

Securities Code 4506

# Integrated Report 2018

# 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 Mission**

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

#### **Management Mission**

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

# Innovation today, healthier tomorrows

#### **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.



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#### Editorial Policy

#### Applicable Period

This report is based on the results for fiscal 2017 (April 1, 2017 to March 31, 2018). Some of the activities described were conducted in fiscal 2018. **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
- GRI Sustainability Reporting Standards

#### Disclaimer Regarding Forward-Looking Statements

This Report contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties.

Accordingly, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein. Information concerning pharmaceuticals (including compounds under development) contained herein is not intended as advertising or as medical advice.

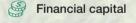
# Business Model for Value Creation

By utilizing our Company's intellectual capital, human capital, and social and relationship capital, while also creating and delivering new value, we contribute to the betterment of healthcare and fuller lives of people worldwide.

At the same time, we generate economic value and strive to boost long-term corporate value.

#### Sources of value creation

Sumitomo Dainippon Pharma recognizes that our intellectual capital, human capital, and social and relationship capital are specific sources of competitiveness.



Manufactured capital

Intellectual capital

Human capital

Social and relationship capital

A Natural capital

#### Value creation process

Rich pipeline, drug discovery capability, leading-edge technology and know-how, broad network related to science, and distinctive R&D capacity in the three focus areas.

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

- New compounds under development: 10
- R&D know-how cultivated in-house as part of our long-standing track record of producing pharmaceutical products.
- Drug discovery initiatives leveraging leading-edge technologies (in-silico, biomarkers, iPS cells, etc.).

#### Oncology Area

- New compounds under development: 9
- R&D focused on our proprietary technologies, such as cancer stemness inhibition, cancer immunomodulation, and kinase inhibition.
- Robust network that includes overseas academic institutions and biotech companies.

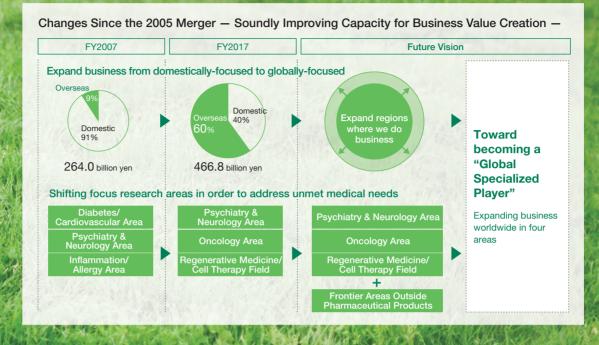
## Excellent human resources and a framework that utilizes the capabilities of individual employees

- Professional Human Resources System utilizing employees with specialization and a strong ability to produce results.
  - Professional Human Resources ("Professional Contributors"): approx. 40

#### A platform supporting global business expansion

- The capacity to roll out new businesses in the global market
  - A robust platform in Japan, North America, and China
  - Rolling out business in Southeast Asia and Europe

- Human resources highly skilled in R&D (technology, expertise, know-how)
- Sincere, talented employees that contribute strongly to the Company
- Business operations leveraging the strengths of acquired overseas subsidiaries
  - Respecting the corporate culture and leveraging subsidiaries' strengths



#### Contributing to sustainable development

Regenerative Medicine / Cell Therapy Field

#### • Ongoing projects: 5

- A top player aiming to commercialize iPS cell-derived cellular medicines.
- A robust network with academic institutions and biotech companies; a technology platform of in-house production facilities and manufacturing know-how.

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- Initiatives for further strengthening human resources
- ✓ Fostering leaders (DSP Academy)
- ✓ Diversity and inclusion initiative targeting active participation by a varied work force

#### Creating innovative pharmaceutical products and contributing to healthcare worldwide

Delivering pharmaceutical products in areas where unmet medical needs are high

Stably supplying high-quality pharmaceuticals

Contributing to the development of medical science through research and development

Contributing to global health





## Improving sustainable corporate value

- Maximizing shareholder value
- Implementing strategic investments

Stakeholder Relationships Supporting Competitive Advantage

# Relationship with Stakeholders

In order to challenge ourselves to create new drugs that deliver value, and to achieve sustainable growth as a research and development-oriented pharmaceutical company with a global presence, we believe that it is necessary to further strengthen relationships with our stakeholders.

Stakeholders	Awareness of the surrounding environment and corresponding relationships
Patients & Healthcare Professionals	While it is certainly necessary to respond to the expectations of patients and healthcare professionals by creating innovative pharmaceutical products in areas and fields with high unmet medical needs, it is also necessary to build more trusting relationships by providing information in a prompt, accurate, and conscientious manner.
Business Partners	While striving—based on fair, open, and free competition—to create business opportunities with new business partners, we also build positive relationships with partners in the spirit of our code of conduct. It is necessary to stably deliver added value as we respond to the globalization of our supply chain. We also coordinate with wholesale partners and examine risks across the entire supply chain as we remain aware of the importance of fulfilling our social responsibility.
Shareholders and Investors	We strive to increase corporate value through constant business development efforts, while meeting shareholder expectations for returns of capital. Furthermore, we believe that it is important to optimize investments for each type of capital in order to meet expectations for sustainable growth, while actively disclosing ESG information and engaging in dialogue.
Employees	People are the wellspring of a company's competitiveness and we dedicate effort toward support systems and culture creation that help each employee fully exercise his or her capabilities. Moreover, we believe that it is important to create workplaces conducive to lively engagement in work tasks, while helping employees have full lives inside and outside the office.
Local Communities	Sumitomo Dainippon Pharma is able to engage in business precisely because of the trust and credibility that society places in us. With an awareness of this fact, and of our role as a corporate citizen, we are called upon to contribute to local communities and to solve social issues in areas where we can leverage our capital. Furthermore, we believe that it is important to proactively endeavor to improve access to healthcare globally.



#### Initiatives and main opportunities for dialogue

<ul> <li>Provide information on the proper use of pharmaceutical products to healthcare professionals through our daily medical information sharing activities.</li> <li>Provide information through our websites (for general audiences, patients, patient families, and healthcare professionals).</li> <li>✓ Use our Health Information Website to share disease-related and</li> </ul>	<ul> <li>other information (for general audiences, patients, and patient families).</li> <li>Use our Medical Information Website to provide product and scientific information (for healthcare professionals).</li> <li>Use our Product Information Center as a dedicated contact point for handling inquiries (from patients, patient families, and healthcare professionals).</li> </ul>
<ul> <li>Evaluate procurement sources following Criteria for Selecting New Business Partners and review said criteria with CSR procurement in mind.</li> <li>Deepen communication and mutual understanding through inspections, interviews, etc.</li> <li>Strengthen BCP policies in order to sustainably deliver added value.</li> </ul>	<ul> <li>Employee training directed at achieving fair and open transactions.</li> <li>Coordinate information sharing activities with wholesale partners and exchange information related to local healthcare.</li> </ul>
<ul> <li>Provide shareholders with explanations and discussion opportunities at General Shareholders' Meetings and facilitate the smooth exercise of voting rights.</li> <li>✓ Avoid selecting days on which numerous shareholders' meetings are taking place and send out convocation notices as early as possible.</li> <li>✓ Business reports and briefings utilizing video.</li> <li>Hold business briefings and accommodate individual requests for interviews.</li> </ul>	<ul> <li>Meetings with institutional investors: 4 meetings in FY2017 (including conference calls)</li> <li>Visits to overseas investors: 1 visit to Europe, 1 to the U.S. in FY2017</li> <li>Briefings for individual investors: 5 briefings in FY2017</li> <li>Appropriate and timely press release communication, disclosure of statutory disclosure materials and voluntary disclosure materials (Integrated Reports (Annual Reports), Shareholder Reports, Fact Books, etc.).</li> </ul>
<ul> <li>Various measures for promoting "Work Style Innovations" (such as holding Work Style Innovation Meetings, etc.).</li> <li>An opinion poll, "DSP Opinion," targeting employee awareness (implemented annually).</li> <li>Face-to-face guidance based on Self-Reports that assist with understanding employees' progress and ambitions.</li> </ul>	<ul> <li>Consultation Desks and Hotlines inside and outside the Company.</li> <li>Director Dialogues allowing for candid exchanges of opinions between employees and board members.</li> <li>Regularly scheduled labor-management consultations.</li> <li>DSP Academy for training selected employees.</li> </ul>
<ul> <li>Visiting lectures by employees at junior high and high schools (classes covering the topic of DNA diagnostics).</li> <li>The Owls Forest Restoration Project in the Sumitomo Dainippon Pharma Forest.</li> </ul>	<ul> <li>Environmental conservation activities, regional contribution activities (Japan, China, the U.S.).</li> <li>Initiatives to improve access to care in low- and middle-income countries through the Access Accelerated program.</li> </ul>

