment of Parkinson's disease. We are contributing to healthcare with CNS MRs who provide high quality information, as well as dialogue and problem solution suggestions for healthcare professionals.

Additionally, with regard to METGLUCO<sup>®</sup>, which requires on-going information on proper usage, we have contracted some tasks related to promotions at health insurance pharmacies to DS Pharma Promo Co., Ltd., founded as a group company in December 2016, and are ensuring effective handling of business.

Through these initiatives, we are working to expand sales of promoted products.

# $-\mathrm{CSR}$ Activities in Marketing

#### **Basic Approach**

Sumitomo Dainippon Pharma defines CSR management as the practice of implementing our Corporate Mission: "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." 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 2016, 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.



## North American Market



#### Net sales / Income of segment



#### **Key Measures**

- Further growth for atypical antipsychotic agent LATUDA<sup>®</sup> and antiepileptic APTIOM<sup>®</sup>.
- Expand sales in the Chronic Obstructive Pulmonary Disease (COPD) area by launching new products

#### Number of MRs (FY2016)

\* MR: Medical Representative

#### FY2016 Main Initiatives and Business Results

LATUDA® surpassed initial sales forecasts with sales of US\$1.25 billion, despite intense market competition, thanks to high quality promotions by MRs dedicated exclusively to LATUDA® since the product's launch, as well as DTC advertising on television and the Internet.

APTIOM<sup>®</sup> is the only once-daily dose, antiepileptic drug available for monotherapy and adjunctive therapy in the treatment of partial-onset seizures. We significantly expanded sales 51.3% year on year as a result of assigning MRs dedicated exclusively to APTIOM<sup>®</sup>, concentrating efforts on promoting it as a strategic product, and aggressively working on sales activities.

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 nine years of continuous revenue growth since its launch in 2007.

Brand Name	Therapeutic Indication	FY 2015	FY 2016	Rate of change (%)	FY 2017 forecast
LATUDA®	Atypical antipsychotic	120.4	135.9	12.9	169.2
BROVANA®	Long-acting beta-agonist	29.9	33.1	10.6	34.4
<b>APTIOM®</b>	Antiepileptic	7.6	11.6	51.3	16.7
Ciclesonide*	Inhaled corticosteroid, Corticosteroid nasal spray	7.0	5.1	(27.0)	1.7
XOPENEX®	Short-acting beta-agonist	6.7	5.1	(23.5)	3.2

#### Sales of Major Products (Billions of yen)

\* Sunovion entered into a definitive agreement to divest the U.S. market rights to ciclesonide products in July 2017.

#### FY2017 Business Plan and Outlook

In FY2017, we will focus efforts on expanding sales of existing strategic products LATUDA<sup>®</sup>, APTIOM<sup>®</sup>, and BROVANA<sup>®</sup>, while growing our COPD franchise that is adding new products.

We will aim for further growth in sales of LATUDA<sup>®</sup> 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<sup>®</sup> and promote monotherapy.

For BROVANA®, we will continue its initiatives of FY2016 to further expand sales by stressing its effectiveness and convenience in COPD treatment to medical professionals. Moreover, we are awaiting New Drug Application (NDA) approval for SUN-101 and expect it to come on the market in FY2017. It is a long-acting muscarinic antagonist (LAMA) treatment for COPD administered via nebulizer and having a different mechanism of action from BROVANA® (a long-acting beta-agonist: LABA).

Also scheduled for launch or start of promotion in FY2017 are three FDA-approved COPD medicines, which all use fixed dose inhalers and are licensed from Novartis. With the addition of these products, Sunovion has the broadest COPD portfolio in the U.S., providing treatment options for people at various stages of COPD, as well as the flexibility for health care providers and patients to choose handheld or nebulized delivery, based on individual needs. UTIBRON<sup>™</sup> NEOHALER<sup>®</sup> was launched in April 2017. Sunovion expects to launch SEEBRI<sup>™</sup> NEOHALER<sup>®</sup> and begin promotion of ARCAPTA<sup>®</sup> NEOHALER<sup>®</sup> in FY2017.

# $-\mathrm{CSR}$ 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 Support**

Sunovion partners with patient advocacy organizations across the U.S., while also developing and assisting premier advocacy programs in order to advance education and awareness across the psychiatry & neurology and respiratory therapeutic areas. Employees participate in various events that raise awareness and funds for these programs.



# **Chinese Market**



#### Net sales / Income of segment





#### **Key Measures**

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

#### Number of MRs (Fiscal 2016)

\* MR: Medical Representatives

# (FY)

341

#### Fiscal 2016 Main Initiatives and Business Results

Sumitomo Dainippon Pharma sells four products in the Chinese market, which are MEROPEN® (brand name in China: MEPEM®), ALMARL®, a therapeutic agent for hypertension, angina pectoris and arrhythmia, SEDIEL®, a serotonin-agonist anti-anxiety drug, and GASMOTIN®, a gastroprokinetic. The 340 MRs (as of March 31, 2017) at our subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. cover 30 provinces and cities (major cities, provinces, and autonomous regions).

In fiscal 2016, the environment continued to be extremely challenging, impacted by changes to the bidding system and by the Chinese government's pharmaceutical distribution regulations (the "two invoices system"). However, as a result of strong performance particularly for MEROPEN<sup>®</sup>, sales on a yuan basis increased 11% over the previous fiscal year.

Additionally, approval for LONASEN<sup>®</sup>, a therapeutic agent for schizophrenia, was received in February 2017. The product launch is scheduled for the beginning of 2018.

Brand Name	Therapeutic Indication	FY 2015	FY 2016	Rate of change (%)	FY 2017 forecast
MEROPEN <sup>®</sup> (billion yen)	Carbapenem antibiotic	15.6	15.4	(1.4)	15.8
MEROPEN <sup>®</sup> (billion RMB)	Carbapenem antibiotic	0.83	0.95	15.5	0.96

#### Sales of Major Products (Billions of yen)

\*1 RMB calculated at: 18.9 yen (fiscal 2015), 16.1 yen (fiscal 2016), 16.5 (fiscal 2017).

#### FY2017 Business Expansion and Outlook

Although growth has lagged due to impacts of on-going factors including the bidding system, sales of our mainstay product MEROPEN<sup>®</sup> have been steady and we forecast net sales growth on a local currency basis.

We will continue making efforts to increase business efficiency and maximize profit by placing staff and targeting customers using market data, while also thoroughly utilizing SFA and having our MRs provide detailed academic information.

# $-\mathrm{CSR}$ Activities in Marketing

#### Compliance with RDPAC Code of Practice

Based on 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, we have established a compliance framework, which we continue to strengthen as we develop our 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 and seasonings such as soup or bouillon.

Additionally, in the chemical product materials business, which includes pharmaceutical excipients, personal care products, coatings and industrial materials, and electronic materials, we are expanding business to a wide range of customers by leveraging our unique technology and expertise, while cooperating with domestic and overseas suppliers.

In May 2015, we launched an information portal site, which has steadily grown its membership and is contributing to maximizing value in the polysaccharide business.

Going forward, we will aim to expand 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 other products 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<sup>™</sup>, a test strip of halitosis as an indicator for canine oral health management in March 2016, and ds PIMOHEART<sup>®</sup> for chronic canine heart failure in April 2016.

For the livestock industries, DS Pharma Animal Health provides VICTAS<sup>®</sup> Soluble Powder 25%, a fluoroquinolone antibiotic for swine, URSO<sup>®</sup>, a bile acid product for cattle, EQVALAN<sup>®</sup> 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 the security and safety of food. In addition, the company deals in feed additives and mixed feeds for maintaining animals' health and improving productivity.

Aiming to commercialize cellular medicines for animals, we established Ikeda Regenerative and Cellular Medicine Center for Animals in April 2016 in Ikeda city (Osaka). DS Pharma Animal Health is the first animal health products manufacturer to focus on producing cellular medicines for clinical trial use and for commercial use. We have begun commercializing cellular medicine using allogeneic canine stem cells. Furthermore, by promoting a New Ventures Program Supporting Animal Health, we are making progress in developing new products based on the most current science.

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



OraStrip™, a test strip of halitosis as an indicator for canine oral health, and ds PIMOHEART®, a therapeutic agent for chronic canine heart failure

#### Diagnostics and Research Materials DS Pharma Biomedical Co., Ltd. http://www.dsp-bio.com/

The company develops and supplies products including but not limited to the following:

-point-of-care testing (POCT) diagnostics for infectious diseases like influenza or Streptococcus, for acute myocardial infarction and the like

-diagnostics to measure bone and calcium metabolism markers -diagnostics to measure drug concentration levels in the blood

-high sensitivity products combining fluorescent detectors and special reagents

The company also works on developing products to measure biomarkers used in companion diagnosis which is performed to predict the efficacy and/or side-effects of drugs before they are administered, and diagnostics for neuropsychiatric disorders, etc. as well.

Furthermore, the company deals in materials for research use, such as cells and cell mediums.

In the future, the company plans to manufacture, market and sell authorized generic (AG) pharmaceuticals.





Highly sensitive fluorescent detector, "Sofia Analyzer J" and its special reagent for Streptococcus

Diagnostics for measuring bone metabolism markers

#### **Corporate Governance**

Sumitomo Dainippon Pharma posts on its 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 three 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 a Nomination and Compensation Committee,\* which has Independent Outside Directors for a majority of its members and holds meetings 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 Director, 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 four members, the majority of which being three Independent Outside Directors, and the chairperson be appointed from the Independent Outside Directors.



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

#### Hidehiko Sato

Hidehiko Sato has a wide range of knowledge and considerable experience, 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. He has been appointed as an Outside Director in the hope that he will be able to contribute to the management of the Company with his knowledge, experience and expertise.

#### Hiroshi Sato

Hiroshi Sato has considerable experience and a wide range of knowledge as a corporate executive, having served as an officer of Kobe Steel, Ltd. for many years. He has been appointed as an Outside Director in the hope that he will be able to contribute to the management of the Company with his experience and knowledge.

#### Yutaka Atomi

Yutaka Atomi has considerable experience and expertise as a medical doctor. He has been appointed as an Outside Director in the hope that he will be able to contribute to the management of the Company with his experience and expertise. 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 be able to contribute to the auditing of the Company using his experience and expertise.

#### Kazuto Nishikawa

Kazuto Nishikawa has considerable experience and expertise as an expert in the fields of tax affairs and finance, having served as the Regional Commissioner of the Tokyo Regional Taxation Bureau and the Director-General of the Inspection Bureau of the Financial Services Agency. He has been appointed as an Outside Audit & Supervisory Board Member in the hope that he will be able to contribute to the auditing of the Company using his experience and expertise.

#### Junsuke Fujii

Junsuke Fujii has considerable experience and a wide range of knowledge as a corporate executive, having served as an officer at Sumitomo Mitsui Banking Corporation, Sumitomo Mitsui Financial Group, Inc. and The Japan Research Institute, Limited. He has been appointed as an Outside Audit & Supervisory Board Member in the hope that he will be able to contribute to the auditing of the Company using his experience and knowledge.

#### 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 matters to be submitted to the Board of Directors for discussion. The Audit & Supervisory Board determines audit policy, task allocation among members and other matters. The Audit & Supervisory Board evaluates the Accounting Auditor based on the evaluation standards established by it, and determines proposals regarding the appointment, dismissal and non-reappointment of the Accounting Auditor to be resolved at the shareholders' meetings.

Accounting audits are conducted by KPMG AZSA LLC, under the audit agreement.

The Company has established the Internal Auditing Department, which reports directly to the Representative Director, President and CEO of the Company. The Internal Auditing Department conducts internal audits for not only the Company but also its subsidiaries to check the basic elements necessary for achieving the objectives of internal control from a fair and independent standpoint. In addition, the Internal Auditing Department evaluates the status of development and operation of the internal control over financial reports in accordance with the Financial Instruments and Exchange Act.

#### Accounting Audits, Remuneration (FY2016)

	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	91

(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 Pharmaceutical Inc., Boston Biomedical, Inc., 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 (FY2016)

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 2016
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 14 times in fiscal 2016
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 11 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 22 times in fiscal 2016
Executive Committee	Executives, including the members of the Board of Directors, the Audit & Supervisory Board, and Executive Officers 24 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 2016

#### The Principal Activities of the Outside Directors and Outside Audit & Supervisory Board Members (FY2016)

Category	Name	Name Principal Activities
Outside Director	Hidehiko Sato	He attended all 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 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 corporate executive.
Harumichi Uc Outside		Of the fourteen (14) meetings held by the Board of Directors and fourteen (14) 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 thirteen (13) meetings held by the Audit & Supervisory Board. He made statements at those meetings as necessary, primarily from the professional standpoint of an attorney.
Audit & Supervisory Board Members	Yutaka Atomi	Among the fourteen (14) meetings held by the Board of Directors and fourteen (14) meetings held by the Audit & Supervisory Board during the fiscal year under review, he attended twelve (12) meetings held by the Board of Directors and all fourteen (14) meetings held by the Audit & Supervisory Board. He made statements at those meetings as necessary, primarily from the professional standpoint of a medical doctor.
	Kazuto Nishikawa	He attended all fourteen (14) meetings held by the Board of Directors and all fourteen (14) 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 expert in the fields of finance and accounting.

#### Directors

The Directors prepare well for meetings of the Board of Directors by proactively collecting the information necessary for promoting discussions at the meetings. The Directors 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. The Directors 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, three 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 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.

#### Message from the Newly Appointed Outside Director

Audit & Supervisory Board Members

The Audit & Supervisory Board Members strive to enhance the effectiveness of audit practices by holding meetings with the Representative Directors on a regular basis, proactively seeking reporting from and discussions with the Directors and employees as necessary and working in collaboration with the Accounting Auditor and the Internal Auditing Department. In addition, the members attend key business meetings, including those of the Board of Directors, to monitor legality and appropriateness of management decisions by the Directors, and proactively audit the implementation status of the internal control system by such means as receiving reports from the Directors and employees on the execution of their duties, requesting additional explanations as necessary and reviewing important approval documents.

I was appointed as a new Outside Director for Sumitomo Dainippon Pharma on June 22, 2017. Prior to that point, I had spent four years as an Outside Audit & Supervisory Board Member. I have been transitioned from that role to the new one and now start participating in management's decision making processes.

For more than 45 years, I have been involved with medicine and healthcare. I have observed a remarkable advance in medical science, though there are still many diseases for which treatment protocols are not fully established. Pharmaceutical companies have garnered high expectations for development of new treatments to meet the unmet medical needs and Sumitomo Dainippon Pharma strives to contribute to medical care through leading-edge technologies.

I will utilize my many years of knowledge and experience in healthcare to bring an outside viewpoint to the Company and fulfill the function of management supervision and vigilance.

## Message from the Newly Appointed Outside Audit & Supervisory Board Member

I was appointed as a new Outside Audit & Supervisory Board Member for Sumitomo Dainippon Pharma on June 22, 2017. As a pharmaceutical company, we are committed to contributing to the realization of health, which is precious to people, by delivering excellent pharmaceutical products. To that end, we are called upon to comply with laws and regulations in our daily activities, while also ensuring fairness, transparency, and a high ethical standard.

As an Audit & Supervisory Board Member supporting corporate governance from an external standpoint, I will exchange information with auditing firms and the Internal Auditing Department, and contribute to further enhancing the Company's governance system through coordination with the other knowledgeable and experienced auditors, while leveraging my diverse background as a corporate executive.



Yutaka Atomi



Junsuke Fujii

#### **Executive Remuneration**

Compensation for the Directors is determined based on a system including performance-linked compensation to enhance incentives for increasing shareholders' value and for achieving sustainable growth. The Board of Directors seeks recommendations for the compensation of the Directors from the Nomination and Compensation Committee, the majority of which consists of Independent Outside Directors, and determines the compensation based on the recommendations from the Nomination and Compensation Committee.