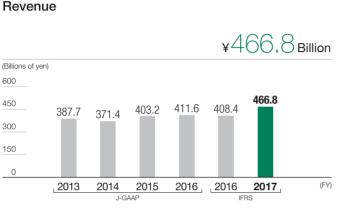
• Volunteer activities in regions with our business bases.

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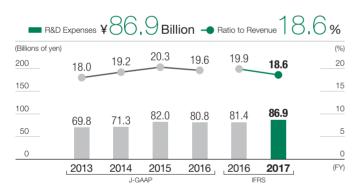
### Financial and Non-Financial Highlights

The Sumitomo Dainippon Pharma Group has adopted the International Financial Reporting Standards (IFRS) for preparing its consolidated financial statements from the fiscal year ended March 31, 2018.

#### **Financial Highlights**

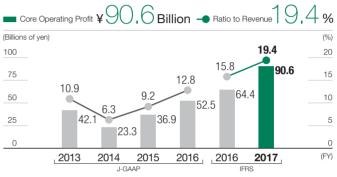


Note: From fiscal 2013 to fiscal 2016, net sales figures are presented in accordance with Japanese GAAP.

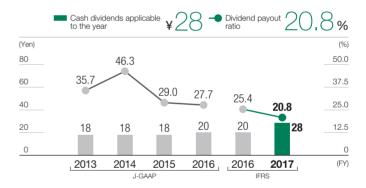


#### R&D Expenses / Ratio to Revenue

# Operating Profit and Ratio to Revenue (Core Operating Profit under IFRS)

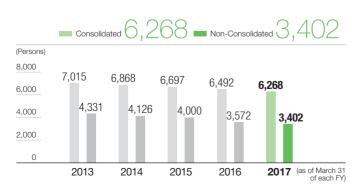


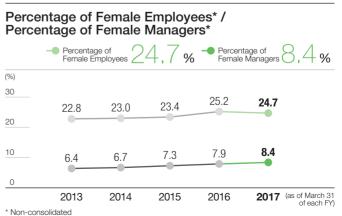
Note: From fiscal 2013 to fiscal 2016, operating income figures and operating margin are presented in accordance with Japanese GAAP.



#### **Non-Financial Highlights**

#### Number of Employees





Note: The numbers for the percentage of female managers represent the percentage as of April 1 of the following fiscal year.

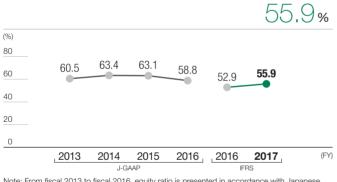
#### Cash Dividends and Dividend Payout Ratio

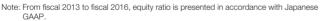


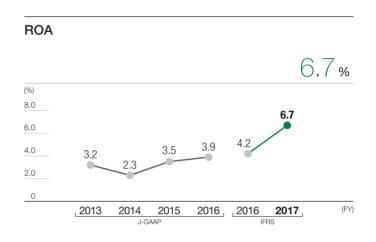
Net Profit Attributable to Owners of the Parent

Note: From fiscal 2013 to fiscal 2016, net income figures are presented in accordance with Japanese GAAP.

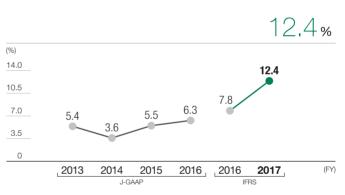
# Ratio of Equity Attributable to Owners of the Parent to Total Assets







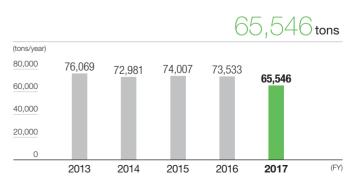




#### Acquisition Rate of Annual Paid Leave\* / Percentage of Male Employees Taking Childcare Leave\*



#### CO<sub>2</sub> Emissions



#### Message from the Chairman

# Accelerating the growth rate and ensuring solid, sustainable growth going forward under a new framework

In April 2018, Sumitomo Dainippon Pharma started operating under a newly designed framework. After having spent the last 10 years as Company president, I became Chairman and Representative Director while Hiroshi Nomura took the wheel as president. In this position, I will strive to strengthen governance, carry on the company culture, and develop human resources.

Under our new framework, we will strive for the kind of value that only Sumitomo Dainippon Pharma can create as we aim for sustainable growth.

Masayo Tada Representative Director, Chairman In October 2005, Sumitomo Dainippon Pharma was created through the merger of Sumitomo Pharmaceuticals and Dainippon Pharmaceutical. The new company embarked on its first steps toward delivering innovative and effective pharmaceutical products not only in Japan, but to people throughout the world. Despite being a domestic-oriented company with more than 90% of sales coming from inside Japan at the time of the merger, we announced a goal of becoming a global company in our 1st Mid-term Business Plan. This included advancing the in-house development of atypical antipsychotic LATUDA<sup>®</sup>. In order to establish an overseas sales organization, we acquired Sepracor Inc. (now Sunovion Pharmaceuticals Inc.) in the U.S. in 2009. These efforts bore fruit, with our overseas sales revenue surpassing 60% of total revenue and LATUDA<sup>®</sup> growing to be a blockbuster drug in North America.

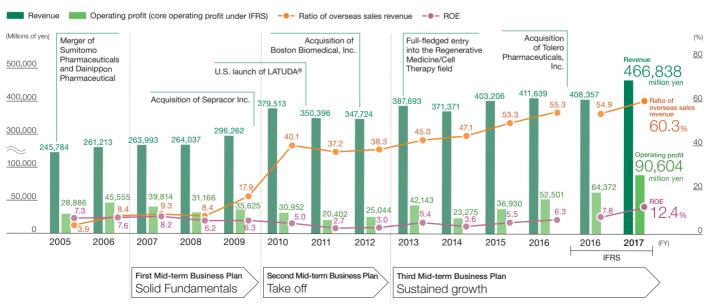
Additionally, in 2012, we acquired U.S. biotech company Boston Biomedical, Inc. This marked our full-fledged entry into the Oncology field—which, along with Psychiatry & Neurology, we made one of our focus research areas. In 2017, our acquisition of Tolero Pharmaceuticals, Inc. allowed us to further enhance our oncology pipeline. Furthermore, given the need to make the Regenerative Medicine/Cell Therapy field an earnings pillar of the future, we are striving to move with greater speed than other companies. In 2013, we created a division dedicated to commercializing regenerative medicine and cell therapy products, with five projects currently underway. In March 2018, we completed construction of the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT). This is the world's first commercial manufacturing plant specifically for allogeneic iPS cell-derived regenerative medicine and cell therapy products.