Compensation for the Directors consists of base compensation and bonuses, and its total amount is within the scope of total compensation approved at the Shareholders' Meeting. Base compensation is set according to position, such as the Representative Directors, while bonuses are determined based on the performance-linked elements according to the degree of achievement in light of the performance goals in the Mid-term and Long-term Business Plans and the individual performance. The Directors contribute a certain ratio of their base compensation every month to the Sumitomo Dainippon Pharma Officers Shareholders' Association to acquire shares of the Company. The Directors hold the shares they acquired during their term of office and for one year after their retirement.

Compensation of the Outside Directors consists of base compensation, and the Company adopts a compensation system where the business performance of the Company is not reflected, for the purpose of securing the supervisory function and independence of the Outside Directors.

Compensation of Audit & Supervisory Board Members consists of base compensation determined by the Audit & Supervisory Board within the scope of total compensation approved at the Shareholders' Meeting.

#### Amount of Executive Remuneration (FY2016)

Category	Number	Amount of Remuneration (Millions of Yen)
Directors	10	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 above includes two Directors who reached the end of their tenure at the conclusion of the 196th Ordinary General Meeting of Shareholders held on June 23, 2016.

3. The respective amounts of remuneration and the like for Directors and Audit & Supervisory Board Members that were determined in the 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 2017 to March 2017 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 2017; and (ii) matters to be discussed for the further enhancement of the effectiveness of the Board of Directors.

#### Topics of the questionnaire:

- 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) Functions of the Nomination and Compensation Committee;
- 5) Support system for Outside Directors and Outside Audit & Supervisory Board Members;
- 6) Roles of Independent Outside Directors;
- Roles of Audit & Supervisory Board Members and the expectations for the Audit & Supervisory Board Members;
- 8) Relationship with stakeholders; and
- 9) Improvements over last fiscal year

Based on the analyzed results of the questionnaire, opinions were exchanged at the meeting of the Board of Directors in April 2017. It was confirmed that the effectiveness of the Board of Directors of the Company has been ensured in general, and it was agreed that the improvements were seen as to the agenda of the fiscal year ended March 31, 2016. At the same time, suggestions were made regarding the prior explanations to the Outside Directors and the Outside Audit & Supervisory Board Members and the provision of information to them at the meeting of the Board of Directors, which would be helpful to further stimulate the discussion by the Board of Directors. In the fiscal year ending March 31, 2018, the Company considers these suggestions as presenting an important agenda, and takes action based on these suggestions.

#### Strategic Shareholdings

Sumitomo Dainippon Pharma does 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 has 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 examines 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 supervises 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 50.65% 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.

#### Major Subsidiaries

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

#### 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 two days 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.

#### **Dialogue 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. Our R&D Meeting was held in February 2017.

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 several times a year and in fiscal 2016 held three such meetings.

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.

#### Updating Our Website

We refreshed and improved our website on March 24, 2017. This renewal was a full update to make the design and layout of the website more quickly and directly accessible. For users of smartphones and tablets, the screen size setting was optimized to provide an optimal view as well.

We will continue to make efforts to provide enhanced disclosure through communications including our 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 order to ensure the reliability of financial reporting, Sumitomo Dainippon Pharma is striving to enhance its internal control system in accordance with the Company's basic framework for internal control as required by Japan's Financial Instruments and Exchange Act.

Specifically, the scope of the system encompasses the company-wide 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. Every year, the President assesses the effectiveness of the design and implementation of the internal control framework, while also confirming the effectiveness of internal control.

#### **Basic Policy for Application of Accounting Standards**

Sumitomo Dainippon Pharma Group is making concrete preparations for the adoption of the International Financial Reporting Standard (IFRS) from the fiscal year ending March 2018 for the purposes of improving the international comparability of the Groups financial statements in the capital markets and improving the business management within the Group by standardization of accounting treatment.

#### **Compliance and Risk Management**

#### Compliance

Sumitomo Dainippon Pharma has declared in our publicly announced Declaration of Conduct our commitment to "comply with laws and regulations, and conduct transparent and fair corporate activities with a good sense of ethics." To put this declaration into practice and ensure full compliance, we have established Compliance Standards and use them as concrete guidelines for business activities.

One of Sumitomo Dainippon Pharma's executive officers is charged with overseeing all compliance matters of Sumitomo Dainippon Pharma and its group companies around the world. Three compliance committees have been set up: the Compliance Committee of Sumitomo Dainippon Pharma, the Compliance Committee of the group companies in Japan and the Compliance Committee of the group companies outside Japan. The Sumitomo Dainippon Pharma executive officer in charge of compliance serves as chair of each of the three committees and reports to the Board of Directors on the committee activities. In fiscal 2016, each compliance committee held two meetings and the details of those meetings were reported to the Board of Directors.

Sumitomo Dainippon Pharma has set up internal and external compliance hotlines through which its officers and employees can make consultations and reports relating to incidents of real or threatened compliance violation, and the Company operates such compliance hotline in an appropriate manner. Similar compliance hotlines have been installed in the group companies in and outside Japan. The officers and employees of such group companies may use the Sumitomo Dainippon Pharma hotlines, if the use of their own compliance hotlines is not appropriate.



#### Framework for compliance implementation

#### **Risk Management**

Sumitomo Dainippon Pharma has enacted a basic policy stipulating the Company's fundamental approach to risk management and has developed a system to appropriately promote risk management for the Group. Under this promotional framework, according to the particularities of each risk, risks are divided into those requiring a horizontal, group-wide approach, and those requiring specific approaches by each company. The Company keeps track of the risk management of the group companies as a whole through reports from each group company, and provides each group company with its guidance, advice and the like when necessary.

In order to address risks bearing an impact on business activities, we have enacted the internal "Risk Management Rule" that clarifies the President's role in overseeing risk management, and specifies a system for promoting risk management of each specific risk. One of the Company's specific initiatives is to carry out annual risk assessments and formulate necessary countermeasures based on the results followed by implementation and evaluation. This is undertaken systematically by each section of the Company working on the solution to each problem.

Additionally, Sumitomo Dainippon Pharma has formulated a business continuity plan (BCP) from the viewpoint of stable supply of the pharmaceutical products that is our social mission, and with the plan assuming the occurrence of a large-scale disaster and an infectious pandemic of new strains of influenza. Furthermore, in order to bolster ability to cope with disasters, etc., the Company has prepared necessary rules and manuals corresponding to each anticipated risk. Employees are educated on these matters through specific training and seminars that the Company holds.

#### Example of Risk Management

Sumitomo Dainippon Pharma has formulated a Business Continuity Plan (BCP) assuming that the occurrence of predicted earthquakes, including an earthquake occurring directly beneath the Tokyo metropolitan area and a large-scale earthquake in the Nankai Trough. Regular training is being carried out to practice disaster response measures. In July 2016, drills were held assuming a large-scale earthquake in the Sanin (western coastal) area of Japan, while drills addressing a Tokyo metropolitan earthquake were held in March 2017. Furthermore, for the purpose of quickly gathering information on employees and their families in times of disaster, all employees are required to give reports confirming their safety via a safety confirmation system. Use of this system is regularly practiced, with participation by all employees, twice a year.

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

Sumitomo Dainippon Pharma formulates its 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

Risk Management System

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.

With regard to personal information and Individual Numbers, the Company has established an internal Personal Information and Personal Identity Number Protection Policy and strives to safeguard this information. Additionally, internal information is appropriately managed and addressed by rules the Company has established in order to handle internal information and preempt insider trading.

Furthermore, the Company works to develop and operate controls that comply with ISO 27001, the international standard on information security. Sumitomo Dainippon Pharma has been striving to align the level of rules on information security in our group companies in Japan, the U.S., Europe, and China. In parallel with this, we are engaged in activities to strengthen measures, including carrying out monitoring to confirm and assess the status of information security efforts.



#### Inventory management, procurement

- Production management
- Workforce surplus/shortfall, employee turnover
- IR, PR response
- Intellectual property right infringement
- Capital management

## Board Members and Executive Officers (As of June 22, 2017)

#### Directors



#### Masayo Tada Representative Director, President and Chief Executive Officer

1968: Joined Sumitomo Chemical Co., Ltd. Solied Scheduling Control of the former Sumitomo Pharmaceuticals Co., Ltd.
 2005: Managing Executive Officer of the former Sumitomo Pharmaceuticals Co., Ltd.

2005: Member of the Board of Directors and Executive

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)



#### Nobuyuki Hara Member, Board of Directors, **Executive Officer**

Executive Director, Corporate Regulatory Compliance & Quality Assurance Division; Regulatory Affairs; Medical Information; Medical Affairs; Drug Development Division

1981: Joined Sumitomo Chemical Co., Ltd. 1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.

Co., Ltd. 2012: Executive Officer of the Company 2017: Member of the Board of Directors and Executive Officer of the Company (to the present)



#### Hiroshi Nomura Representative Director, **Executive Vice President**

Global Corporate Planning; External Affairs; Corporate Secretariat & Industry Affairs; Personnel; Finance & Accounting

1981: Joined Sumitomo Chemical Co., Ltd

1981: Joined Sumitomo Chemical Co., Ltd.
2008: Joined the Company
2008: Joined 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
2017: Representative Director and Executive Vice President of the Company

- President of the Company (to the present)



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

1968: Joined the National Police Agency 2002: Commissioner General of the National Police Agency 2011: Admitted to the Bar (Japan)

- 2011: Outside Audit & Supervisory Board Member of the Company 2011: Outside Director of JS Group Corporation
- (ourrently, 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)



#### 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 (to the present)





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

1970: Joined Kobe Steel, Ltd. 2009: President and Representative Director of Kobe Steel, I td.

- Steel, Ltd. 2013: Chairman of the Board and Representative Director of Kobe Steel, Ltd. 2014: Outside Member of the Board of Directors of the
- 2016: Senior Adviser of Kobe Steel, Ltd. (to the present) 2016: Outside Director of Sumitomo Electric Industries,
- Ltd. (to the present)



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

Regenerative & Cellular Medicine Office: Regenerative & Cellular Medicine Kobe Center; Drug Research Division

1989: Joined Sumitomo Chemical Co., Ltd. Joined the former Sumitomo Pharmaceuticals Co., Ltd.
 Secutive Officer of the Company
 Kenutive Officer of the Board of Directors and Executive

Officer of the Company (to the present)

#### Yutaka Atomi Member, Board of Directors (Outside)

- 1970: Intern Doctor at the First Department of Surgery of the Faculty of Medicine of the University of Tokyo 1988: Visiting Researcher at the Department of Surgery of the University of California, San Francisco
  1992: Professor at the First Department of Surgery of the School of Medicine of Kyorin University
  2004: Dean of the School of Medicine of Kyorin University
- University 2010: President of Kyorin University (to the present) 2013: Outside Audit & Supervisory Board Member of the
- 2017: Outside Member of the Board of Directors of the Company (to the present)

#### Audit & Supervisory Board Members



#### Nobuo Takeda Audit & Supervisory Board Member

1975: Joined Sumitomo Chemical Co., Ltd. 2005: Executive Officer of the former Sumitomo Pharmaceuticals Co., Ltd. 2005: Executive Officer of the Company 2010: Audit & Supervisory Board Member of the Company (to the present)



#### Yoshinori Oh-e Audit & Supervisory Board Member

1982: Joined the Company 2010: Executive Officer of the Company 2014: Senior Executive Officer of the Company 2017: Corporate Advisor of the Company 2017: Audit & Supervisory Board Member of the Company (to the present)



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

- 1973: Joined Mori Sogo (currently, Mori Hamada &
- Matsumoto) (to the present) 1980: Admitted to the Bar (New York) 2010: Outside Audit & Supervisory Board Member of the
- Company (to the present) 2012: Auditor of KEIDANREN (Japan Business Federation) (to the present) 2015: Outside Director and Member of the Audit and
  - Supervisory Committee of Suntory Beverages & Food Limited (to the present)



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

- 1971: Joined the Ministry of Finance
  2001: Director-General of the Inspection Bureau of the Financial Services Agency
  2013: Outside Audit & Supervisory Board Member of the Company (to the present)
  2014: Nonmember Inspector of the Hyogo Prefectural
- Credit Federation of Agricultural Cooperatives (to the present)

Audit & Supervisory Board Member

1976: Joined Sumitomo Bank (currently, Sumitomo

1976: Joined Sumitomo Bank (currently, Sumitomo Mitsui Banking Corporation)
2009: Director and Senior Managing Executive Officer of Sumitomo Mitsui Banking Corporation
2015: Director and Chairman of The Japan Research Institute, Limited (to the present)
2016: Outside Audit & Supervisory Board Member of House Foods Group Inc. (to the present)
2016: Outside Audit & Supervisory Board Member of The Royal Hotel, Limited (to the present)
2017: Outside Audit & Supervisory Board Member of The Royal Hotel, Limited (to the present)
2017: Outside Audit & Supervisory Board Member of the Company (to the present)

Company (to the present)

Junsuke Fujii

(Outside)

### Executive Officers

#### Nobuhiko Tamura

Senior Executive Officer Chairman and CEO, Sunovion Pharmaceuticals Inc.

#### Yoshiharu Ikeda

Senior Executive Officer Executive Director, Manufacturing Division; Technology Research & Development Division

#### Kazuo Koshiva

Senior Executive Officer Global Oncology Office; Oncology Clinical Development Unit; Oncology Strategy Unit; DSP Cancer Institute; Global Head of Oncology

#### Hiroyuki Baba

Executive Officer Senior Director, Global Corporate Planning; Legal Affairs; Intellectual Property; IT Management & Digital Transformation

#### Hajime Kinuta

**Executive Officer** Senior Director, Corporate Governance; Corporate Service Center

#### Hidevuki Harada

**Executive Officer** Executive Director, Drug Research Division

#### Mitsuyuki Taniquchi

**Executive Officer** Deputy Executive Director, Sales & Marketing Division

#### Atsuko Higuchi

Executive Officer Corporate Governance (External Communications); Personnel (Diversification)

#### Shigeyuki Nishinaka

**Executive Officer** 

Senior Director, Global Business Development; International Business Management

#### Antony Loebel

#### Executive Officer

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

#### Patricia S. Andrews

**Executive Officer** CEO, Boston Biomedical, Inc.



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## We position practicing our Corporate Mission as one and the same with CSR-based management.

## Our approach to CSR-based management

Sumitomo Dainippon Pharma defines the practice of its 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," as CSR-based management. Sumitomo Dainippon Pharma sets



Hajime Kinuta Executive Officer Senior Director, Corporate Governance; Corporate Service Center

forth its commitment to serve society in the 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. Through business activities conforming to our Declaration of Conduct, we are committed to providing products that are truly needed, while fulfilling our social responsibility as a corporation through wide-ranging initiatives that include the strengthening of our corporate governance system, thoroughly ensuring compliance, social contribution activities in and outside Japan, promotion of diversification, and active communication with diverse stakeholders.

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 changes in the globalization of business and society with a focus on organizational governance, human rights, labor practices, the environment, fair operating practices, consumer issues, and community involvement and development.

Moreover, we have been striving to participate in several partnership initiatives globally to undertake "SDG 3: Ensure healthy lives and promote well-being for all at all ages" of the Sustainable Development Goals (SDGs) of the United Nations.

#### Contribution to the Achievement of Goal 3 of the SDGs: "Good Health and Well-being"

The United Nations has officially announced 17 Sustainable Development Goals to be accomplished by 2030, including "Goal 3: Good Health and Well-being," as an applicable agenda for healthcare.

Sumitomo Dainippon Pharma continues to make efforts for Access to Healthcare, through creating innovative new drugs with leading-edge



technologies in the focus therapeutic areas of Psychiatry & Neurology and Oncology, as well as new areas such as disease fields where no approved drugs exist and Regenerative Medicine & Cell Therapy, and providing support for countries and regions where the medical systems need to be improved.