Looking back, I feel that the readiness to challenge ourselves and the tireless efforts of all of our Group directors and employees has yielded these results, for which I am deeply grateful. Going forward, as Chairman of the Board of Directors, I will strive to strengthen governance, while also, in the role of supporting management, dedicate effort to human resources development and policies to carry on our culture of taking on challenges.

Sumitomo Dainippon Pharma has established a solid organization oriented toward growth and has laid the foundations for the future through the 1st to 3rd Mid-term Business Plans. Under the new leadership of President Nomura, we will further accelerate our growth and ensure a strong, sustainable future.

I ask all of our stakeholders for your generous understanding and continued support.

Representative Director, Chairman



#### Post-Merger Trajectory

Note: FY2005 does not include business results for the former Sumitomo Pharmaceuticals Co., Inc. from April – September 2005. Note: Starting from FY2017, the Group has adopted the International Financial Reporting Standards (IFRS). Note: From fiscal 2005 to fiscal 2016, net sales and operating income figures are presented in accordance with Japanese GAAP.

#### Message from the President

As a globally active leader in research and development, our aim is sustainable growth and the improvement of corporate value by providing innovative new drugs and healthcare solutions.

> I am the new president of Sumitomo Dainippon Pharma, having assumed the position on April 1, 2018. Since Sumitomo Dainippon Pharma's merger in October 2005, we have aggressively pursued globalization of our business and have achieved steady growth. My most important mission as president is to further strengthen and expand the business foundation that has supported our growth while at the same time realizing ongoing sustainable development. To this end, we will effectively leverage management resources and strive to create new value that incorporates a broad range of knowledge and expertise. I also want the Company to continue making contributions to the advancement of society, as this brings a sense of pride and satisfaction to our stakeholders, while continuing to be a company that deserves your support and respect.

#### **Hiroshi Nomura**

Representative Director, President and Chief Executive Officer

#### Looking back over fiscal 2017 (year ended March 31, 2018), how would you rate the Group's business performance?

#### We achieved revenue and profit gains in Japan, North America and China while also posting steady results in research and development.

Fiscal 2017 performance saw higher year-on-year sales and profit, with increases not only in Japan and China but also in North America, for record revenue of ¥466.8 billion, an increase of ¥58.5 billion. Sales of Trulicity® and AIMIX® did well in Japan while, in North America, LATUDA® was a significant leader, with support from APTIOM® and other lines in contributing to higher sales. Selling, general and administrative expenses decreased in Japan, but rose overall by ¥14.8 billion year-on-year to ¥186.2 billion as a result of increased marketing costs in North America, with the launches of new drugs in the chronic obstructive pulmonary disease (COPD) area and other upcoming launch products. Research and development costs rose ¥5.5 billion year-on-year to ¥86.9 billion due to development costs for imeglimin, apomorphine, and oncology projects. Consequently, core operating profit increased by ¥26.2 billion year-on-year to ¥90.6 billion and net profit attributable to owners of the parent rose by ¥22.1 billion year-on-year to ¥53.4 billion. Regarding dividends, based on the Company's performance, we paid an ordinary dividend of ¥18, plus a ¥10 special dividend, for a total of ¥28 per share.

In terms of R&D, we received approval in the U.S. for

LONHALA® MAGNAIR® and succeeded in pivotal studies covering four products: a new indication for TRERIEF® (approval received in Japan), dasotraline (application submitted in the U.S.), apomorphine (application submitted in the U.S.), and LONASEN® transdermal patch formulation (application submitted in Japan). Additionally, with regard to enhancing our pipeline, which we have positioned as a key challenge, seven products began clinical studies and one product advanced to a Phase 2 study. These and other results made fiscal 2017 an extremely substantial year in terms of both sales and R&D.

Regarding our progress in achieving the targets of the 3rd Mid-Term Business Plan (MTBP) covering fiscal years 2013 through 2017, we couldn't bring any in-house development products to market in Japan, where we are aiming to establish a strong business foundation, according to the plan. However, overseas, with LATUDA® becoming a blockbuster drug in North America, strong gains were made in sales. In R&D, lurasidone, under development in Japan, napabucasin, and other products did not reach the market, and those entering clinical studies were fewer than targeted; however, we were able to enhance our development pipeline through in-licensing and acquisitions, which ensured a certain measure of results alongside the progress made with R&D in the Regenerative Medicine and Cell Therapy field. Furthermore, on the organizational management front, we were able to produce results through proactive initiatives, such as continuously pursuing operational efficiency and CSR, and building a dynamic corporate culture while developing talent.

Against that backdrop, we recognize that our overall highest priority challenges are expanding our development product pipeline and boosting the success rate of R&D.

(Billions of ven)

			Year-on-Year		
	FY2016	FY2017	Change	Rate of Change (%)	
Revenue	408.4	466.8	58.5	14.3	
Core operating profit	64.4	90.6	26.2	40.8	
Operating profit	40.3	88.2	47.9	118.9	
Net profit attributable to owners of the parent	31.3	53.4	22.1	70.7	

Note: Starting from the fiscal year ended March 31, 2018 (FY2017), the Group has adopted the International Financial Reporting Standards (IFRS) for preparing its consolidated financial statements. Financial data showing profit and loss for the previous fiscal year (FY2016) are also represented under the IFRS.

To coincide with adoption of the IFRS, the Group has set an original performance indicator for the Company's recurring profitability in the form of "core operating profit."

"Core operating profit" is calculated by deducting from operating profit any gains and losses resulting from non-recurring factors that the Group designates. Among the main non-recurring items are impairment losses, business structure improvement expenses, litigation-related expenses, and changes in fair value of contingent consideration related to company acquisitions.

#### Please give us some details about key initiatives in fiscal 2018 (year ending March 31, 2019).

#### We are striving to strengthen our business foundation for sustainable growth, both within, and outside of, Japan.

In April 2018, we established the Japan Business Unit with the objective of strengthening our domestic operations. As a virtual organization encompassing sales, development, manufacturing, and quality assurance—existing organizations delineated by their functions—the Unit is charged with proposing strategies relating to challenges that are particular to Japan and carrying them out in a timely manner. Under this framework, we will, of course, devote efforts to strengthening our mainstay products while also focusing on in-licensing, alliances and building an efficient sales organization. Furthermore, because we are seeking to enhance the efficiency of our production framework, we plan to transition from our current four-plant structure to two plants by the end of fiscal 2018.

In North America, while working to maximize the product value of LATUDA<sup>®</sup>, we will continue to devote efforts to expanding sales of APTIOM<sup>®</sup>, BROVANA<sup>®</sup>, and, following its April 2018 launch, LONHALA<sup>®</sup> MAGNAIR<sup>®</sup>. We will also establish an efficient sales organization for new products, including dasotraline and apomorphine, both of which are expected to be approved in fiscal 2018. In China, effort will go into maintaining sales of mainstay product MEROPEN<sup>®</sup>, while achieving early market penetration with LONASEN<sup>®</sup>, which was launched in February 2018. receive three approvals for dasotraline (ADHD, U.S.), apomorphine (OFF episodes associated with Parkinson's disease, U.S.), and TRERIEF® (Parkinsonism in Dementia with Lewy Bodies, Japan, approved in July 2018). In the Oncology area, we will accelerate development toward timely NDAs for alvocidib (acute myeloid leukemia, U.S.) and napabucasin (colorectal cancer, pancreatic cancer; U.S. & Japan). In the Regenerative Medicine and Cell Therapy field, the Phase 2 study for SB623, targeting chronic stroke, is progressing in the U.S. Meanwhile, for allogeneic iPS cell-derived regenerative medicine and cell therapy products, we plan to commence company-initiated clinical studies with Healios K.K., targeting age-related macular degeneration. Also an investigator-initiated study is being conducted for a treatment of Parkinson's disease, which we are working on for use in practice, in collaboration with the Center for iPS Cell Research and Application (CiRA) at Kyoto University.

Among these development products, we are expecting approval of dasotraline and apomorphine in fiscal 2018, and alvocidib, napabucasin, DSP-7888 and SB623 in fiscal 2019 or beyond. As post-LATUDA candidates, we would like to grow peak future global sales of each product to ¥50 billion or higher. We have expectations for napabucasin and SB623 to reach blockbuster status.

As a matter of course, we will also continue to consider new in-licensing and M&A in order to further expand our product pipeline. And, with a view to improving the success rate for R&D projects, we are working to strengthen our platform technologies that are directly connected to pipeline advancement, such as in-silico/Al technology and iPS drug discovery, while also strengthening translational research through integrating our research and development.



#### Please explain your R&D plans and the market launch targets for "post-LATUDA" candidates.

#### We will accelerate development of promising new drugs in each field, aiming for a steady stream of approvals and market launches.

For fiscal 2018, we are planning R&D investment on the level of ¥85 billion, or roughly on par with that for fiscal 2017.

In the Psychiatry & Neurology area, during fiscal 2018, we are aiming to submit two NDAs for dasotraline (binge eating disorder, U.S.) and transdermal patch formulation of LONASEN<sup>®</sup> (schizophrenia, Japan, applied in July 2018), and we expect to

Given the postponement of the Mid-Term Business Plan announcement, can you provide some details regarding your medium- to long-term strategies for future growth?



We will devote efforts to distinctive new drug development and generation of new business as we increase our presence in the global market.

In light of the lawsuit we filed against the LATUDA® ANDA filers\*, we postponed the planned March 2018 announcement of the

Mid-Term Business Plan covering the five years from fiscal 2018 through 2022, and we will decide on the timing of the announcement once there is clarity on the course of that litigation.

Consequently, I cannot give numerical targets at this time, but our medium- to long-term growth strategies are to formulate innovative pharmaceutical products in our three focus areas with high unmet medical needs: Psychiatry & Neurology, Oncology, and Regenerative Medicine and Cell Therapy.

In the Psychiatry & Neurology area, we will not only devote efforts to researching individual diseases with high unmet medical needs, including creating fundamental treatments for treatment-resistant psychiatric and neurological disorders, but we will also target drug discovery in overlapping areas of psychiatry and neurology, including psychological symptoms stemming from neurodegenerative disorders such as Alzheimer's disease and Parkinson's disease. In Oncology, we will aim to develop distinctive new drugs from the three approaches of cancer stemness inhibitors, kinase inhibitors, and cancer immunomodulation, while growing business in these areas. In the Regenerative Medicine and Cell Therapy field, we are currently driving forward a total of five projects: treatment for chronic stroke using allogeneic mesenchymal stem cells, treatments for age-related macular degeneration, Parkinson's disease, retinitis pigmentosa, and spinal cord injury using allogeneic iPS cell-derived cells. Going forward, we will proactively participate in global leading-edge projects as our contribution to the establishment of new medical technologies.

In addition to these, we are exploring underlying technologies and moving forward with marketability surveys, as we strive to pioneer frontier fields for new business in healthcare areas other than pharmaceuticals with the aim of building a second earnings pillar alongside our Pharmaceutical Business. Within Japan, and in other major markets, there is growing pressure for medical costs to be reduced. The social role of healthcare services that support the maintenance of people's health and prevention of disease progression is also becoming steadily greater. Based on the pool of knowledge that we have built up over many years in the fields of pharmaceuticals and healthcare, Sumitomo Dainippon Pharma is using the latest digital technology to explore the potential for new healthcare solutions. Over the next five years, we will first launch new businesses and then work to grow and make them profitable over the subsequent five years. In the five years beyond that, we would like to foster those ventures to become the fourth pillar of our business.

In formulating the next Mid-Term Business Plan (MTBP), our intention is to outline five-year-increment growth strategies based on our long-term vision for the coming 15 years. We plan to incorporate the strategies of the first five-year period as key measures in the MTBP. Consequently, 15 years from now, we



aim to be a "Global Specialized Player" delivering differentiated pharmaceutical products in each business area and medical and healthcare solutions to people worldwide.

\* Stands for Abbreviated New Drug Application, an application submitted to the U.S. FDA for approval to market a generic drug product.

#### Please tell us about some specific initiatives and results for strengthening corporate governance and the Company's corporate foundation.

#### We are building a highly effective governance system and directing efforts toward selective, grade-specific training with a view to enhancing the individual capacities of our employees.

Sumitomo Dainippon Pharma is targeting sustainable growth and increased medium- to long-term corporate value, while continually working to reinforce our corporate governance systems. We have taken steps to strengthen each system, including formulating the Basic Policy on Corporate Governance and establishing a Nomination and Compensation Committee (in October 2015), newly establishing the Corporate Governance Department (in April 2016), and re-establishing our risk management framework (in January 2017). Furthermore, in



June 2018, with the aim of increasing gender diversity on the Board of Directors, we welcomed our newest Outside Director. Our three Outside Directors are individuals who have been active in the fields of government administration, medicine, and corporate management. Moreover, our three Outside Audit & Supervisory Board Members include an expert in tax and finance, a corporate executive, and an attorney. Hence, our Board of Directors and Audit & Supervisory Board are very diversified and they leverage individual viewpoints and specializations to provide multi-faceted checks and balances for Sumitomo Dainippon Pharma's management. Through this series of initiatives, we are committed to steadily elevating the effectiveness of our corporate governance.

Meanwhile, our initiatives for strengthening the Company's corporate foundation include introducing, from fiscal 2016, a new personnel system (Professional Human Resources System) aimed at improving employees' abilities to produce results, and also the DSP Academy, which is a selective, career grade-specific training system. The DSP Academy is aimed at the early selection of talented personnel, and then providing them with training to foster leadership and management skills. From young employees through mid-career employees and managers, personnel of different grades are chosen for their ambition and potential to receive training using case studies, action learning, and various other types of instruction. Going forward, we will strengthen our education and training programs for improving the individual capabilities of employees, with a view to developing professionals who possess and demonstrate solid originality and the ability to produce results.

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



Through our business, we continue to contribute to the resolution of a wide range of social issues, including those related to health and welfare.

Sumitomo Dainippon Pharma believes that the core objective of our CSR management is implementing our Corporate Mission,

#### Sustainable Development Goals (SDGs)

In September 2015, the United Nations selected SDGs for the purpose of solving global problems such as poverty and energy consumption. The 17 goals that were finalized are being pursued worldwide, targeting attainment by 2030.

Goal 3: "Good Health and Well-being" was established in the area of public health. Sumitomo Dainippon Pharma continues to challenge itself in innovative new drug discovery using leading-edge technology in the focus research areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine and Cell Therapy. We are also working to support activities in countries and regions where there are needs for improved healthcare systems as we strive to help solve problems related to access to healthcare in such areas.



"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 other words, our philosophy is to respond to unmet medical needs, which is a critical social issue, and deliver our innovative pharmaceutical products and solutions as we grow in tune with society by contributing to the realization of a sustainable society.