#### ISO26000 Core Subjects and Principal Activities

ISO26000 Core Subjects	Applicable item of the "Declaration of Conduct"	Principal	Activities	Page
Organizational Governance	Declaration of Conduct ① Declaration of Conduct ② Declaration of Conduct ③ Declaration of Conduct ④ Declaration of Conduct ⑤ Declaration of Conduct ⑤ Declaration of Conduct ⑦	<ul> <li>Implementation of Japan's Corporate Governance Code</li> <li>Optimizing the Management Structure, Audit System, and Internal Control Systems</li> </ul>	<ul> <li>Risk Management</li> <li>Compliance Implementation</li> <li>Appropriate Information Disclosure and Management</li> </ul>	P.17 P.41-4
Human Rights	Declaration of Conduct ① Declaration of Conduct ② Declaration of Conduct ④ Declaration of Conduct ⑤	<ul> <li>Respect for Human Rights</li> <li>Eradicating All Forms of Discrimination</li> <li>Clinical Studies Put the Human Rights of Subjects First</li> </ul>	<ul> <li>Respect for Human Rights in Supply Chain Labor Conditions</li> <li>Initiatives to Prevent Harassment</li> <li>Building Good Relationship with the Labor Union</li> </ul>	P.22 P.30
Labor Practices	Declaration of Conduct ① Declaration of Conduct ③ Declaration of Conduct ④ Declaration of Conduct ④	<ul> <li>Creating a Workplace Environment That Allows Employees to Focus Confidently on Their Work</li> <li>Implementing Health and Safety Risk Assessments</li> <li>Supporting the Betterment and Growth of Employee Health and Mental Wellbeing</li> <li>Promoting Dialogue between Management and Employees</li> </ul>	<ul> <li>Promoting "Work Style Reforms" (improve usage rate of paid leave, prevent overwork, etc.)</li> <li>Promoting Employment of Persons with Disabilities</li> <li>Promoting Diversification</li> <li>Operating of Consultation Desks and Hotlines</li> </ul>	P.6 P.17-1 P.53-5
Environment	Declaration of Conduct ① Declaration of Conduct ③ Declaration of Conduct ③ Declaration of Conduct ⑦	<ul> <li>Basic Environmental Policies</li> <li>Environmental Accounting</li> <li>Perspective on Environmental Impact</li> <li>Mid-term Environmental Plan</li> </ul>	<ul> <li>Activities to Conserve Energy and Contribute to Addressing Global Warming</li> <li>Effective Use of Resources</li> <li>Initiatives on Biodiversity</li> <li>Initiatives on Water Resources</li> </ul>	P.30 P.58-6
Fair Operating Practices	Declaration of Conduct Declaration of Conduct Declaration of Conduct	<ul> <li>Appropriate Information Disclosure and Management</li> <li>Protecting and Managing Personal Information</li> <li>Preventing the Falsification and Leakage of Information</li> <li>Corporate Activities Attaching Importance to Transparency</li> </ul>	<ul> <li>Establish Proper Relationships with Medical Institutions and Patient Groups</li> <li>Fair Promotion Activities</li> <li>Implementing "Ethics in Procurement" as part of CSR Procurement</li> <li>Respect for Intellectual Property Rights</li> <li>Reinforcement of Information Security</li> </ul>	P.29-3 P.32 P.36 P.38 P.39 P.46-4
Consumer Issues	Declaration of Conduct ① Declaration of Conduct ② Declaration of Conduct ③	<ul> <li>Initiatives to Improve Access to Healthcare</li> <li>Contributing to the United Nations' Sustainable Development Goals (SDGs)</li> <li>Initiatives to Provide High-quality Pharmaceuticals</li> <li>Encouragement of Proper Use of Pharmaceuticals</li> </ul>	<ul> <li>Recognizing and Understanding the Needs of Customers</li> <li>Running a Medical Information Website, a Health Information Website, and a Pharmaceuticals Information Center</li> <li>Ethical Considerations in Human Tissue Research, Animal Experimentation, and so on</li> </ul>	P.5 P.18 P.22 P.30 P.31-3 P.51 P.56
Community Involvement and Development	Declaration of Conduct ① Declaration of Conduct ② Declaration of Conduct ④ Declaration of Conduct ⑥ Declaration of Conduct ⑦	<ul> <li>Our Policy on Social Contribution Activities</li> <li>Stakeholder Engagement</li> <li>Stakeholder Dialogue</li> <li>Initiatives for Global Health</li> </ul>	<ul> <li>Support through Employee Participation</li> <li>Support through Donation</li> <li>Social Support</li> <li>Activities of Global Group Companies</li> </ul>	P.5 P.18 P.32 P.38 P.45 P.53 P.57-5

CSR Activities http://www.ds-pharma.com/csr/

# Labor Practices

#### Promoting Initiatives with 2017 as "Year One for Work Style Reforms"

In order for us to increase our corporate competitiveness, it is vital to transition to workstyles with a strong awareness of time, and with high added value and productivity. Furthermore, we recognize that achieving work-life balance is an issue that cannot be avoided if we are to have an active, diverse work force. Hence, we held a seminar in March 2017 for all employees, after which we held training for all management rank employees in order to promote work style reforms at each worksite. In addition to this, we have carried out initiatives throughout the year, including no overtime days and



other measures to curb long working hours, as well as measures to encourage employees to take their paid leave.

In regards to our work from home system, in June 2016, we launched a system to support employees involved in childcare or nursing care and plan to make more employees eligible for the system in order to leverage it as a way to achieve higher employee productivity.

#### Main Initiatives

Establish a Senior Work Style Reform Officer

Hold seminars on work style reforms, balancing childcare/nursing care and work, promoting the active participation of women, and so on

Hold training for all management rank employees related to work style reforms

Curb long working hours

- Rationalize work tasks and hold meetings to reassess work styles at each worksite
- Thoroughly managing work hours

Encourage improvement of the usage rate for paid leave • Achieve a 60% utilization rate for paid leave in

- fiscal 2016 • Encourage employees to consistently take their
- Encourage employees to consistently take their paid leave

Expand the work from home system

#### 💻 Major Items Reported on Our Website

- Promoting Human Resources Development (see p. 17, 54)
- Achieving Work-life Balance (see p. 6, 18, 53)
  Supporting Women's Active Participation (see p. 11, 54)
- Implementing Health and Safety Risk Assessments
  Supporting the Betterment and Growth of Employee
- Health and Mental Wellbeing • Promoting Dialogue between Management and
- Employees (see p. 18, 53)
- Operating Consultation Desks and Hotlines
- Promoting Employment of People with Disabilities
  Building Good Labor-Management Relations
- \*Page numbers refer to those in this pamphlet

Promoting Dialogue between Management and Employees

Every year, we conduct an opinion poll called "DSP OPINION" for all employees. Its purpose is to gauge employees' understanding of and comfort with our business policies and HR systems, their satisfaction with their supervisors and workplace environments, and their satisfaction with their own personal development. The overall response rate was 97% in the survey conducted in July 2016. Survey results are reported to the Board of Directors, while efforts are made, when necessary, to work with related departments to solve issues. Furthermore, the President and directors visit each business site to have direct dialogue with employees to explain Company circumstances and policies, while also addressing opinions expressed in the surveys.



The President teaching during the Management Course

#### Establishing the DSP Academy for Training Select Employees

Sumitomo Dainippon Pharma is building a stronger corporate culture and improving business results through human resources training. We have positioned fiscal 2016 as "Year one for investment in education/ training" and have started rebuilding our personnel development system. One link in this process was establishing in July 2016 the DSP Academy, which is a career grade-specific training system.

The DSP Academy selects different grades of students, from young employees

to mid-career employees and managers, who possess ambition and potential. These students are offered courses that include the Management Course, taught by President Masayo Tada and aimed at fostering future top-level managers.

We aim to develop professional employees able to produce results by continuing to promote the establishment of company-wide training programs for increasing individual skills, including training for improving employee capacities. No. of participants in the DSP Academy\* \* Expected participants over five years

400



DSP Academy (Select Employee Training)



Sumitomo Dainippon Pharma has vigorously strived for active participation by women as one focus of our efforts on diversification. We have formulated a Voluntary Action Plan on Promotion of Women to Managerial and Board Position, as recommended by the Japan Business Federation, in addition to formulating a General Business Owner Action Plan, as required under the Act on Promotion of Women's Participation and Advancement in the Workplace, which came into force in April 2016. We have set a goal of at least 10% female managerial staff in 2020. As of March 2017, women accounted for approximately 8% of managerial staff and approximately 13% of Director positions, or above, at Sumitomo Dainippon Pharma. In April 2017, we appointed an executive officer in charge of diversification.



# Fair Operating Practices



Company values and fundamental principles

Please see p. 1 "Profile" for details on our Corporate Mission and other statements



- CSR-based Procurement (see p. 30)
- Respect for Intellectual Property Rights
- Reinforcement of Information Security (see p. 48)
- Ensuring thorough Awareness of Compliance
- Standards (see p. 47)
- \*Page numbers refer to those in this pamphlet

#### **CSR-based Management for Responding to Socio-Economic Changes Inside and Outside Japan**

We recognize that to continue to meet the expectations of society it is important to promote CSR-based management corresponding to socio-economic changes.

We comprehensively revised our Declaration of Conduct in April 2017, taking into account such considerations as the tightening of ethics in the pharmaceutical manufacturing industry and the formulation and revision of domestic and international guidelines, including the UN SDGs, ISO 26000, the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice, and Japan's Corporate Governance Code.

#### Declaration of Conduct (revised April 2017)

In order to promote CSR-based management, it is necessary to cultivate "a culture open to challenges" that enables individuals to proactively engage in innovation and reform. In order to further spread awareness of our Declaration of Conduct, which articulates the Company's basic approach to CSR, we promote internal communication both periodically and continuously. A corporate blog of CSR-related information and discussions at each worksite was launched, for consideration of the connections between work tasks and the Declaration of Conduct.

#### Follow through the global slogan "Innovation today, healthier tomorrows." We constantly pursue self-innovation to deliver innovative products and services with speed so that people around the world can lead healthier and more fulfilling lives. Pursue trustworthy corporate activities. We comply with laws and regulations, and conduct transparent and fair corporate activities with a good sense of ethics. We resolutely sever all relations with antisocial forces and organizations that pose a threat to the order and security of civil society. Positively disclose information and properly manage information. 1 We disclose corporate information in a timely and appropriate manner. We take appropriate measures to protect and manage personal and customer information acquired through corporate activities. Help employees reach their full potential. We respect diversity, character and personality of employees. We ensure a safe and pleasant working environment, and provide employees the opportunity to develop their skills and abilities. Respect human rights. We respect the rights of all people associated with our company in conducting corporate activities. We do not discriminate or harass anyone. In addition, we reject child labor and forced labor. Positively address global environmental issues. We positively initiate measures in acknowledgment of environmental issues, which are common challenges to humanity and important requirements for corporate sustainability and activities. Build harmonious relationships with society. We engage in community involvement activities including philanthropy by communicating with all of stakeholders. We conduct business by taking into consideration the local culture and customs of the countries and regions, and contribute toward the development of the local economy and society.



#### Initiatives to Improve Access to Healthcare

Improving access to healthcare is one of the important missions of a pharmaceutical company. Sumitomo Dainippon Pharma is actively striving to improve access to healthcare in order to help achieve Goal 3 of the United Nations' Sustainable Development Goals: "Good Health and Well-being." Additionally, since we recognize that global health is an issue on a worldwide scale, we value the importance of SDG 17, "Partnerships for the Goals," and are working towards solutions by collaborating with government agencies, international institutions, research institutions, and civil society.

Access Accelerated	As a partnership activity with 24 pharmaceutical companies doing business globally, Sumitomo Dainippon Pharma is striving to improve access to care for non-infectious diseases in low- and lower middle income countries, focusing on Africa and Asia.
Health Improvement Program for Mothers and Children	Sumitomo Dainippon Pharma provides a health improvement program for mothers and children in the Kampong Cham District, Cambodia. Working with a nonprofit organization (NPO), local governments, and communities, we are striving to provide health checkups for infant and pregnant women, regular education and training on nutrition and hygiene, and home visits by healthcare providers.
Initiatives to Control Malaria	Working with NPOs, local governments, and local communities in Zambia, Tanzania, and Indonesia, Sumitomo Dainippon Pharma is distributing mosquito nets and simple test kits, in addition to carrying out education support activities and, inside Japan, hosting malaria education events.
Capacity Building and Patient Advocacy	Sumitomo Dainippon Pharma is supporting capacity building and patient advocacy as a part of efforts to improve access to healthcare. This includes implementing a project for training nurses in Bangladesh, a project for training physicians and implementing medical examinations for tuberculosis in Haiti.
Participating in the GHIT Fund	Sumitomo Dainippon Pharma participates in the Global Health Innovative Technology (GHIT) Fund. Through participation in the GHIT Fund, we are exploring the possibilities to apply our innovative drug discovery technologies to neglected tropical diseases (NTDs) and malaria, for which there are significant unmet medical needs.

#### Aajor Items Reported on Our Website

- Initiative for Access to Healthcare (see p. 5, 18, 56)
- Initiatives for Stable Supply (see p. 29-30)
- Initiatives to Provide High-quality Pharmaceuticals (see p. 31-32)
- Recognizing and Understanding the Needs of Our Customers (see p. 30, 32, 56)
- Communication with Customers (see p. 32) Running a Medical Information Website, a Health Information Website, and a Pharmaceuticals Information Center

\*Page numbers refer to those in this pamphlet



# Community Involvement and Development

#### Providing Learning Opportunities Leveraging Our Strengths as a Pharmaceutical Company

Since 2012, we have been providing visiting lectures at junior high and high schools. This allows us to provide learning opportunities that enable children who will shape the future to grow in good health and exercise their potential to the fullest.

These visiting lectures cover topics on DNA diagnostics. After employees give an explanation of genetics, students watch a DVD presenting a hypothetical story in which a DNA diagnosis can indicate whether or not one will develop an incurable disease in the future. Students discuss in groups whether they would have such a diagnosis, and then share their thoughts with the lecturers. The objective of the program is to have students practice being receptive to the opinions of others with regard to topics on life and ethics that do not have clear right or wrong answers, while also fostering the ability to come to one's own conclusions.

These activities to date have garnered praise and received the Encouragement Award in the large corporation category of the Ministry of Economy, Trade and Industry's 7th Career Education Award.

#### Kajor Items Reported on Our Website

- Our Policy on Social Contribution Activities
- Stakeholder Engagement
- Stakeholder Dialogue (see p. 18, 32, 38, 45, 53)
- Initiatives for Global Health (see p. 5, 18, 56) Support through Employee Participation
- (see p. 38, 57, 58)
- Support through Donation
- Social Support (see p. 57)
- Activities of Global Group Companies (see p. 38, 58)
- \*Page numbers refer to those in this pamphlet



Schools using DSP visiting lectures / No. of attendees

schools

attendees

No. of employees teaching courses



#### Supporting the Japan Epilepsy **Research Foundation**

Established to commemorate the 90th anniversary of the former Dainippon Pharmaceutical Co., Ltd., the Japan Epilepsy Research Foundation (JERF) works to promote research on treatments in the field of epilepsy, while contributing to the health and healthcare of the public, and runs on contributions from Sumitomo Dainippon Pharma and donors. The Foundation provides grants and commendations related to epilepsy. In fiscal 2016, JERF provided 12 research grants, two overseas study grants, and two Japan Epilepsy Research Grants for Inviting Overseas Researchers to Japan. Sumitomo Dainippon Pharma will continue to contribute to the improvement of healthcare and welfare through its support of the Japan Epilepsy Research Foundation.

#### The Owls Forest Restoration Project in the Sumitomo Dainippon Pharma Forest

To commemorate the 10th anniversary of its merger, Sumitomo Dainippon Pharma carried out a range of activities for one year from October 2015 to September 2016. The activities were a means of expressing gratitude to those in local communities and included social contribution efforts by directors and employees at social welfare facilities, in addition to environmental conservation efforts. One of those activities is the Owls Forest Restoration Project, which is scheduled as a five-vear initiative for biodiversity. This project makes use of the Adopt Forest Program of Kishiwada city, Osaka prefecture, and is being carried out in cooperation with a local NPO called the Konoyama Conservation Club.