Our stance of addressing social issues through our business activities is also aligned with achieving the Sustainable Development Goals (SDGs) promoted by the United Nations. Sumitomo Dainippon Pharma has announced its commitment to the SDGs, including Goal 3: "Good Health and Well-being," which we emphasize in pursuing our business activities. For instance, as an activity based on Goals 3 and 17: "Partnerships for the Goals," from 2017, we have allied with more than 20 pharmaceutical companies around the world to participate in the Access Accelerated Project, which works to improve access to medical care for non-communicable diseases in developing countries. We are also focusing on initiatives to achieve Goal 12: "Responsible Consumption and Production," for proper pharmaceutical use.

Furthermore, while referencing the 17 objectives of the SDGs, we engaged in internal debate on the social issues that we should address through our business activities. Classifying them according to the two perspectives of importance and relevance to our business, we created a materiality map with issues ranked by priority.

One of those high-priority issues where we have devoted effort to is "work style innovation," in accordance with Goal 8: "Decent Work and Economic Growth." Rather than promoting work style innovations through a uniform, Company-wide approach, each of our divisions, from sales and R&D through manufacturing sites and Head Office functions, has its own unique way of executing business and reviewing work styles according to actual on-site circumstances. Work Style Innovation Meetings, held by each division since fiscal 2017, provide one opportunity to carry out such reviews. The meetings include discussions aimed at achieving work styles characterized by high efficiency and productivity. Some results have already emerged, such as reducing overtime hours and increasing the utilization rate for paid leave. Going forward, we will continue to proactively adopt innovative ideas and pursue achievement of both higher productivity and better work-life balance. As a company, we will support work style innovations at each business site by expanding the work-from-home system and the staggered-work-hour system, while also transforming the office environment through the introduction of open, unassigned desk spaces.

Sumitomo Dainippon Pharma is also directing efforts toward diversity and inclusion; for example, by promoting

the participation of female professionals. Specific initiatives in recent years include offering subsidies for users of non-registered childcare facilities in an effort to provide an environment in which female employees can work with peace of mind, and holding training sessions for managers and female workers to encourage and facilitate a transformation in awareness. Going forward, we will further enhance these measures as we work toward achieving our goal of boosting our current proportion of female managerial staff from 8.4% to 10% by fiscal 2020.

# $\sum_{7}$ Do you have a message for stakeholders?



#### Sumitomo Dainippon Pharma will accelerate R&D and strive to pioneer new business opportunities as we pursue further increases in corporate value.

In terms of results for fiscal 2018 (year ending March 31, 2019), we are forecasting slightly increased year-on-year revenue of ¥467.0 billion and decreased core operating profit of ¥77.0 billion, down by ¥13.6 billion year-on-year due to increased selling, general and administrative expenses associated with launches of new products and other investments. Regarding dividends, in line with our basic policy of offering stable dividends, we plan to pay an ordinary dividend of ¥20 per share, including a ¥2 special dividend.

Going forward, we will continue to develop innovative new drugs, focusing on the Psychiatry & Neurology area and Oncology, while working to rapidly commercialize products in the Regenerative Medicine and Cell Therapy field and achieving sustainable growth by steadily bringing competitive new drugs to market. Similarly, we will challenge ourselves to aggressively develop frontier fields with strong future growth potential, such as digital healthcare. While endeavoring to be a "Global Specialized Player," a research and development-oriented organization with a unique presence in the world, we will continue to pursue further corporate value. We look forward to the ongoing support of all of our stakeholders.

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Representative Director, President and Chief Executive Officer

# TOPICS 2017

#### Completed Construction of the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT)

Construction was completed on our regenerative and cellular medicine manufacturing plant, located inside our Central Research Laboratories. The two-story, 2,915 m<sup>2</sup> facility is the world's first commercial manufacturing plant dedicated to allogeneic iPS cell-derived regenerative/cell therapy medicines. The plant allows compliance with the current standards, including GCTP (the production and quality management requirement for regenerative medical technologies/products). Once regulatory approvals for the products are obtained, we plan to engage in commercial production as well as investigational drug production at this plant. (See p. 23 "Focus" for details)





#### Drug Research Division Organizational Restructuring: Name Changed to the "Research Division"

In order to accelerate innovative new drug creation, we restructured our R&D framework and renamed it the Drug Research Division. Accompanying this change, we also adopted a new Project-based Research Management System. We will steadfastly steer research projects (drug discovery themes) with project leaders taking a central role and we will unite the entire Research Division as we aim to maximize research project progress and boost the rate of successful results.

(See p. 19 "Research and Development" for details)

#### Successful Pivotal Studies for Four Late-Stage Development Products; Three New Drug Applications Submitted

In fiscal 2017, pivotal studies succeeded for four late-stage development products and, for three of them, we submitted new drug applications in Japan and the U.S.

Product	Proposed indication	Submission Date
dasotraline	Attention-deficit hyperactivity disorder (ADHD)	August 30, 2017 (U.S.)
Apomorphine	OFF episodes associated with Parkinson's disease	March 29, 2018 (U.S.)
TRERIEF®	Parkinsonism in dementia with Lewy bodies (DLB)	August 30, 2017 (Japan) (Approval received on July 2, 2018)
LONASEN® (transdermal patch)	Schizophrenia	July 31, 2018 (Japan)

#### Promoting "Work Style Innovation" and Diversity & Inclusion

Sumitomo Dainippon Pharma designated 2017 as "Year One for Work Style Innovation" and carried out various initiatives.

- Held Work Style Innovation Meetings at each work site; used the meetings as opportunities to reassess work styles in each workplace
- Formulated the Declaration of Health Innovation (October 2017)
- · Received "Platinum Kurumin" certification as a good company supporting child rearing (July 2017)
- Received "Eruboshi" certification (three stars) as a company that promotes the active involvement of female employees (November 2017)
- Expanded the work from home system (October 2017)





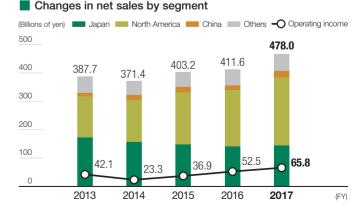
#### Supporting Initiatives to Strengthen **Domestic Business**

In April 2018, we established the Japan Business Unit as a cross-functional virtual organization. Having this unit clarifies strategic and investment allocations for our business in Japan, for which we aim to strengthen earnings through integrated business operations.

Additionally, in April 2018, we launched a sales and marketing co-promotion in Japan with Pfizer Japan Inc. for the antidepressant EFFEXOR®, manufactured and sold by Pfizer. Moreover, we commenced a Phase 3 study for imeglimin (type 2 diabetes) in-licensed from Poxel SA and commenced Phase 1 studies for dasotraline (ADHD) and alvocidib (acute myelogenous leukemia).

#### Achieved Sales and Profit Gains in Each Segment in Japan, the U.S., and China, **Record-High Consolidated Net Sales and Operating Income**

In North America, considerable growth of LATUDA® sales contributed to increased sales and profit over the prior fiscal year. In Japan, sales of Trulicity® and other products grew, making up for the dip in sales from long-listed drugs and helping increase sales and profit. Similarly, in China, performance was steady, mainly on the back of MEROPEN®, and we achieved increased sales and profit. As a result, we set new records in both Group net sales and operating income.



Note: Net sales and operating income figures for all fiscal years are in accord with Japanese accounting standards



We are maintaining aggressive research & development investment in particular for three focus areas.



#### **Focus Research Areas**



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

# Remodeling our R&D Organization for More Productive New Drug Development

In order to enhance our attractive development pipeline with greater productivity, we revamped the research organization and consequently renamed it the Drug Research Division in October 2017.

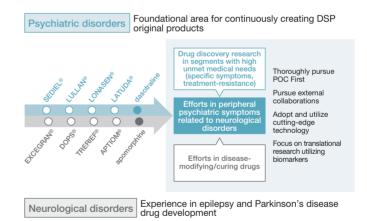
As a part of this organizational realignment, we also applied a new "Project-based Research Management System." Previously, different departments were in charge of early-stage and late-stage research programs. Going forward, Project Leaders, in many cases the originator of the project, will lead the project from the start through the later stages, and have budget authority. Additionally, to speed up decision making, Project Leaders will report directly to the Senior Executive Research Director. Project Directors will oversee projects overall, and will offer support for moving each project forward, to accelerate drug discovery.



#### Direction of R&D: Intersection of Psychiatry and Neurology

In psychiatry, we are challenging ourselves to tackle treatment-resistant psychiatric disorders, leveraging our disease area expertise and results. In neurology, we are making progress in research and development aiming to discover fundamental disease modifying drugs for neurodegenerative and other disorders. We will combine our initiatives in these two disease areas to address the challenges of peripheral psychiatric symptoms related to neurological disorders.

With the objective of increasing the success rate of R&D, we are continuing to strengthen drug discovery platforms such as in-silico/AI technology and iPS drug discovery, and to enhance translational research by integration of research and development division in the Psychiatry & Neurology area.



#### Fiscal 2018 objectives

#### Two NDAs

Dasotraline (U.S.): binge eating disorder (BED) LONASEN® (transdermal patch formulation, Japan)\*1: schizophrenia

#### Three treatment approvals

Dasotraline (U.S.): attention-deficit hyperactivity disorder (ADHD) TRERIEF® (Japan)\*<sup>2</sup>: Parkinsonism in Dementia with Lewy Bodies (DLB) Apomorphine (U.S.): OFF episodes associated with Parkinson's disease

\*1 Application for LONASEN® transdermal patch submitted in July 2018.

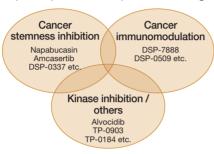
\*2 Approval for a new indication for TRERIEF® received in July 2018.

#### **Oncology Area**

# Aiming to Build a Unique Pipeline through Strong Group Collaboration

Sumitomo Dainippon Pharma's basic strategy in this therapeutic area is to conduct research and development with a focus on cancer stemness inhibitors, cancer peptide vaccines, and kinase inhibitors and deliver unique, unprecedented products through

collaboration with Boston Biomedical and Tolero so as to contribute to the treatment of cancer patients.



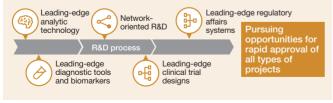
# Pursuing Smart R&D Anticipating Environmental Changes in the Oncology Area

In the Oncology area, the demand for better therapeutic outcomes is rising, while the development success rate is falling. Competition is intensifying as the disease itself becomes more segmented and drug discovery-related technology and science advance for each form of cancer. An R&D model (Smart R&D) that is significantly more compact and quicker than conventional models, while also achieving a high success rate, is critical amidst these changes in the development environment.

Sumitomo Dainippon Pharma will utilize leading-edge analytic technology, diagnostic tools, and biomarkers as we promote network-oriented R&D leveraging external parties. As a result, we will design leading-edge clinical trials and pursue opportunities for rapid approval under the latest regulatory affairs systems.

#### Smart R&D

A model utilizing cutting-edge technologies and pharmaceutical regulatory and development methods that are distinctive in the Oncology area, enabling more compact, rapid and successful R&D



#### Fiscal 2018 objectives

Promote development to accelerate NDAs for napabucasin, alvocidib, etc.

#### Regenerative Medicine / Cell Therapy Field

# Quickly Establishing Commercial Manufacturing Capability for Regenerative and Cellular Medicines

In order to resolve one of the greatest bottlenecks in the commercialization of such products, namely, the development of their production system, we completed the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT) in March 2018. With the assistance of our industry-academia alliance partners, the facility will use allogeneic iPS cells to manufacture clinical trial and commercial products for age-related macular degeneration, Parkinson's disease, retinitis pigmentosa, spinal cord injury, and other conditions.

From the foundational stages to commercial manufacturing, we will establish integrated platform technology related to iPS cell-derived cellular medicines, aiming to introduce regenerative cellular medicines as early as possible.

#### Fiscal 2018 objectives

Promote development of SB623, allogeneic iPS cell-derived medicines (age-related macular degeneration, Parkinson's disease and others)

#### **Developing Frontier Fields**

Sumitomo Dainippon Pharma is dedicating effort to three focus areas: Psychiatry & Neurology, Oncology, and Regenerative Medicine / Cell Therapy. In addition to these, we want to target new frontier fields in healthcare areas other than pharmaceuticals in order to establish a second earnings pillar of the future. Building on the foundation of our pharmaceutical products business, we are exploring complementary projects and opportunities.



#### Alliances with Outside Institutions

#### Signing a Licensing Agreement with JCR Pharmaceuticals for Blood-Brain Barrier Penetration Technology

Sumitomo Dainippon Pharma signed a licensing agreement with JCR Pharmaceuticals for discovering treatments for central nervous system diseases by applying J-Brain Cargo<sup>®</sup> blood-brain barrier penetration technology.

This agreement will give us exclusive R&D and commercialization rights, in Japan and North America, for specific central nervous system disorders.

#### Joint Research with the Kitasato Institute, Targeting New Treatments for Antimicrobial-Resistant Bacterial Infections

Sumitomo Dainippon Pharma signed a joint drug discovery research agreement with the Kitasato Institute for infections caused by bacteria with antimicrobial resistance (AMR). Pursuant to this agreement, a group led by Dr. Satoshi Omura, Distinguished Emeritus Professor of Kitasato University and the 2015 laureate of the Nobel Prize in Physiology or Medicine, will collaborate in therapeutic drug discovery research for antimicrobial resistant bacterial infections with a research group from Sumitomo Dainippon Pharma. Leveraging the experience and track record of the two groups, we will aim to provide groundbreaking anti-infective drugs through original approaches.



A press conference on joint research efforts with the Kitasato Institute

#### **Intellectual Property**

Sumitomo Dainippon Pharma recognizes that intellectual property is an essential part of the business 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 establish intellectual property in 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.

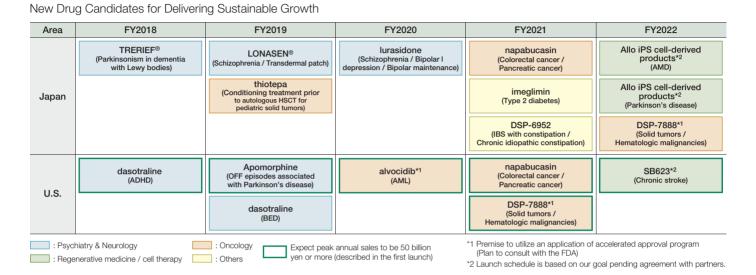
Since clinical studies are conducted during the intermediate stages of confirming the efficacy (effectiveness) and safety of drug candidates, our clinical studies follow such regulations as Japan's ministerial ordinance on GCP (Good Clinical Practice), which was established to protect the human rights,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



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

#### LATUDA® (lurasidone hydrochloride)

#### Developed in-house, Formulation: oral

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

Product Launch Target (as of August 1, 2018)

#### Dasotraline (SEP-225289)

**Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral** SEP-225289 is a dopamine and norepinephrine reuptake inhibitor (DNRI). SEP-225289 has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval.

#### Apomorphine hydrochloride (APL-130277)

### Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics), Formulation: sublingual film

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.