At the 0.45-hectare Sumitomo Dainippon Pharma Forest in Sangayamacho, Kishiwada city, our goal is to prevent the expansion of neglected bamboo groves and restore the deteriorated woodland area. By doing so, we hope to regenerate and maintain a rich natural environment to enable the owl, which is at the top of the area's ecological pyramid, to survive.

In fiscal 2016, a total of 166 employees gathered a total of 10 times to participate in the project. Workers groomed the woodland by, for example, cutting back bamboo, while also setting up birdhouses in order to protect and allow local wild birds to increase in numbers.

Going forward, we will continue initiatives for biodiversity, focusing on the Owls Forest Restoration Project.





No. of participants in social contribution activities

999

(Counting only the number of Sumitomo Dainippon Pharma participants)



#### Implementing "Hands On!" Community Service Activities

Our U.S. subsidiary Sunovion Pharmaceuticals Inc. has been carrying out its "Hands On!" community service program every year since 2012. To date, Sunovion has contributed more than 20,000 volunteer hours in the states of Massachusetts and New Jersey, where the company has offices. During fiscal 2016, the program was expanded to include more areas across the U.S., as well as the U.K. and Canada. 321 Sunovion employees participated in 19 volunteer projects in social services, healthcare, education, and the environment. (See p. 38 for related information)

# 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 2016 to fiscal 2018).

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**

INPUT

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 (FY2016)

**Raw Material Consumption** 

(excluding metals) ..... 5.283t

products (metals) ······ 19t • PRTR substances ····· 1,911t

• Ground water ...... 330.303t

······ 889t

Raw materials for

Raw materials for

 Product packaging materials

Water Consumption

products

Energy Consumption (crude oil equivalent) Total energy Annual Implementation Plan To formulate an Annual Implementation Plan as an action plan for achieving

the goals of the Mid-term Environmental Plan

#### **Mid-term Environmental Plan**

To formulate a Mid-term Environmental Plan comprising specific measures for implementing the basic environmental policies

#### **Basic Environmental Policies**

 Development of products and technologies with less environmental burden
 Promotion of business activities with less environmental burden
 Environmental protection activities involving the whole Company
 Compliance with laws and regulations, and voluntary initiatives
 Education and awareness promotion
 Environmental protection activities for regional communities

Communication

#### OUTPUT

•••	Released into the Atmosphere         • CO2 emissions (from energy sources)       73,533t         • Organic chlorinated chemical substances       5.4t         • SOX       0.2t         • NOX       43.5t         • Ash dust emissions       0.9t         • PRTR substances       6.5t         Released into Water Systems         • Total amount of wastewater       877,064t         • BOD       10.5t         • COD       5.4t         • Phosphorus       0.1t         • Nitrogen       1.0t         • PRTR substances       0.0t         Not: The BOD, COD, phosphorus, nitrogen and PRTR substances shown here are the amounts released into public waterways and sewerage systems
0	Waste Amount of waste generated
	•• ••

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

Logistics

**Business Activities** 

Offices

Research and development

Manufacturing

#### Mid-term Environmental Plan (fiscal 2016-2018)

environmental education

system for employees

Train key persons in environmental management

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 2016, we made steady progress in most areas, except for a few objectives. In the future, we will continue to pursue further improvements.

Goals of Special Importance	Objectives	Progress in FY2016	Degree of Progress
1. 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 an increase in the volume of PRTR substances handled, atmospheric emissions of these substances increased approximately 36% over the previous fiscal year, but emission rates (emission volume/amount handled) were held nearly the same year on 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 FY2016 stood at 89.6% of the level in FY2005 and 99.4% 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: 101.7% of FY2015	
	more per year, respectively	Per-unit CO <sub>2</sub> emissions: 102.5% of FY2015	$\square$
. 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 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
3. 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% (FY2016 result 0.2%)	0
I. 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 three plants and two research laboratories, but not achieved at one plant (increased waste due to production site restructuring)	
	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 activities of group companies	Conducted environmental audits at two group companies in Japan, and held meeting in September 2016 to exchange information on the environmental management of domestic group companies	0
6. Promote communication	Understand environmental risks that corporate activities can present to the local community	Gained understanding of most risks and implemented countermeasures	0
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	Educational activities and initiatives concerning biodiversity are carried out at each business site. The entire Company is carrying out a five-year plan called the Owls Forest Restoration Project.	0
3. Enhance	Establish and implement environmental education	Formulated environmental education plan at each work site and implemented education in	0

accordance with plans

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

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

_	2007	2008	2009	2010	2011
RESULTS OF OPERATIONS:					
Net sales	¥261,213	¥263,993	¥264,037	¥296,262	¥379,513
Overseas sales revenue	22,032	24,521	22,051	53,015	152,226
Ratio of overseas sales revenue	8.4%	9.3%	8.4%	17.9%	40.1%
Cost of sales	99,346	99,385	103,741	112,263	110,030
Selling, general and administrative expenses	116,312	124,794	129,130	148,374	238,531
(Research and development costs)	40,870	47,266	52,819	51,371	68,160
(Ratio of net sales)	15.6%	17.9%	20.0%	17.3%	18.0%
Operating income	45,555	39,814	31,166	35,625	30,952
Operating margin	17.4%	15.1%	11.8%	12.0%	8.2%
Income before income taxes	38,415	41,457	32,168	31,423	25,050
Net income attributable to owners of the parent	22,605	25,592	19,988	20,958	16,796
Comprehensive income (loss)	_	_	_	27,148	(12,066)
FINANCIAL POSITION:					
Current assets	¥234,313	¥251,063	¥263,540	¥287,555	¥333,000
Net property, plant and equipment	65,241	70,280	69,105	74,084	69,794
Total assets	382,535	399,791	391,295	626,743	589,868
Current liabilities	56,039	67,915	53,350	265,000	157,204
Long-term liabilities	20,484	13,598	13,449	18,260	108,681
Net assets	306,012	318,278	324,496	343,483	323,983
OTHER STATISTICS:					
Capital expenditures	¥ 9,543	¥ 15,491	¥ 10,569	¥ 6,471	¥ 8,663
Depreciation and amortization	12,008	11,870	11,455	18,650	44,628
EBITDA	54,875	48,802	41,970	56,448	77,971
PER SHARE OF COMMON STOCK:					
Basic net income	¥ 56.86	¥ 64.39	¥ 50.30	¥ 52.75	¥ 42.27
Net assets	767.52	800.63	816.49	864.51	815.44
Cash dividends applicable to the year	14.00	18.00	18.00	18.00	18.00
FINANCIAL INDICATORS:					
ROE	7.6%	8.2%	6.2%	6.3%	5.0%
ROA	5.8%	6.5%	5.1%	4.1%	2.8%
Equity ratio	79.8%	79.6%	82.9%	54.8%	54.9%
Dividend payout ratio	24.6%	28.0%	35.8%	34.1%	42.6%

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 ¥112 to US\$1.00, the approximate rate of exchange at March 31, 2017.
 2. On June 19,2014, Dainippon Sumitomo Pharma Co., Ltd changed its name to Sumitomo Dainippon Pharma Co., Ltd. in preparation for global development.
 3. Sumitomo Dainippon Pharma Co., Ltd. acquired Sepracor Inc. (now Sunovion Pharmaceutical Inc.) in October 2009. Consolidated results for the fiscal year ended March 31, 2010 include the results of this company for 2.5 months (October 15 - December 31, 2009).

Millions of yen						Percent change	Thousands of U.S. dollar (Note 1)
2012	2013	2014	2015	2016	2017	2017/2016	2017
¥350,396	¥347,724	¥387,693	¥371,371	¥403,206	¥411,639	2.1%	\$3,675,348
130,243	133,125	174,286	174,911	215,055	227,495	5.8%	2,031,205
37.2%	38.3%	45.0%	47.1%	53.3%	55.3%	0.070	2,001,200
98,857	101,686	104,100	101,228	104,471	100,071	(4.2%)	893,491
231,137	220,994	241,450	246,868	261,805	258,809	(1.1%)	2,310,794
56,891	59,844	69,804	71,304	82,034	80,819	(1.5%)	721,598
16.2%	17.2%	18.0%	19.2%	20.3%	19.6%	. ,	,
20,402	25,044	42,143	23,275	36,930	52,759	42.9%	471,063
5.8%	7.2%	10.9%	6.3%	9.2%	12.8%		
16,328	18,158	34,709	33,755	39,561	47,217	19.4%	421,580
8,630	10,044	20,061	15,448	24,697	28,991	17.4%	258,848
2,396	37,174	45,165	60,108	5,579	21,145	279.0%	188,794
¥334,251	¥333,439	¥359,612	¥401,699	¥421,585	¥376,454	(10.7%)	\$3,361,196
66,697	69,862	72,689	65,160	61,825	59,254	(4.2%)	529,054
559,410	607,219	659,033	711,584	707,717	793,951	12.2%	7,088,848
105,966	124,831	131,208	156,844	179,723	228,447	27.1%	2,039,705
134,217	133,140	129,285	103,719	81,521	104,847	28.6%	936,134
319,227	349,248	398,540	451,021	446,473	460,657	3.2%	4,113,009
¥ 8,742	¥ 12,384	¥ 23,421	¥ 10,676	¥ 9,785	¥ 10,619	8.5%	\$ 94,813
40,232	35,085	26,777	19,226	20,267	18,618	(8.1%)	166,232
59,880	60,333	68,101	43,095	55,780	72,844	30.6%	650,393
Yen						Percent change	U.S. dollars
¥ 21.72	¥ 25.28	¥ 50.49	¥ 38.88	¥ 62.16	¥ 72.97	17.4%	\$ 0.65
803.47	879.03	1,003.11	1,135.21	1,123.76	1,159.47	3.2%	10.35
18.00	18.00	18.00	18.00	18.00	20.00	11.1%	0.18
2.7%	3.0%	5.4%	3.6%	5.5%	6.4%		
1.5%	1.7%	3.2%	2.3%	3.5%	3.9%		
57.1%	57.5%	60.5%	63.4%	63.1%	58.0%		
82.9%	71.2%	35.7%	46.3%	29.0%	27.4%		

4. 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 2017. 5. EBITDA = income before income tax + interest expenses – interest income + depreciation and amortization + amortization of goodwill – extraordinary income (loss)

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

During the fiscal year ended March 31, 2017, the Japanese economy remained on a mild recovery path, with corporate earnings showing improvements due to a pick-up in consumer spending and exports. In overseas economy, the U.S. economy continued to expand, driven chiefly by increased consumer spending, and the Chinese economy showed signs of a turnaround as government economic packages began to take effect. Going forward, the U.S. and British governments' policy developments, prospects of Chinese and other emerging economies, and impacts of financial and capital market fluctuations all warrant attention.

In the pharmaceutical sector, authorities around the world are attempting to come up with a series of measures to curb prices of brand-name drugs and promote use of generic drugs in a bid to put the brakes on their ever-increasing social security benefits expenditures, which serves to lower businesses' visibility. Amid these circumstances, the increasing difficulty of developing new drugs, rising R&D expenses, and intensifying international competition are forcing businesses to run high risks.

Against this backdrop, the Group strove to boost sales of three of its strategic products, namely, AIMIX<sup>®</sup> (therapeutic agent for hypertension), TRERIEF<sup>®</sup> (therapeutic agent for Parkinson's disease), and LONASEN<sup>®</sup> (atypical antipsychotic; generic name: blonanserin), in Japan, while at the same time providing scientific information on Trulicity<sub>®</sub> (GLP-1 receptor agonist indicated for type 2 diabetes), which was launched in FY2016, in order to accelerate its penetration into the market.

In North America, Sunovion Pharmaceuticals Inc. (hereinafter referred to as "Sunovion") continued to pour its resources into expanding sales of the global strategic product LATUDA (atypical antipsychotic; generic name: lurasidone hydrochloride) and other mainstay products. For the purpose of gaining a Psychiatry & Neurology pipeline, in October 2016 Sunovion acquired Cynapsus Therapeutics Inc., a Canadian biotechnology company that specializes in the Psychiatry & Neurology area (hereinafter referred to as "Cynapsus"). In December 2016, Sunovion then acquired the exclusive rights to market three approved therapeutic agents for patients with chronic obstructive pulmonary disease (COPD) in the U.S. from two Novartis affiliates (hereinafter referred to as "Novartis") with a view toward expanding its respiratory portfolio.

In the Oncology area, Boston Biomedical, Inc. (hereinafter referred to as "Boston Biomedical"), expedited clinical development of napabucasin (product code: BBI608) by placing top priority on an early U.S. launch of the drug. In January 2017, the Company acquired the U.S. biotechnology company Tolero Pharmaceuticals, Inc. (hereinafter referred to as "Tolero"), which specializes in research and development of therapeutic agents in the oncology and hematologic disorders areas, through a U.S. holding company that is wholly owned by the Company.

#### **Operating Results**

#### Net Sales

Net sales in Japan during the fiscal year ended March 31, 2017 decreased, with the April 2016 NHI price revisions and a drop in sales of long-listed products having a significant impact, while North America saw a substantial sales increase on the back of steady growth for LATUDA<sup>®</sup> and other mainstay products. On a consolidated basis, net sales increased by 2.1% year-on-year to 411,639 million yen.

#### **Operating Income**

Operating income increased by 42.9% year-on-year to 52,759 million yen as, in addition to the lower cost of sales, selling, general, and administrative expenses showed a decrease due to reduction of selling and other expenses in Japan.

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

Net income attributable to owners of the parent increased by 17.4% year-on-year to 28,991 million yen, as the Company reported a gain on sales of investment securities under extraordinary income and business structure improvement expenses under extraordinary loss due to implementation of the Early Retirement Program.

#### **Financial Condition**

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

Current assets decreased by 45,131 million yen from the previous fiscal year-end, as marketable securities and short-term loans receivable decreased while cash and time deposits increased. Fixed assets decreased due to sales of some equity holdings, but nevertheless increased by 131,365 million yen from the previous fiscal year-end owing to a considerable rise in goodwill and in-process research and development following the acquisition of Cynapsus and Tolero. As a result, total assets increased by 86,234 million yen from the previous fiscal year-end to 793,951 million yen.

#### -Liabilities

Total liabilities increased by 72,050 million yen from the previous fiscal year-end to 333,294 million yen, due mainly to an increase in reserve for sales rebates, as well as an increase in short-term loans, deferred tax liabilities, and fair value of contingent consideration on account of the acquisitions, although there was a decrease in payment of income taxes payable, as well as payment of long-term loans payable and redemption of bonds payable.

#### -Net assets

Net assets increased by 14,184 million yen from the previous fiscal year-end to 460,657 million yen, due primarily to an

increase in retained earnings, despite a decrease in unrealized gains on available-for-sale securities. The shareholders' equity ratio as of the end of the fiscal year under review was 58.0%.

#### Status of cash flows

#### -Net cash provided by operating activities

Cash flows provided by operating activities decreased by 27,790 million yen from the previous fiscal year to 21,625 million yen, owing to a major increase in business structure improvement expenses, income taxes, and other payments, although there were factors that contributed to an increase in cash, including a rise in notes and accounts payable, accounts payable-other, and reserves, in addition to an increase in income before income taxes.

#### -Net cash used in investing activities

Cash flows used in investing activities increased by 75,617 million yen from the previous fiscal year to 59,730 million yen, due to the purchase of shares of subsidiaries following the acquisition of Cynapsus (current Sunovion CNS Development Canada ULC) and Tolero, even though there were proceeds from collection of short-term loans receivable and sales of investment securities.

#### -Net cash provided by financing activities

Cash flows provided by financial activities increased by 52,487 million yen from the previous fiscal year to 9,882 million yen, as the Company took out short-term loans for acquisitions while repaying long-term loans payable and redeeming bonds.

#### -Cash and cash equivalents

After factoring in the impact of foreign currency translations applied to cash and cash equivalents, the balance of cash and cash equivalents as of March 31, 2017 amounted to 105,604 million yen, a decrease of 29,972 million yen from the end of the previous fiscal year.