#### **Oncology Area**

#### Napabucasin (BBI608)

Developed in-house (Boston Biomedical, Inc.), Formulation: oral

BBI608 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways such as 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. BBI608 has been shown to inhibit STAT3 pathways, Nanog pathways and  $\beta$ -catenin pathways in preclinical studies.

#### Adegramotide/Nelatimotide (DSP-7888) Developed in-house, Formulation: injection

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 CTL-inducing peptide alone may be achieved. DSP-7888 is expected to be an option for a wide range of patients.

#### Alvocidib (DSP-2033)

#### In-licensed from Sanofi S.A., Formulation: injection

Alvocidib is a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), a member of cyclindependent 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 anticancer activity observed with alvocidib.

#### Other Areas

#### Imeglimin (PXL008)

#### In-licensed from Poxel SA, Formulation: oral

Imeglimin is the first clinical candidate in a new chemical class of oral agents called the Glimins by the World Health Organization. Imeglimin has a unique mechanism of action that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the liver, muscles, and the pancreas, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis.

### Striving to quickly commercialize regenerative medicine and cell therapy

# Completing Construction of the SMaRT Regenerative Medicine and Cell Therapy Manufacturing Plant

On March 1, 2018, we completed construction of the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT), located on the premises of our Central Research Laboratories in Suita, Osaka. The plant marks our first major step toward commercializing products in the Regenerative Medicine and Cell Therapy field as we build robust manufacturing technology based on the rich experience and know-how we have accumulated to date.



#### World's First Commercial Manufacturing Facility for Allogenic iPS Cell-derived Medicines

Since the 1990s, Sumitomo Dainippon Pharma has been fully engaged in regenerative research on the central nervous system, which has allowed us to accumulate a wealth of experience and know-how. In 2013, we established a division dedicated to the Regenerative Medicine and Cell Therapy Business, with five projects currently underway.

# 200 Billion Yen

Net sales from our Regenerative Medicine and Cell Therapy Business are forecast to grow globally to reach 200 billion yen in 2030. In recent years, regenerative medicine has made dramatic progress, though there are still many hurdles to clear in order to deliver products to patients. One of those hurdles is manufacturing facilities. Whether inside or outside Japan, there are still few sites that meet the various regulations, such as GMP.\*

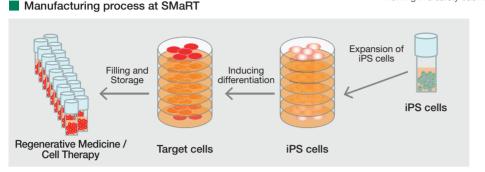
At Sumitomo Dainippon Pharma, we made the decision to build a manufacturing facility specifically for regenerative medicine and cell therapy products, breaking ground on the project in February 2017. Construction was completed in March 2018, when we finished our regenerative medicine and cell therapy manufacturing plant (called SMaRT), located on the premises of our Central Research Laboratories.

The two-story, 2,915-m<sup>2</sup> facility is the world's first commercial manufacturing plant dedicated to allogeneic iPS cell-derived regenerative medicine and cell therapy products.

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



Working in a safety cabinet





High-throughput cell sorter for selecting only the target cells

#### Enabling a Stable Supply of High-Quality Cells

At SMaRT, we take iPS cells supplied from external master cell banks, such as the Center for iPS Cell Research and Application (CiRA), Kyoto University, and expand them, then induce differentiation to the target cells and tissues (such as retinal cells, neural cells, etc.), then create regenerative medicine and cell therapy products.

This induced differentiation process may also require steps to select specific target cells. In each step of the overall process, we analyze and evaluate various items as we rigorously manage the manufacturing approach.

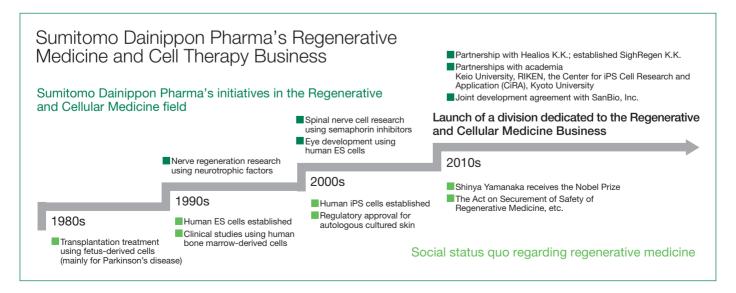
When manufacturing regenerative medicine and cell therapy products, it is extremely difficult to reliably create cells of the same high quality in every batch, and, commercializing them is a significant challenge. We are striving to utilize our research and manufacturing technologies to craft supremely high quality products.

Once regulatory approvals for the products are obtained, we plan to engage in commercial production as well as investigational drug production at this plant.

#### Creating a Core Business by 2030

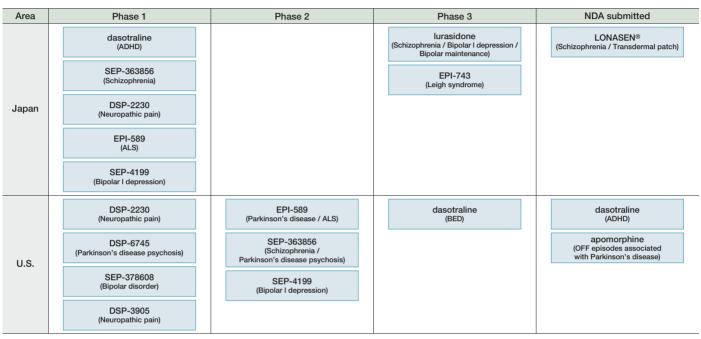
Sumitomo Dainippon Pharma is driving research and development using allogeneic iPS cells in four diseases: age-related macular degeneration, Parkinson's disease, retinitis pigmentosa, and spinal cord injury. In addition, we are carrying out a Phase 2b study in the U.S. in collaboration with SanBio, Inc. for SB623, a mesenchymal stem cell-derived treatment targeting chronic stroke. We are striving every day to be able to deliver regenerative medicine and cell therapy products as quickly as possible, while aiming to grow this segment into one of our core businesses by 2030.





### **Development Pipeline**

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



(As of August 1, 2018)

#### Dasotraline (SEP-225289)

A New Drug Application (NDA) for adult and pediatric attention-deficit hyperactivity disorder (ADHD) was submitted to the U.S. Food and Drug Administration (FDA). We are preparing for approval and product launch during fiscal 2018. In Japan, we are conducting a Phase 1 study targeting ADHD.

Furthermore, we have attained favorable results of the Phase 3 study for binge eating disorder (BED) in the U.S. Based on the results of this study and the Phase 2/3 study, we are aiming to apply for approval in the U.S. during fiscal 2018.

#### Lurasidone

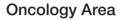
In Japan, we completed Phase 3 studies targeting bipolar I depression and bipolar maintenance, while we have an ongoing Phase 3 study targeting schizophrenia. We are aiming to submit simultaneous applications for approval of these indications in Japan during fiscal 2019.

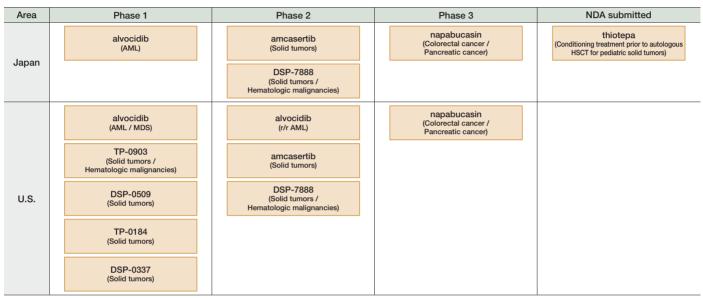
#### LONASEN® transdermal patch formulation

Regarding the transdermal patch formulation of atypical antipsychotic LONASEN<sup>®</sup> being jointly developed with Nitto Denko Corporation, the Phase 3 study in Japan achieved its primary endpoints and showed favorable tolerability. Based on the results from this study, we submitted an application for approval in July 2018.