#### Allocation of the Company's Profits

The customary allocation of a portion of the Company's profits to its shareholders in an appropriate manner is one of the Company's most important management policies.

The Company's basic policy is to make dividend 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 placing high importance on distribution of surplus in a manner that reflects the Company's performance, the Company seeks to make decisions on dividends from a comprehensive perspective, while actively investing in its future growth, ensuring a solid management base, and enhancing its financial status in order to further increase its corporate value. The Company believes that it is important to allocate profits to its shareholders consistently.

In FY2016 (year ended March 31, 2017), the Company achieved a record-high operating income of 50.0 billion yen, owing primarily to expanded sales of LATUDA®, thereby meeting the target for the FY2017 (year ending March, 2018), which was laid out in the 3rd Mid-Term Business Plan(MTBP), one year ahead of schedule.

Given the abovementioned basic policy on profit distribution to shareholders and earnings results of the FY2016, the Company paid a year-end dividend of 11 yen per share, which comprises an ordinary dividend of 9 yen and a special dividend of 2 yen, thus making the annual dividend of 20 yen per share.

Since the level of operating income is expected to surpass 50.0 billion yen, a target laid out in the 3rd MTBP, for the fiscal year ending March 2018, the Company plans to pay an annual dividend of 20 yen per share for the next term , the same amount as declared for the fiscal year ended March 2017, with an ordinary dividend of 9 yen being paid at the interim and an ordinary dividend of 9 yen and a special dividend of 2 yen being paid at the year end.

#### Forecasts for the Year Ending March 31, 2018

In Japan, the Company will attempt to maximize sales of TRERIEF<sup>®</sup>, LONASEN<sup>®</sup>, and Trulicity<sub>®</sub>, but it expects net sales to remain flat year-on-year due to the ongoing decline in sales of long-listed drugs. In North America, on the other hand, net sales are expected to increase, owing primarily to a scheduled launch of glycopyrronium bromide (product code: SUN-101) and contributions from the three treatment options for patients with chronic obstructive pulmonary disease (COPD), which were in-licensed last year from Novartis, in addition to sales expansion of LATUDA<sup>®</sup> and APTIOM<sup>®</sup>. All things considered, net sales are expected to reach 464.0 billion yen, up by 52.4 billion yen from the previous fiscal year.

The Company expects gross profit to advance as net sales increase. Meanwhile, selling, general and administrative expenses are likely to increase due to a new launch in North America and progress in clinical studies of Cynapsus's apomorphine hydrochloride (product code: APL-130277) and Tolero's alvocidib, both of which were acquired in the previous fiscal year. As a result, the Company expects operating income of 65.0 billion yen, up by 12.2 billion yen year-on-year, and net income attributable to owners of the parent company of 44.0 billion yen, up by 15.0 billion yen.

Note: Foreign currency exchange rates used for the forecasts are: 1 USD = 110 JPY, 1 RMB = 16.5 JPY

### Financial Section Business Risks

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

Forward-looking statements in the discussion of the risks below reflect the judgment of the Group as of March 31, 2017.

#### 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 projects in the pipeline may not be successfully developed and launched to the market because of the growing difficulty of development of new drugs. It is possible that some development projects may be delayed or abandoned. 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

Pharmaceutical products are approved only after rigorous safety testing, at different stages of development, and rigorous screening by the competent authorities in all the countries involved. 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 drugs and promotion of generic drug use, while 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 liable to decrease due to competition from the products in the same area from other manufacturers or from a launch of generic products following the expiration of a patent period or the like. 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 joint 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 pharmaceuticals 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 "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 pharmaceuticals 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 they complete 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.

#### Close or shutdown of a plant

The Group can envision scenarios in which the Group's plant is closed 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 the 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 the financial market situation will cause 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 incur 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 overseas business activity mainly in the regions of 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 that 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 information management

Since the Group uses a variety of information systems, there is the possibility of business being interrupted by a system malfunction, computer virus, or the like. Additionally, since the Group holds a large amount of confidential information that includes personal information, an external leak of the data could have a significant and negative impact on the Group's operating results and financial position resulting from compensation for damages, administrative sanctions, loss of social credibility, or the like.

#### 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 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.

### Financial Section Consolidated Balance Sheets

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries March 31, 2017 and 2016

	Million	Millions of yen				
ASSETS	2017	2016	2017			
CURRENT ASSETS:						
Cash and time deposits (Notes 3 and 5)	¥ 71,409	¥ 54,923	\$ 637,580			
Marketable securities (Notes 3, 5 and 6)	34,195	81,039	305,313			
Receivables:						
Trade notes (Note 5)	2,670	2,512	23,839			
Trade accounts (Note 5)	109,029	105,316	973,473			
Due from parent company, unconsolidated subsidiaries and						
affiliates (Notes 5 and 13)	16,819	48,513	150,170			
Allowance for doubtful receivables	(4)	(4)	(36)			
Total	128,514	156,337	1,147,446			
Inventories (Note 4)	68,807	59,589	614,348			
Deferred tax assets (Note 9)	60,956	63,992	544,250			
Other current assets	12,573	5,705	112,259			
Total current assets	376,454	421,585	3,361,196			

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

Land	6,265	6,269	55,938
Buildings and structures	95,726	95,280	854,696
Machinery and equipment	111,939	113,233	999,455
Construction in progress	3,113	1,497	27,795
Total	217,043	216,279	1,937,884
Accumulated depreciation	(157,789)	(154,454)	(1,408,830)
Net property, plant and equipment	59,254	61,825	529,054

#### INVESTMENTS AND OTHER ASSETS:

Investment in unconsolidated subsidiaries and affiliates (Notes 5)	1,867	1,819	16,670
Investment securities (Notes 5 and 6)	46,168	58,613	412,214
Goodwill (Note 15)	90,565	76,950	808,616
In-process research and development (Note 15)	193,971	60,145	1,731,884
Other intangible assets	19,775	19,486	176,562
Asset for retirement benefits (Note 10)	647	67	5,777
Deferred tax assets (Note 9)	711	2,314	6,348
Other assets	4,539	4,913	40,527
Total investments and other assets	358,243	224,307	3,198,598
TOTAL	¥ 793,951	¥ 707,717	\$ 7,088,848

	Million	Millions of yen			
IABILITIES AND NET ASSETS	2017	2016	(Note 1) 2017		
CURRENT LIABILITIES:	2011	2010	2011		
Short-term loans payable (Note 5 and 8)	¥ 40,000	¥ 1,010	\$ 357,143		
Current portion of long-term debt (Notes 5 and 8)	18,000	22,000	160,715		
Payables:	10,000	22,000	100,710		
Trade notes (Note 5)	106	93	946		
Trade accounts (Notes 5, 6 and 7)	50,413	42,436	450,116		
Due to parent company, unconsolidated subsidiaries and	00,410	42,400	400,110		
affiliates (Notes 5 and 13)	1,494	1,111	13,339		
Total	52,013	43,640	464,401		
Income taxes payable (Note 5)	8,818	26,358	78,732		
Accrued expenses	98,563	79,297	880,027		
Other current liabilities	11,053	7,418	98,687		
Total current liabilities	228,447	179,723	2,039,705		
	220,447	113,120	2,003,700		
ONG-TERM LIABILITIES:					
Long-term debt (Notes 5 and 8)	10,000	28,000	89,286		
Liability for retirement benefits (Note 10)	13,498	16,159	120,518		
Fair value of contingent consideration	39,909	8,968	356,330		
Deferred tax liabilities (Note9)	32,584	16,209	290,929		
Other liabilities (Note 8)	8,856	12,185	79,071		
Total long-term liabilities	104,847	81,521	936,134		
COMMITMENTS AND CONTINGENT LIABILITIES (Notes 14 and 20):					
Shareholders' equity (Note 11)					
Common stock: authorized – 1,500,000,000 shares in the years ended					
March 31, 2017 and 2016; issued — 397,900,154 shares in the					
years ended March 31, 2017 and 2016	22,400	22,400	200,000		
Capital surplus	15,861	15,861	141,616		
Retained earnings	363,628	341,402	3,246,678		
Treasury stock, at cost:600,484 shares in the year ended March 31, 2017					
and 598,599 shares in the year ended March 31, 2016	(667)	(663)	(5,955		
Total shareholders' equity	401,222	379,000	3,582,339		
Accumulated other comprehensive income (loss)					
Accumulated other comprehensive income (loss)           Unrealized gains (losses) on available-for-sale securities	18,440	25,293	164,643		
	18,440 (20)	25,293 (13)			
Unrealized gains (losses) on available-for-sale securities			(179		
Unrealized gains (losses) on available-for-sale securities Deferred gains (losses) on hedges	(20)	(13)	(179 408,286		
Unrealized gains (losses) on available-for-sale securities Deferred gains (losses) on hedges Foreign currency translation adjustments	(20) 45,728	(13) 48,025	(179 408,286 (42,080		
Unrealized gains (losses) on available-for-sale securities Deferred gains (losses) on hedges Foreign currency translation adjustments Remeasurements of defined benefit plans	(20) 45,728 (4,713)	(13) 48,025 (5,832)	164,643 (179 408,286 (42,080 530,670 4,113,009		

### Financial Section Consolidated Statements of Income

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

	Millions	of yen	Thousan U.S. do (Note	ollars
	2017	2016	201	7
NET SALES (Note 12)	¥ 411,639	¥ 403,206	\$ 3,675	5,348
COST OF SALES (Notes 12 and 13)	100,071	104,471	893	3,491
Gross profit	311,568	298,735	2,781	,857
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Notes 2 and 13)	258,809	261,805	2,310	).794
Operating income	52,759	36,930		1,063
OTHER INCOME (EXPENSES):				
Interest and dividend income (Note 13)	1,780	1,657	15	5,893
Interest expense	(631)	(920)		5,634)
Foreign exchange gains (losses)	1,237	(2,993)		1,045
Gain on sales of investment securities (Note 6)	5,754	6,107		1,375
Gain on sales of property, plant and equipment	120	10	1	1,071
Restructuring (Note 18)	(10,872)	(613)	(97	7,071)
Impairment loss (Notes 2 (h) and 17)	_	(553)		_
Loss on discontinuation of R&D programs	(2,006)	_	(17,	,911)
Other — net	(924)	(64)	(8,	,251)
Other income (expenses) — net	(5,542)	2,631	(49	,483)
INCOME BEFORE INCOME TAXES	47,217	39,561	421	1,580
INCOME TAXES (Note 9):				
Current	16,115	39,587	143	3,884
Deferred	2,111	(24,723)	18	8,848
Total income taxes	18,226	14,864	162	2,732
NET INCOME	¥ 28,991	¥ 24,697	\$ 258	8,848
NET INCOME ATTRIBUTABLE TO:				
Owners of the parent	¥ 28,991	¥ 24.697	\$ 258	3.848
Non-controlling interests	-		÷	_
	Ye	n	U.S. dollars (Note 1)	
PER SHARE OF COMMON STOCK:			· · · ·	
Basic net income	¥ 72.97	¥ 62.16	\$	0.65
Cash dividends applicable to the year	20.00	18.00		0.18

## Consolidated Statements of Comprehensive Income (Loss)

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016	Millions o	f yen	Thousands of U.S. dollars (Note 1)
	2017	2016	2017
NET INCOME	¥ 28,991	¥ 24,697	\$ 258,848
OTHER COMPREHENSIVE INCOME (LOSS):			
Unrealized gains (losses) on available-for-sale securities (Note 19)	(6,661)	2,194	(59,473)
Deferred gains (losses) on hedges (Note 19)	(7)	(15)	(63)
Foreign currency translation adjustments (Note 19)	(2,297)	(20,002)	(20,509)
Remeasurements of defined benefit plans (Note 19)	1,119	(1,295)	9,991
Total other comprehensive income (loss) (Note 19)	(7,846)	(19,118)	(70,054)
COMPREHENSIVE INCOME (LOSS)	21,145	5,579	188,794
COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO:			
Owners of the parent	21,145	5,579	188,794
Non-controlling interests	-	_	_

## Financial Section Consolidated Statements of Changes in Net Assets

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

	Thousands	of shares	s Millions of yen										
				Sha	areholders' eq	uity		Accur	Accumulated other comprehensive income (loss)				
	Issued number of shares of common stock	Number of treasury stocks	Common stock	Capital surplus	Retained earnings	Treasury stock	Total share- holders' equity	Unrealized gains (losses) on available- for-sale securities	Deferred gains (losses) on hedges	Foreign currency translation adjustments	Remeasure- ments of defined benefit plans	Total accumulated other comprehensive income (loss)	e Total net assets
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)				(3)	(3)						(3)
Sales of treasury stock		0		1		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
BALANCE, APRIL 1, 2016	397,900	(599)	¥ 22,400	¥ 15,861	¥ 341,402	¥ (663)	¥ 379,000	¥ 25,293	¥ (13)	¥ 48,025	¥ (5,832)	¥ 67,473	¥ 446,473
Cumulative effects of changes in accounting policies.					386		386	(192)	I			(192)	194
Restated balance			22,400	15,861	341,788	(663)	379,386	25,101	(13)	48,025	(5,832)	67,281	446,667
Cash dividends, ¥18.00 per share					(7,151)		(7,151)						(7,151)
Net income attributable to owners of the parent					28,991		28,991						28,991
Purchases of treasury stock		(2)				(4)	(4)						(4)
Sales of treasury stock		0		0		0	0						0
Change of scope of equity method													
Decrease due to change in fiscal period of consolidated subsidiaries													
Net change in items other than shareholders' equity								(6,661)	(7)	(2,297)	1,119	(7,846)	(7,846)
BALANCE, MARCH 31, 2017	397,900	(601)	¥ 22,400	¥ 15,861	¥ 363,628	¥ (667)	¥ 401,222	¥ 18,440	¥ (20)	¥ 45,728	¥ (4,713)	¥ 59,435	¥ 460,657

		Thousands of U.S. dollars (Note 1)									
		Shareholders' equity					Accumulated other comprehensive income (loss)				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total share- holders' equity	Unrealized gains (losses) on available- for-sale securities	Deferred gains (losses) on hedges	Foreign currency translation adjustments		Total accumulated other comprehensiv income (loss)	
BALANCE, APRIL 1, 2016	\$ 200,000	\$141,616	\$ 3,048,232	\$ (5,919)	\$ 3,383,929	\$ 225,830	\$ (116)	\$ 428,795	\$ (52,071)	\$602,438	\$ 3,986,367
Cumulative effects of changes in accounting policies.			3,446		3,446	(1,714)				(1,714)	1,732
Restated balance	200,000	141,616	3,051,678	(5,919)	3,387,375	224,116	(116)	428,795	(52,071)	600,724	3,988,099
Cash dividends, U.S.\$ 0.16 per share			(63,848)		(63,848)						(63,848)
Net income attributable to owners of the parent			258,848		258,848						258,848
Purchases of treasury stock				(36)	(36)						(36)
Sales of treasury stock		0		0	0						0
Change of scope of equity method											
Decrease due to change in fiscal period of consolidated subsidiaries											
Net change in items other than shareholders' equity						(59,473)	(63)	(20,509)	9,991	(70,054)	(70,054)
BALANCE, MARCH 31, 2017	\$ 200,000	\$141,616	\$ 3,246,678	\$ (5,955)	\$ 3,582,339	\$ 164,643	\$ (179)	\$ 408,286	\$ (42,080)	\$ 530,670	\$ 4,113,009

## Financial Section Consolidated Statements of Cash Flows

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

	Millions	Millions of yen		
	2017	2016	2017	
OPERATING ACTIVITIES:				
Income before income taxes	¥ 47,217	¥ 39,561	\$ 421,580	
Adjustments for:	ŕ	·		
Depreciation and amortization	13,058	14,287	116,589	
Impairment loss	_	553	_	
Amortization of goodwill	5,560	5,980	49,643	
Increase (decrease) in liability for retirement benefit	(1,664)	1,045	(14,857)	
Provision for other liabilities	18,421	18,787	164,473	
Interest and dividend income	(1,780)	(1,657)	(15,893)	
Interest expense	631	920	5,634	
Loss (gain) on sales of investment securities	(5,754)	(6,107)	(51,375)	
Restructuring	10,872	613	97,071	
Loss on discontinuation of R&D programs	2,006	_	17,911	
Changes in assets and liabilities:				
Decrease (increase) in receivables	(3,629)	(6,879)	(32,402)	
Decrease (increase) in inventories	(9,266)	(3,026)	(82,732)	
Increase (decrease) in payables	9,975	3,171	89,063	
Other — net	(8,832)	(2,417)	(78,857)	
Subtotal	76,815	64,831	685,848	
Interest and dividend received	1,834	1,744	16,375	
Interest paid	(352)	(644)	(3,143)	
Payment for restructuring	(10,849)	(585)	(96,866)	
Income taxes paid	(45,823)	(15,931)	(409,134)	
Net cash provided (used) by operating activities	21,625	49,415	193,080	
	,•_•	10,110	,	
INVESTING ACTIVITIES:				
Purchases of property, plant and equipment	(8,133)	(5,383)	(72,616)	
Purchases of intangible assets	(5,327)	(4,358)	(47,563)	
Proceeds from sales of investment securities	8,935	6,383	79,777	
Purchases of investment securities	(357)	(297)	(3,188)	
Purchase of investments in subsidiaries resulting in change in scope of consolidation	(84,349)	(_0.)	(753,116)	
Net decrease (increase) in short-term loans receivable	29,855	(2,089)	266,563	
Other — net	(354)	21,631	(3,160)	
Net cash provided (used) by investing activities	(59,730)	15,887	(533,303)	
	(00,100)	10,001	(000,000)	
FINANCING ACTIVITIES:				
Proceeds from short-term loans payable	39,036	1,080	348,536	
Repayment of long-term loans	(12,000)	(6,530)	(107,143)	
Redemption of bonds	(10,000)	(30,000)	(89,286)	
Dividends paid	(7,151)	(7,152)	(63,848)	
Other — net	(3)	(3)	(27)	
Net cash provided (used) in financing activities	9,882	(42,605)	88,232	
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(1,749)	(8,224)	(15,616)	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(29,972)	14,473	(267,607)	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	135,576	122,794	1,210,500	
Increase (decrease) in cash and cash equivalents resulting from change in the			1,210,000	
fiscal period of subsidiaries	¥ 105 604	(1,691) V 125 576	¢ 040 902	
CASH AND CASH EQUIVALENTS, END OF YEAR (Note 3) See Notes to Consolidated Financial Statements.	¥ 105,604	¥ 135,576	\$ 942,893	
Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### 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 ¥112 to U.S.\$1.00, the approximate rate of exchange on March 31, 2017. 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 2016 consolidated financial statements to conform to the classifications applied in 2017. These reclassifications have had no effect on the previously reported net income or retained earnings.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### a. Principles of Consolidation

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

The consolidated financial statements include the accounts of the Company and its 16 significant subsidiaries. Under the control concept, those companies in which the Company directly or indirectly is able to exercise control over operations are consolidated.

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 12 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.

#### 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.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### 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 mainly 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 mainly 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.

#### j. Research and Development Costs

Research and development costs are charged to income as incurred. Research and development costs included in selling, general and administrative expenses for the years ended March 31, 2017 and 2016 were ¥80,819 million (\$721,598 thousand) and ¥82,034 million, respectively.

#### k. Income Taxes

The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred tax assets and liabilities are measured at the tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted by the balance sheet date.

#### I. Foreign Currency Translation

All short-term and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates prevailing at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statements of income. Financial statements of overseas subsidiaries are translated into Japanese yen at the year-end rate for all assets and liabilities and at weighted average rates for income and expense accounts. Differences arising from such translation are shown as "Foreign currency translation adjustments" in a component of net assets.

#### m. Derivative Financial Instruments

Foreign exchange contracts are utilized to hedge the 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.

#### 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 397,300 thousand and 397,303 thousand for the years ended March 31, 2017 and 2016, 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.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### 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 have applied the "Guidance on Recoverability of Deferred Tax Assets" (ASBJ Guidance No.26, March 28, 2016 (hereinafter, "Guidance No.26").) from the beginning of the current fiscal year and revised a part of the accounting treatment regarding judgment of recoverability of deferred tax assets.

With regard to the application, in accordance with the provisions on transitional implementation indicated in Paragraph 49 (4) of Guidance No.26, the differences between the amount of deferred tax assets and deferred tax liabilities when Paragraph 49 (3) ① to ③ of Guidance No.26 are applied at the beginning of the current fiscal year, and the amount of deferred tax assets and deferred tax liabilities at the end of the previous fiscal year have been added to or subtracted from retained earnings and accumulated other comprehensive income (loss) at the beginning of the current fiscal year.

As a result, at the beginning of the current fiscal year, deferred tax assets (in "Investments and other assets") increased by 194 million yen, retained earnings increased by 386 million yen and unrealized gains on available-for-sale securities decreased by 192 million yen.

Reflecting these impacts on net assets at the beginning of the current fiscal year, retained earnings increased by 386 million yen and unrealized gains on available-for-sale securities decreased by 192 million yen.

#### q. Reclassifications

Certain reclassifications of the financial statements and accompanying footnotes for the year ended March 2016 have been made to conform to the presentation for the year ended March 31, 2017.

#### 3. SUPPLEMENTARY CASH FLOW INFORMATION

#### 1) Cash and cash equivalents

Cash and cash equivalents as at March 31, 2017 and 2016 for purposes of the consolidated statements of cash flows consisted of the following: Thousands of

	Millions of yen			U.S. dollars	
	2017	2016		2017	
Cash and time deposits	¥ 71,409	¥ 54,923	\$	637,580	
Time deposits with maturities over three months	-	(386)		-	
Marketable securities with a maturity of three months or less when purchased	34,195	81,039		305,313	
Cash and cash equivalents	¥ 105,604	¥ 135,576	\$	942,893	

As at March 31, 2016, a time deposit of ¥386 million was pledged as collateral for a letter of credit issued by a bank.

#### 2) Significant non-cash transactions

As a result of the acquisitions of Cynapsus Therapeutics Inc. dated October 21, 2016 and Tolero Pharmaceuticals, Inc. dated January 25, 2017, the Group increased assets and liabilities in the amount of ¥ 150,653 million (\$1,345,116 thousand) and ¥ 29,982 million (\$267,696 thousand), respectively. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the end of acquisitions and payments for acquisition of Cynapsus and Tolero, net of cash acquired, respectively.

	Millions of yen	Thousands of U.S. dollars
Current assets	¥ 1,184	\$ 10,571
Fixed assets	129,628	1,157,393
Goodwill	19,841	177,152
Current liabilities	(8,522)	(76,089)
Long-term liabilities	(21,460)	(191,607)
Net assets acquired	120,671	1,077,420
Accrued amounts in payment for acquisition	(35,268)	(314,893)
Cash and cash equivalent of Cynapsus and Tolero	(1,054)	(9,411)
Payment for acquisitions	¥ 84,349	\$ 753,116

#### 4. INVENTORIES

Inventories at March 31, 2017 and 2016 consisted of the following:

Millions	U.S. dollars	
2017	2016	2017
¥ 54,973	¥ 48,101	\$ 490,830
3,357	3,207	29,973
10,477	8,281	93,545
¥ 68,807	¥ 59,589	\$ 614,348
	¥ 54,973 3,357 10,477	¥ 54,973         ¥ 48,101           3,357         3,207           10,477         8,281

#### 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 of 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 short-term financial instruments such as Money Management Funds 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 two years from March 31, 2017. 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

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

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, President and Chief Executive Officer, transactions are then executed and the related entries posted. The results of derivative transactions are also reported to the Representative Director, President and Chief Executive Officer. Certain consolidated subsidiaries also set forth internal policies pertaining to forward exchange contracts and engage in transactions in accordance therewith. 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, 2017 and 2016 were as follows:

	Millions of yen			
	2017			
	Book values	Fair values	Difference	
(1) Cash and time deposits	¥ 71,409	¥ 71,409	¥ —	
(2) Trade notes	2,670	2,670	_	
(3) Trade accounts	109,029	109,029	—	
(4) Due from parent company, unconsolidated subsidiaries and affiliates	16,819	16,819	_	
(5) Marketable securities and investment securities	72,980	72,980	—	
Total assets	¥ 272,907	¥ 272,907	¥ —	
(1) Trade notes	106	106	_	
(2) Trade accounts	50,413	50,413	—	
(3) Due to parent company, unconsolidated subsidiaries and affiliates	1,494	1,494	_	
(4) Short-term loans payable	40,000	40,000	_	
(5) Income taxes payable	8,818	8,818	_	
(6) Bonds payable (*1)	20,000	20,209	209	
(7) Long-term loans payable (*2)	8,000	8,026	26	
Total liabilities	¥ 128,831	¥ 129,066	¥ 235	
Derivative transactions	¥ (31)	¥ (31)	¥ —	

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

(\*2) Long-term loans payable are the amount of current portion of long-term loans payable.

	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	390		
(6) Bonds payable (*1)	30,000	30,390	75		
(7) Long-term loans payable (*2)	20,000	20,075	¥ 465		
Total liabilities	¥ 121,008	¥ 121,473	¥ —		
Derivative transactions	¥ 181	¥ 181	¥ —		

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

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

	Thousands of U.S. dollars				
	2017				
	Book values	Fair values	Difference		
(1) Cash and time deposits	\$ 637,580	\$ 637,580	\$ —		
(2) Trade notes	23,839	23,839	—		
(3) Trade accounts	973,473	973,473	—		
(4) Due from parent company, unconsolidated					
subsidiaries and affiliates	150,170	150,170	-		
(5) Marketable securities and investment securities	651,607	651,607	_		
Total assets	\$ 2,436,669	\$ 2,436,669	\$ —		
(1) Trade notes	946	946	_		
(2) Trade accounts	450,116	450,116	_		
(3) Due to parent company, unconsolidated					
subsidiaries and affiliates	13,339	13,339	_		
(4) Short-term loans payable	357,143	357,143	_		
(5) Income taxes payable	78,732	78,732	_		
(6) Bonds payable (*1)	178,571	180,438	1,867		
(7) Long-term loans payable (*2)	71,429	71,661	232		
Total liabilities	\$ 1,150,276	\$ 1,152,375	\$ 2,099		
Derivative transactions	\$ (277)	\$ (277)	\$ —		

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

(\*2) Long-term loans payable are the amount of current portion of long-term loans payable.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

(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

 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 has a new identical loan been 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	Thousands of U.S. dollars		
	2017	2016	2017	
Unlisted shares	¥ 6,350	¥ 6,355	\$ 56,697	
Investment in unconsolidated subsidiaries and affiliates	1,867	1,819	16,670	
Investment in limited partnership	1,033	614	9,223	

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

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

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

	Millions of yen			
	2017			
	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years
Cash and time deposits	¥ 71,409	¥ —	¥ —	¥ —
Trade notes	2,670	_	_	_
Trade accounts	109,029	—	_	—
Due from parent company, unconsolidated subsidiaries and affiliates	16,819	_	_	_
Marketable securities and investment securities:				
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)	4,000	_	_	_
Total	¥ 203,927	¥ —	¥ —	¥ —

	Millions of yen			
		20	16	
	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	¥ —	¥ —	¥ —

	Thousands of U.S. dollars				
			20	17	
	,	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years
Cash and time deposits	\$	637,580	\$ —	\$ —	\$ -
Trade notes		23,839	_	_	_
Trade accounts		973,473	_	_	-
Due from parent company, unconsolidated subsidiaries and affiliates		150,170	_	_	_
Marketable securities and investment securities:					
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)		35,714	_	_	_
Total	\$ ·	1,820,776	\$	\$	\$

Other securities

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### 6. MARKETABLE SECURITIES AND INVESTMENT SECURITIES

Marketable securities and investment securities as of March 31, 2017 and 2016 consisted of the following:

	Millions	Millions of yen		
	2017	2016	2017	
Current:				
Government / local government bonds	-	—	-	
Corporate bonds	-	_	-	
Negotiable certificates of deposits	¥ 4,000	¥ 11,100	\$ 35,714	
MMF	30,195	69,939	269,599	
Total	¥ 34,195	¥ 81,039	\$ 305,313	
Noncurrent:				
Equity securities	¥ 38,785	¥ 51,644	\$ 346,295	
Trust fund investments and other	-	_	-	
Total	¥ 38,785	¥ 51,644	\$ 346,295	

The carrying amount and aggregate fair value of marketable securities and investment securities as at March 31, 2017 and 2016 were as follows:

	Millions of yen					
		2017				
	Cost	Unrealized gains	Unrealized losses	Fair value		
Available-for-sale securities:						
Equity securities	¥ 12,652	¥ 26,133	¥ 0	¥ 38,785		
Government / local government bonds	_	—	_	—		
Corporate bonds	_	_	_	_		

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	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	_	_	_	_		

		Thousands of U	.S. dollars		
	2017				
	Cost	Unrealized gains	Unrealized losses	Fair value	
Available-for-sale securities:					
Equity securities	\$ 112,964	\$ 233,331	\$0	\$ 346,295	
Government / local government bonds	-	_	_	_	
Corporate bonds	_	_	_	_	
Other securities	_	_	_	_	

Proceeds from sales of available-for-sale securities were ¥8,935 million (\$79,777 thousand) and ¥6,383 million for the years ended March 31, 2017 and 2016, respectively. Realized gains from sales of available-for-sale securities were ¥5,754 million (\$51,375 thousand) and ¥6,107 million for the years ended March 31, 2017 and 2016, and costs on sales of available-for-sale securities were ¥3,181 million (\$28,402 thousand) and ¥277 million for the years ended March 31, 2017 and 2016, respectively. The cost of securities sold when computing realized gains was determined using the moving average method.

On March 31, 2017, investment securities of ¥68 million (\$607 thousand) were pledged as collateral for accounts payable of ¥70 million (\$625 thousand). On March 31, 2016, investment securities of ¥52 million were pledged as collateral for accounts payable of ¥77 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, 2017 were as follows:

- 1) Currency related derivative transactions for which hedge accounting is not applied Not applicable
- 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		Irs
		Contract	amounts		Contract a	mounts	
Trans	action type	Total	Portion over 1 year	Fair value	Total	Portion over 1 year	Fair value
	eign exchange vard contracts Buy contracts						
	USD	¥ 1,900	_	¥ (28)	\$ 16,965	_	\$ (250)
	EUR	473	-	(2)	4,223	_	(18)
	THB	221	-	(1)	1,973	-	(9)
	Total	¥ 2,594	-	¥ (31)	\$ 23,161	-	\$ (277)

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		Th	ousands of U.S. dolla	ars		
		Contract amounts		Contract amounts		t amounts Contrac		Contract amounts	
Trans	action type	Total	Portion over 1 year	Fair value	Total	Portion over 1 year	Fair value		
	eign exchange vard contracts Buy contracts								
	USD	¥ 430	-	_	\$ 3,839	-	-		
	EUR	52	-	_	464	_	-		
	GBP	-	-	_	_	_	-		
	THB	23	_	_	206	_	_		
	Total	¥ 505	-	-	\$ 4,509	_	—		

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

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

1) Currency related derivative transactions to which hedge accounting is not applied Transaction except market transaction

		Millions of yen		
	Contract	amounts		
Transaction type	Total	Portion over 1 year	Fair value	Valuation difference
Foreign exchange forward contracts				
Sell contracts				
USD	¥ 15,692	_	¥ 201	¥ 201
Total	¥ 15,692	-	¥ 201	¥ 201

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				
Contract	Contract amounts			
Total Portion over 1 year		Fair value		
¥ 2,321	_	¥ (22)		
481	_	2		
139	_	(0)		
¥ 2,941	_	¥ (20)		
	Total <b>¥ 2,321</b> <b>481</b> <b>139</b>	Contract amounts           Total         Portion over 1 year           ¥ 2,321         —           481         —           139         —		

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				
Transaction type	Total	Portion over 1 year	Fair value			
Foreign exchange forward contracts						
Buy contracts						
USD	¥ 491	_	-			
EUR	55	_	-			
GBP	5	-	-			
THB	10	_	-			
Total	¥ 561	_	_			

#### 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 0.13% at March 31, 2017.

Long-term debt at March 31, 2017 and 2016 were as follows:

	Millions	s of yen	Thousands of U.S. dollars
	2017	2016	2017
Unsecured loans from banks and financial institutions, due 2016 to 2017 with average interest rate of 0.90-1.25%	¥ 8,000	¥ 20,000	\$ 71,428
Unsecured bonds due 2016 with average interest rate of 0.54%		10,000	
Unsecured bonds due 2017 with average interest rate of 1.11%	10,000	10,000	89,286
Unsecured bonds due 2018 with average interest rate of 0.82%	10,000	10,000	89,286
Total	¥ 28,000	¥ 50,000	\$ 250,000
Less current portion	(18,000)	(22,000)	(160,714)
Long-term debt, less current portion	¥ 10,000	¥ 28,000	\$ 89,286

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

Year Ending March 31	Millions of yen	Thousands of U.S. dollars
2017	¥ 18,000	\$ 160,714
2018	10,000	89,286
Total	¥ 28,000	\$ 250,000

Other liabilities include deposits received from customers in the amount of ¥6,301 million (\$56,259 thousand) as of March 31, 2017, bearing interest at an average rate of 4.61%, and ¥5,991 million as of March 31, 2016, bearing interest at an average rate of 4.86%.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### 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 30.8% and 33.0% for the years ended March 31, 2017 and 2016 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, 2017 and 2016 were as follows:

	Millions	Millions of yen		
	2017	2016	2017	
Deferred tax assets:				
Accrued bonuses to employees	¥ 5,930	¥ 3,539	\$ 52,946	
Reserve for sales rebates	12,299	16,579	109,813	
Accrued enterprise taxes	665	1,874	5,938	
Liability for retirement benefits	4,908	4,966	43,821	
Loss on devaluation of investment securities	589	626	5,259	
Research and development costs	8,712	8,171	77,786	
Inventories	4,072	4,813	36,357	
Net operating loss carried forward	16,582	6,964	148,054	
Amortization of intangible assets	10,393	12,686	92,795	
Tax credit for research and development costs of overseas subsidiaries	5,196	3,107	46,393	
Unrealized gain on inventories	27,992	25,024	249,929	
Other	6,583	11,237	58,775	
Gross deferred tax assets	103,921	99,586	927,866	
Valuation allowance	(16,963)	(11,904)	(151,455)	
Total deferred tax assets	¥ 86,958	¥ 87,682	\$ 776,411	
Deferred tax liabilities:				
Unrealized gains on available-for-sale securities	¥ (7,999)	¥ (10,980)	\$ (71,420)	
Asset for retirement benefits	(964)	—	(8,607)	
Deferred gain on sales of fixed assets	(690)	(697)	(6,161)	
Tax effect of intangible assets related to business combination	(47,056)	(24,735)	(420,143)	
Refund of capital surplus of a subsidiary	(405)	(405)	(3,616)	
Undistributed earnings of foreign subsidiaries	(484)	(311)	(4,321)	
Other	(277)	(457)	(2,474)	
Total deferred tax liabilities	¥ (57,875)	¥ (37,585)	\$ (516,742)	
Net deferred tax assets	¥ 29,083	¥ 50,097	\$ 259,669	

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, 2017 and 2016 was as follows:

	2017	2016
Normal statutory tax rate	30.8%	33.0%
Increase (decrease) in taxes due to:		
Expenses not deductible for tax purposes	3.7	4.8
Non-taxable dividend income	(0.4)	(0.4)
Tax credits for research and development costs	(10.9)	(14.9)
Amortization of goodwill	3.6	5.0
Change in valuation allowance	10.7	8.8
Effect of revised corporate tax rate	-	3.0
Tax effects attributable to investments in subsidiaries	0.4	(0.2)
Other	0.7	(1.5)
Effective tax rate	38.6%	37.6%

#### 10. RETIREMENT AND SEVERANCE BENEFITS

The liability for retirement benefits as at March 31, 2017 and 2016 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	Thousands of U.S. dollars	
	2017	2016	2017
Balance at the beginning of the fiscal year	¥ 92,912	¥ 92,042	\$ 829,571
Service cost	3,372	3,408	30,107
Interest cost	932	920	8,321
Actuarial gain	(639)	144	(5,705)
Benefits paid	(6,731)	(3,632)	(60,098)
Past service costs	377	_	3,366
Other	50	30	447
Balance at the end of fiscal year	¥ 90,273	¥ 92,912	\$ 806,009

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

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Balance at the beginning of the fiscal year	¥ 76,753	¥ 78,529	\$ 685,295
Expected return on plan assets	1,434	1,443	12,803
Actuarial gain	998	(2,786)	8,911
Contributions paid by the employer	2,203	2,296	19,670
Benefits paid	(4,077)	(2,729)	(36,402)
Balance at the end of the fiscal year	¥ 77,311	¥ 76,753	\$ 690,277

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

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Balance at the beginning of the fiscal year	¥ (67)	¥ (174)	\$ (598)
Retirement benefit costs	7	172	63
Benefits paid	(4)	(37)	(36)
Contributions paid by the employer	(45)	(44)	(402)
Other	(1)	16	(9)
Balance at the end of the fiscal year	¥ (110)	¥ (67)	\$ (982)

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Funded retirement benefit obligations Plan assets	¥ 78,358 (79,005)	¥ 79,348 (78,323)	\$ 699,625 (705,402)
	(647)	1,025	(5,777)
Unfunded retirement benefit obligations	13,498	15,067	120,518
Total Net liability (asset) for retirement benefits at the end of the fiscal year	12,851	16,092	114,741
Liability for retirement benefits Asset for retirement benefits	13,498 (647)	16,159 (67)	120,518 (5,777)
Total Net liability (asset) for retirement benefits at the end of fiscal year	¥ 12,851	¥ 16,092	\$ 114,741

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

Note: Includes plan applied simplified method.

#### 5) Retirement benefit costs

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Service cost	¥ 3,372	¥ 3,408	\$ 30,107
Interest cost	932	920	8,321
Expected return on plan assets	(1,434)	(1,443)	(12,804)
Net actuarial loss amortization	510	1,587	4,554
Past service costs amortization	(180)	(366)	(1,607)
Retirement benefit costs applied simplified method	7	172	63
Other	270	468	2,411
Total retirement benefit costs for the fiscal year	¥ 3,477	¥ 4,746	\$ 31,045

Other than those above, the Company recorded ¥10,872 million (\$97,071 thousand) and ¥613 million of special retirement benefit for the years ended March 31, 2017 and 2016 respectively.

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

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Past service costs	¥ (570)	¥ (366)	\$ (5,089)
Actuarial gains and losses	2,147	(1,342)	19,169
Total	¥ 1,577	¥ (1,708)	\$ 14,080

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

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Unrecognized past service costs	¥ (850)	¥ (1,420)	\$ (7,589)
Unrecognized actuarial gains and losses	7,674	9,821	68,518
Total	¥ 6,824	¥ 8,401	\$ 60,929

#### 8) Plan assets

i) Plan assets comprise:

	2017	2016
Bonds	50.3%	54.3%
Equity securities	17.1%	14.0%
Cash and cash equivalents	4.8%	5.1%
General account	10.6%	10.5%
Other	17.2%	16.1%
Total	100.0%	100.0%

Note: "Other" mainly consists of investment trust.

Retirement benefit trusts set up for corporate pension plans account for 7.9 percent and 6.6 percent of total plan assets at March 31, 2017 and 2016, 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, 2017 and 2016 (expressed as weighted averages) were as follows:

	2017	2016
Discount rate	1.0 $\sim$ 3.2%	1.0%
Long-term expected rate of return	2.0%	2.0%
Estimated salary increase rate	$3.8{\sim}5.8\%$	$3.8 \sim 5.8\%$

#### 2. Defined contribution plans

The amount of required contributions to the defined contribution plans of the Company and consolidated subsidiaries was ¥2,895 million (\$25,848 thousand) and ¥2,992 million for the years ended March 31, 2017 and 2016, 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 22, 2017, the shareholders approved year-end cash dividends of ¥11.00 (\$0.10) per share, amounting to ¥4,370 million (\$39,018 thousand). These appropriations have not been accrued in the consolidated financial statements as of March 31, 2017. 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 ¥20.00 (\$0.18) per share.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### **12. TRANSACTIONS** Transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., unconsolidated WITH PARENT subsidiaries and affiliates for the years ended March 31, 2017 and 2016 were as follows: COMPANY, Thousands of UNCONSOLIDATED Millions of yen U.S. dollars **SUBSIDIARIES** 2017 2016 2017 AND AFFILIATES \$ 2,304 Sales ¥ 258 ¥ 268 Purchases 7,351 7,633 65,634

#### 13. RELATED PARTY TRANSACTIONS

Major transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., for the years ended March 31, 2017 and 2016 were as follows:

odo of

	Millions of yen		U.S. dollars	
	2017	2016	2017	
Purchases of products	¥ 3,729	¥ 3,673	\$ 33,295	
Payment of other expenses	852	1,138	7,607	
Loans (Collection)	(29,855)	2,089	(266,563)	
Interest income	239	292	2,134	

The balances due to or from the parent company, Sumitomo Chemical Co., Ltd., as at March 31, 2017 and 2016 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Receivables	¥ 16,806	¥ 48,553	\$ 150,054
Payables	1,015	666	9,063

#### 14. LEASES

The minimum lease payments under non-cancelable operating leases as of March 31, 2017 and 2016 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Due within one year	¥ 950	¥ 1,010	\$ 8,482
Due after one year	5,871	6,656	52,420
Total	¥ 6,821	¥ 7,666	\$ 60,902

#### 15. BUSINESS COMBINATIONS

Business combination through acquisition

#### **Cynapsus Therapeutics Inc.**

- a. Summary of the business combination
  - Name of the acquired company and the contents of its business operations Name of the acquired company: Cynapsus Therapeutics Inc. ("Cynapsas") Contents of the business operations: Developing pharmaceuticals for Parkinson's disease
- 2. Main reason for the business combination

Sunovion Pharmaceuticals Inc.("Sunovion") focuses on the Psychiatry & Neurology area and promotes the atypical antipsychotic agent Latuda<sup>®</sup> and antiepileptic drug Aptiom<sup>®</sup>. Sunovion concluded that this acquisition contribute to expand Psychiatry & Neurology portfolio, one of its key therapeutic areas, through the acquisition of Cynapsus and their product for Parkinson's disease.

- 3. Date of business combination October 21, 2016 (U.S. Eastern Standard Time)
- 4. Legal form of business combination Acquisition of shares for cash consideration
- 5. Name of the company after combination Sunovion CNS Development Canada ULC.
- 6. Ratio of voting rights acquired 100%
- 7. Main grounds for reaching a decision on the acquiring company

It is because Sunovion CNS Development Canada ULC(old company) acquired shares of Cynapsus in exchange for cash. On the closing day, a new company with the same name was established with amalgamation of Cynapsus Therapeutics Inc. and Sunovion CNS Development Canada ULC (old company).

- b. Period of performance of the acquired company included in the consolidated financial statements From October 21, 2016 to March 31, 2017
- c. Acquisition cost and consideration of the acquired company and the breakdown thereof

		Millions of yen	Thousands of U.S. dollars
Purchase	consideration (cash)	¥ 63,238	\$ 564,625
Acquisition cost		¥ 63,238	\$ 564,625

d. Major acquisition-related costs and amounts

Advisory fees and others ¥681 million (\$6,080 thousand)

- e. Amount of goodwill, reason for recognition, amortization method and amortization period
  - 1. Amount of goodwill: ¥1,255 million (\$11,205 thousand)
  - 2. Reason for recognition: As the acquisition cost exceeded the net amount of assets acquired and liabilities assumed, the difference has been posted as goodwill.
  - 3. Amortization method and amortization period: Straight-line method over 20 years
  - 4. The amount of goodwill is a temporarily calculated amount.
- f. Total assets acquired and liabilities assumed on the date of business combination and the main breakdown thereof

	Millions of yen	Thousands of U.S. dollars
Current assets	¥ 1,025	\$ 9,152
Fixed assets	69,775	622,991
Total assets	70,800	632,143
Current liabilities	8,416	75,143
Long-term liabilities	401	3,580
Total liabilities	¥ 8,817	\$ 78,723

g. Amount allocated to intangible fixed assets other than goodwill and amortization period for the entity is as follows:

Description		Amortization period	
Description	Millions of yen		Amonization penou
In-process research and development	¥ 69,686	\$ 622,196	Estimated useful life

h. Allocation of acquisition cost

The allocation of acquisition cost was not completed at the end of the consolidated fiscal year ended March 31, 2017 and the cost is recognized based on reasonable information available at that point of time.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

i. Estimated impact on the consolidated statement of income in the current consolidated fiscal year, if it is assumed that the business combination was concluded on April 1, 2016, and the method of calculation

	Millions of yen	Thousands of U.S. dollars		
Sales	¥ —	\$ —		
Income before income taxes	(3,262)	(29,125)		
Net income	(3,262)	(29,125)		

(Method by which estimated amounts were calculated)

The estimated amounts were calculated as the differences between sales and income calculated on the assumption that the business combination was concluded on the first day of this consolidated fiscal year and information on sales and income contained in the consolidated statement of income of the acquiring company.

The estimated amounts of impact have not been audited.

#### **Tolero Pharmaceuticals, Inc.**

a. Summary of the business combination

- Name of the acquired company and the contents of its business operations
   Name of the acquired company: Tolero Pharmaceuticals, Inc.
   Contents of the business operations: Research and Development of pharmaceuticals in the areas
   of oncology and hematological disorders
- 2. Main reason for the business combination

Tolero Pharmaceuticals, Inc. (Tolero) is a biotechnology company in the U.S. specializing in research and development of therapeutic agents in the areas of oncology and hematological disorders. Tolero possesses excellent drug discovery capabilities for kinase inhibitors and other drug targets, and they are developing six compounds, including cyclin-dependent kinase 9 (CDK9) inhibitor alvocidib, which is under clinical development for hematologic malignancies. It is expected that this acquisition will help the Company to reinforce our oncology pipeline to add these compounds. And also high drug discovery abilities in Tolero contribute to create a continuous flow of development compounds going forward to achieve sustainable growth of the Group.

3. Date of business combination

January 25, 2017 (U.S. Pacific Standard Time)

4. Legal form of business combination

Acquisition of shares for cash consideration

- 5. Name of the company after combination Tolero Pharmaceuticals, Inc.
- 6. Ratio of voting rights acquired 100%
- 7. Main grounds for reaching a decision on the acquiring company It is because Dainippon Sumitomo Pharma America Holdings, Inc. which is the U.S. holding Company wholly-owned by the Company, acquired shares in exchange for cash.
- b. Period of performance of the acquired company included in the consolidated financial statements From January 25, 2017 to March 31, 2017

c. Acquisition cost and consideration of the acquired company and the breakdown thereof

		Millions of yen	Thousands of U.S. dollars
Purchase	Consideration (cash)	¥ 22,164	\$ 197,893
Fair value of cor	tingent consideration	¥ 35,269	\$ 314,902
Acquisition cost		¥ 57,433	\$ 512,795

- d. Major acquisition-related costs and amounts Advisory fees and others ¥1,067 million (\$9,527 thousand)
- e. Amount of goodwill, reason for recognition, amortization method, amortization period
  - 1. Amount of goodwill: ¥18,586 million (\$165,946 thousand)
  - 2. Reason for recognition: As the acquisition cost exceeded the net amount of assets acquired and liabilities assumed, the difference has been posted as goodwill.
  - 3. Amortization method and amortization period: Straight-line method over 20 years
  - 4. The amount of goodwill is a temporarily calculated amount.
- f. Total assets acquired and liabilities assumed on the date of business combination and the main breakdown thereof

	Millions of yen	Thousands of U.S. dollars
Current assets	¥ 160	\$ 1,428
Fixed assets	59,853	534,402
Total assets	60,013	535,830
Current liabilities	107	955
Long-term liabilities	21,058	188,018
Total liabilities	¥ 21,165	\$ 188,973

g. Nature of the contingent consideration for acquisition set out in the business combination contract and the accounting treatment policy for the current and subsequent consolidated fiscal years

- 1. Nature of the contingent consideration for acquisition
- The contingent consideration for acquisition is a contract under which an additional payment shall be made upon the achievement of predetermined milestone.
- Accounting treatment policy for the relevant and subsequent consolidated fiscal years The above-mentioned contingent consideration for acquisition has been recognized according to U.S. accounting standards.
- h. Amount allocated to intangible fixed assets other than goodwill and amortization period for the entity is as follows:

Description		Amortization period	
Description	Millions of yen	Thousands of U.S. dollars	Amonization period
In-process research and development	¥ 59,843	\$ 534,313	Estimated useful life

i. Allocation of acquisition cost

The allocation of acquisition cost was not completed at the end of the consolidated fiscal year ended March 31, 2017 and the cost is recognized based on reasonable information available at that point of time.

j. Estimated impact on the consolidated statement of income in the current consolidated fiscal year, if it is assumed that the business combination was concluded on April 1, 2016 and the method of calculation

	Millions of yen	Thousands of U.S. dollars
Sales	¥ —	\$ —
Income before income taxes	(758)	(6,768)
Net income	(758)	(6,768)

(Method by which estimated amounts were calculated)

The estimated amounts were calculated as the differences between sales and income calculated on the assumption that the business combination was concluded on the first day of this consolidated fiscal year and sales and income contained in the consolidated statement of income of the acquiring company.

The estimated amounts of impact have not been audited.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### 16. SEGMENT INFORMATION

#### 1) Outline of reportable segments

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

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

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

Accounting method for business segment reporting is the same as presented in Note 2 "Summary of Significant Accounting Policies." Income by reportable segment is calculated based on operating income before R&D costs. Intersegment sales and transfers are calculated based on current market prices.

Assets and liabilities by reportable segment are not shown because such information is not used to make decisions regarding resource allocation and performance measurement.

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

Segment information for the Group for the years ended March 31, 2017 and 2016 were as follows:

	Millions of yen						
		2017					
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Net sales							
Sales to customers	¥ 140,848	¥ 197,889	¥ 17,624	¥ 11,567	¥ 367,928	¥ 43,711	¥ 411,639
Intersegment sales and transfers	50	—	_	—	50	75	125
Total	140,898	197,889	17,624	11,567	367,978	43,786	411,764
Income of segment	38,307	83,289	6,743	2,804	131,143	2,407	133,550
Others							
Depreciation and amortization	4,237	3,572	327	431	8,567	99	8,666
Amortization of Goodwill	_	5,560	_	_	5,560	_	5,560

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					
	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

	Thousands of U.S. dollars						
		2017					
	Japan North America China Other Regions Subtotal Other Business						Total
Net sales							
Sales to customers	\$ 1,257,571	\$ 1,766,866	\$ 157,357	\$ 103,277	\$ 3,285,071	\$ 390,277	\$ 3,675,348
Intersegment sales and transfers	447	_	_	_	447	669	1,116
Total	1,258,018	1,766,866	157,357	103,277	3,285,518	390,946	3,676,464
Income of segment	342,027	743,652	60,205	25,036	1,170,920	21,491	1,192,411
Others							
Depreciation and amortization	37,830	31,893	2,920	3,848	76,491	884	77,375
Amortization of Goodwill	_	49,643	_	_	49,643	_	49,643

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

	Millions	of yen	U.S. dollars
Net sales	2017	2016	2017
Reportable segments total	¥ 367,978	¥ 361,066	\$ 3,285,518
Net sales of "Other Business" category	43,786	42,359	390,946
Elimination of intersegment transactions	(125)	(219)	(1,116)
Net sales in the consolidated statements of income	¥ 411,639	¥ 403,206	\$ 3,675,348

	Millions	Thousands of U.S. dollars	
Income	2017	2016	2017
Reportable segments total	¥ 131,143	¥ 117,128	\$ 1,170,920
Income of "Other Business" category	2,407	1,821	21,491
Research and development costs	(80,819)	(82,034)	(721,598)
Elimination of intersegment transactions	28	15	250
Operating income in the consolidated			
statements of income	¥ 52,759	¥ 36,930	\$ 471,063
	Millions	s of yen	Thousands of U.S. dollars
Other items	2017	2016	2017
Depreciation and amortization			
Reportable segments total	¥ 8,567	¥ 8,931	\$ 76,491
Other Business	99	152	884
Adjustment	3,755	3,561	33,527
The amount in the consolidated financial statements	¥ 12,421	¥ 12,644	\$ 110,902
Amortization of goodwill			
Reportable segments total	¥ 5,560	¥ 5,980	\$ 49,643
Other Business	_		_
Adjustment	_	_	
The amount in the consolidated financial statements	¥ 5,560	¥ 5,980	\$ 49,643

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

#### 5) Other information

Sales information by product or service for the Group for the years ended March 31, 2017 and 2016 were as follows: Thousands of

	Millions	U.S. dollars	
Sales to customers	2017	2016	2017
Pharmaceuticals	¥ 367,928	¥ 360,924	\$ 3,285,071
Other products	43,711	42,282	390,277
Total	¥ 411,639	¥ 403,206	\$ 3,675,348

Geographical segment information for the Group for the years ended March 31, 2017 and 2016 were as follows:

	Millions	U.S. dollars	
Net sales	2017	2016	2017
Japan	¥ 186,354	¥ 190,156	\$ 1,663,875
U.S.	193,706	181,085	1,729,518
Other regions	31,579	31,965	281,955
Total	¥ 411,639	¥ 403,206	\$ 3,675,348

Draparty, plant and aggingment	Millions	Millions of yen			
Property, plant and equipment	2017	2016	2017		
Japan	¥ 49,372	¥ 51,852	\$ 440,821		
U.S.	8,534	8,513	76,197		
Other regions	1,348	1,460	12,027		
Total	¥ 59,254	¥ 61,825	\$ 529,045		

latangible accete	Millions	Thousands of U.S. dollars	
Intangible assets	2017	2016	2017
Japan	¥ 7,668	¥ 8,792	\$ 68,464
U.S.	296,366	147,241	2,646,125
Other regions	277	548	2,473
Total	¥ 304,311	¥ 156,581	\$ 2,717,062

Sales information by major customer for the Group for the years ended March 31, 2017 and 2016 were as follows:

Net sales	Millions of yen		Thousands of U.S. dollars
Name of major customer and related segment	2017	2016	2017
McKesson Corporation / North America	¥ 70,003	¥ 62,474	\$ 625,027
Cardinal Health Inc. / North America	49,594	47,778	442,804
AmerisourceBergen Corporation/ North America	45,784	42,168	408,786

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

				Millions of yen			
				2017			
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	¥ —	¥ —	¥ —	¥ —	¥ —	¥ —	¥ —
Amortization of goodwill	—	5,560	—	—	5,560	_	5,560
Balance of goodwill	—	90,565	—	—	90,565	_	90,565

					Millions of yen					
		2016								
-	Japan	North	n America	China	Other Regions	SL	ibtotal	Other Busine	SS	Total
Impairment loss	¥ 33	¥	263	¥ —	¥ —	¥	296	¥ 257	¥	553
Amortization of goodwill	_		5,980	_	_		5,980	_		5,980
Balance of goodwill	_	7	6,950	_	_	7	6,950	_		76,950

	Thousands of U.S. dollars						
	2017						
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	\$ —	\$ -	\$ —	\$ —	\$ -	\$ —	\$ -
Amortization of goodwill	_	49,643	_	—	49,643	- 1	49,643
Balance of goodwill	—	808,616	—	-	808,616	; _	808,616

#### **17. IMPAIRMENT LOSS**

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

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

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 book value.

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%.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2017 and 2016

18. RESTRUCTURING	Restructuring carried out in the year ended March 31, 201 business structure and organization including the early reti Restructuring carried out in the year ended March 31, business structure and organization in the Company.	rement progra	m in the Compa	ny.
19. OTHER COMPREHENSIVE INCOME (LOSS)	Components of other comprehensive income (loss) for t were as follows:		ed March 31, 20	17 and 2016 Thousands of U.S. dollars
		2017	2016	2017
	Unrealized gains on available-for-sale securities			
	Amount arising during the period under review	¥ (3,499)	¥ 10,358	\$ (31,241)
	Reclassification adjustment for gains (losses) included in net income	(5,952)	(7,430)	(53,143)
	Before income tax effect adjustment	(9,451)	2,928	(84,384)
	Amount of income tax effect	2,789	(734)	24,902
	Unrealized gains on available-for-sale securities, net of tax	¥ (6,661)	¥ 2,194	\$ (59,473)
	Deferred gains or losses on hedges			
	Amount arising during the period under review	¥ (11)	¥ (22)	\$ (98)
	Amount of income tax effect	4	7	35
	Deferred gains or losses on hedges, net of tax	¥ (7)	¥ (15)	\$ (63)
	Foreign currency translation adjustment	V (0.007)	V (00 000)	¢ (00 500)
	Amount arising during the period under review	¥ (2,297)	¥ (20,002)	\$ (20,509)
	Foreign currency translation adjustment	(2,297)	(20,002)	(20,509)
	Remeasurements of defined benefit plans			
	Amount arising during the period under review	¥ 1,248	¥ (2,929)	\$ 11,143
	Reclassification adjustment for gains (losses) included in net income	329	1,221	2,937
	Before income tax effect adjustment	1,577	(1,708)	14,080
	Amount of income tax effect	(458)	413	(4,089)
	Remeasurements of defined benefit plans, net of tax	¥ 1,119	¥ (1,295)	\$ 9,991
	Total other comprehensive income (loss)	¥ (7,846)	¥ (19,118)	\$ (70,054)

#### 20. CONTINGENT LIABILITIES

Contingent liabilities for guarantees as of March 31, 2017 and 2016 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2017	2016	2017
Loans guaranteed— Employee's housing loans guaranteed	¥ 67	¥ 101	\$ 598

## 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, 2017 and 2016, 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, 2017 and 2016, 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, 2017 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 1 to the consolidated financial statements.

KPMG AZSA LLC

June 22, 2017 Osaka, Japan

#### **Principal Shareholders**

(As of March 31, 2017)

Name	No. of Shares Held (Thousands of Shares)	
Sumitomo Chemical Co., Ltd.	201,134	50.63
Inabata & Co., Ltd.	25,582	6.44
The Master Trust Bank of Japan, Ltd. (Trust account)	17,153	4.32
Japan Trustee Services Bank, Ltd. (Trust account)	10,089	2.54
Nippon Life Insurance Company	7,581	1.91
Japan Trustee Services Bank, Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa Insurance Co., Ltd.	4,435	1.12
Sumitomo Dainippon Pharma Employee shareholders' association	3,687	0.93
Trust & Custody Services Bank, Ltd. (Security investment trust account)	3,477	0.88

#### **Composition of Shareholders**

(As of March 31, 2017)



Note: Percentage of shareholding is calculated excluding treasury stock (600,484 shares).

#### Share Price Range and Trading Volume



## External Evaluations of Sumitomo Dainippon Pharma Group on Sustainability



#### **FTSE4Good Index Series**

The FTSE4Good Index Series is created by the global index provider FTSE Russell (U.K.) to measure the performance of companies demonstrating strong Environmental, Social and Governance (ESG) practices. Sumitomo Dainippon Pharma has been independently assessed according to the FTSE4Good criteria, and has continuously satisfied the requirements to become a constituent of this index series since 2003.



#### **MSCI Global Sustainability Indexes**

The MSCI Global Sustainability Indexes is a globally renowned SRI (Socially Responsible Investment) index generated MSCI Inc. of the U.S. Sumitomo Dainippon Pharma has been independently assessed according to the MSCI Global Sustainability Indexes criteria, and has continuously satisfied the requirements to become a constituent of these indexes since 2010.



Japan

#### **FTSE Blossom Japan Index**

The FTSE Blossom Japan Index is created by the global index provider FTSE Russell (U.K.) to measure the performance of Japanese companies demonstrating strong Environmental, Social and Governance (ESG) practices. Sumitomo Dainippon Pharma has been independently assessed according to the FTSE Blossom Japan Index criteria, and has satisfied the requirements to become a constituent of this index as of June 2017.



#### 2017 Constituent MSCI Japan ESG Select Leaders Index

#### MSCI Japan ESG Select Leaders Index

The MSCI Japan ESG Select Leaders Index targets 50% of the free float-adjusted market capitalization of each Global Industry Classification Standard (GICS®) Sector and is designed to target companies that have high Environmental, Social and Governance (ESG) performance. Sumitomo Dainippon Pharma has been independently assessed according to the MSCI Japan ESG Select Leaders Index criteria, and has satisfied the requirements to become a constituent of this index as of June 2017.



# MSCI (1) 2017 Constituent MSCI Japan Empowering Women Index (WIN)

#### **MSCI Japan Empowering Women Index (WIN)**

The MSCI Japan Empowering Women Index (WIN) aims to represent the performance of companies that are leading within their GICS® sector groups in terms of promoting and maintaining gender diversity while also meeting certain quality factor criteria. Sumitomo Dainippon Pharma has been independently assessed according to the MSCI Japan Empowering Women Index (WIN) criteria, and has satisfied the requirements to become a constituent of this index as of June 2017.



#### **SNAM Sustainability Index**

The SNAM Sustainability index is created by the SOMPO JAPAN Nippon Asset Management (SOMPO JAPAN), and is used in SRI (socially responsible investment) fund for pension funds or institutional investors to invest widely in companies with the high ESG (environment, society, governance) evaluation ratings. Sumitomo Dainippon Pharma was selected to this index as of June 2017.



#### Morningstar Socially Responsible Investment Index

MS-SRI is a socially responsible investment stock index of 150 companies selected from about 4,000 listed Japanese companies by Morningstar based on their social guality. Sumitomo Dainippon Pharma was selected to the index as of January 2017.



#### Corporate Data As of April 1, 2017

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Name	Sumitomo Dainippon Pharma Co., Ltd.
Establishment	May 14, 1897
Date of Merger	October 1, 2005
Osaka Head Office	6-8 Doshomachi 2-chome, Chuo-ku, Osaka 541-0045, Japan TEL: +81-6-6203-5321 FAX: +81-6-6202-6028
Tokyo Head Office	13-1, Kyobashi 1-chome, Chuo-ku, Tokyo 104-8356, Japan TEL: +81-3-5159-2500 FAX: +81-3-5159-2945
Capital	¥22.4 billion
Total Number of Shares Issued	397,900,154
Stock Exchange Listing	Tokyo Stock Exchange
Securities Code	4506
Independent Public Accountants	KPMG AZSA LLC
Fiscal Year-end	March 31
Ordinary General Meeting of Shareholders	June

Administrator of Shareholders' Register	Sumitomo Mitsui Trust Bank, Limited
Lead Managers	(Main) Daiwa Securities Co., Ltd.; (Sub) SMBC Nikko Securities Inc., Nomura Securities Co., Ltd.
Main Banks	Sumitomo Mitsui Banking Corporation Sumitomo Mitsui Trust Bank, Limited The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Key Facilities	Osaka Head Office (Osaka), Tokyo Head Office (Tokyo), 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.) Tolero Pharmaceuticals, Inc. (U.S.) Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (China)





Japan



Member of SNAM Sustainability Index 2017





2017 Constituent MSCI Japan ESG Select Leaders Index

2017 Constituent MSCI Japan Empowering Women Index (WIN)





IR Site http://www.ds-pharma.com/ir/



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

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