#### Apomorphine (APL-130277)

Our Phase 3 clinical study in patients with Parkinson's disease (PD) who experience motor fluctuations (OFF episodes) in the U.S. met its primary and key secondary endpoints, and the agent was also generally well-tolerated by study participants. Based on the results from this study, we submitted an NDA to the FDA in March 2018. We expect to receive approval during fiscal 2018.





(As of August 1, 2018)

#### Napabucasin (BBI608)

We are conducting a global Phase 3 study for colorectal cancer (combination therapy / CanStem 303C study) and a global Phase 3 study for pancreatic cancer (combination therapy / CanStem 111P study). In fiscal 2018, we are promoting both studies as our highest priority initiatives, aiming to apply for approval for colorectal cancer during fiscal 2020 and for pancreatic cancer during fiscal 2021 in the U.S. and Japan. We are aiming for market launch in Japan and the U.S. in fiscal 2021 for the indications of colorectal cancer and pancreatic cancer.

#### Alvocidib (DSP-2033)

We are conducting a global Phase 2 study (combination therapy / Zella 201 study) targeting relapsed and refractory patients with acute myeloid leukemia (AML). This study is composed of two stages, with stage 2 having recently commenced. Based on the interim analysis results of the study, we are aiming to apply for approval in the U.S. during fiscal 2019. Additionally, we have started a Phase 1 study targeting newly diagnosed patients with AML, as well as a study targeting myelodysplastic syndromes. A clinical study targeting AML is also underway in Japan.

#### **DSP-7888**

We are conducting a global Phase 2 study targeting glioblastoma. Also, a Phase 2 study targeting myelodysplastic syndromes (MDS) and a Phase 1/2 study targeting pediatric malignant glioma are ongoing in Japan.

#### **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. We completed construction of a manufacturing plant for regenerative medicine & cell therapy (SMaRT) at our Central Research Laboratories (Suita, Osaka) in March 2018. Preparations at SMaRT are moving forward for building a clinical study product manufacturing framework, and for commercially manufacturing allogeneic iPS cell-derived medicines.

Regenerative Medicine/Cell Therapy Business Plan
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Proposed indication	Partner	Region (planned)	Cell type	Clinical research	Clinical study
Chronic stroke (SB623)	SanBio	North America	Allo mesenchymal stem cell		In progress (Phase 2b study)
AMD (age-related macular degeneration)	Healios RIKEN	Japan	Allo iPS cell-derived retinal pigment epithelium	In progress	Preparing for start
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto Univ CiRA	Global	Allo iPS cell-derived dopamine neural progenitor		Started an investigator-initiated clinical study in August 1, 2018 (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor	Preparing for start	
Spinal cord injury	Keio Univ Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	Preparing for start	

(As of August 1, 2018)

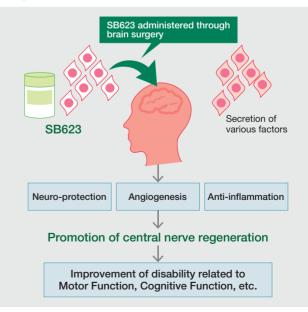
#### Chronic Stroke (SB623)

In-licensed from SanBio

SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. SB623 is expected to be effective for chronic stroke, which currently has no effective treatments available, by promoting regeneration of central nerve cells. Unlike autologous cell therapies that require individualized cell preparation at the clinical site, 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 joint development and license agreement for exclusive marketing 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. Enrollment for this study was completed in December 2017 and results are expected in the first half of 2019.

#### Expected Mode of Action



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

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

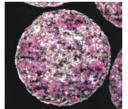
Sumitomo Dainippon Pharma concluded a joint development agreement with Healios K.K. in December 2013, and established a joint venture company SighRegen K.K. through investment with Healios K.K. in February 2014. Aiming to commercialize products using iPS cells, we are pursuing joint development with Healios K.K. and promoting examinations for manufacturing to take place at SighRegen K.K. Currently, we are moving forward with preparations to commence company-initiated clinical studies with Healios K.K.

#### Parkinson's disease

#### Dopaminergic neural progenitor cells (allogeneic 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 Hospital started, in fiscal 2018, 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



Dopaminergic neural progenitor cells (stained for specific markers)

acquire manufacturing and marketing approval for the cells as a regenerative medicine product.

#### Retinitis pigmentosa Photoreceptor cells (allogeneic iPS cell-derived)

In the eye disease field, Sumitomo Dainippon Pharma is conducting research into regenerative medicine for retinitis pigmentosa as well as age-related macular degeneration. In basic research, Sumitomo Chemical Co., Ltd. in partnership with RIKEN has already become the first in the world to succeed in 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 (allogeneic 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.

#### **Other Areas**

Area	Phase 1	Phase 2	Phase 3	NDA submitted
Japan		DSP-6952 (IBS with constipation / Chronic idiopathic constipation)	imeglimin (Type 2 diabetes)	

(As of August 1, 2018)

#### Imeglimin (PXL008)

Imeglimin, in-licensed from Poxel SA in October 2017, is a candidate for an orally administered treatment of type 2

diabetes with a new mechanism of action. In December 2017, Sumitomo Dainippon Pharma and Poxel started a Phase 3 clinical study in Japan targeting type 2 diabetes. In-Licensing, Partnerships & Acquisitions

Strategically considering in-licensing and partnerships for products and development candidates, and acquisitions in order to expand our pipeline.



# Expanding Our New Product Pipeline through In-Licensing, Partnerships, and Acquisitions

While aggressively striving for in-house development, Sumitomo Dainippon Pharma is also expanding its new product pipeline through in-licensing, partnerships, and acquisitions.

In carrying out these considerations, we are prioritizing products for which we can leverage our sales platforms and that will quickly contribute to earnings.

In October 2017, we signed a strategic partnership agreement for development and commercialization with Poxel SA for Imeglimin, under development as a therapeutic agent for type 2 diabetes. The agreement applies to Japan, China, S. Korea, Taiwan, and nine countries in SE Asia. In December, we collaborated with Poxel to start a Phase 3 study for Imeglimin. We also signed a co-promotion contract, applicable within Japan, in March 2018 for EFFEXOR®, an antidepressant for which Pfizer Japan Inc. holds manufacturing and marketing approval.

#### The Global Business Development Department

Sumitomo Dainippon Pharma's Global Business Development Department fulfills a central role in our Group's pharmaceutical business M&A, in- and out-licensing, and partnerships.

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 carefully examine the product. This may include working with the Research Division to see if the mechanism of action of the compound is suitable, 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.

#### Major recent acquisitions

		Major development products				
Company acquired	Company acquired Date acquired		Development stage (at the time of acquisition)	Development location	Proposed indication	
		Alvocidib (Generic name)	Phase 2	U.S., Canada	Cancer	
Tolero Pharmaceuticals, Inc. (U.S.) January 2017	lonuon 2017	TP-0903	Phase 1	U.S.	Cancer	
	TP-1287	Preclinical	—	—		
		TP-0184	Preclinical	—	-	
Cynapsus Therapeutics Inc. (Canada)	October 2016	APL-130277	Phase 3	U.S.	Parkinson's disease	

#### Major recent in-licensed products

Brand name / Generic name / Product code	Indication / Proposed indication	Licensed from	Date of licensing	Development stage (at the time of licensing/partnership)	Territory (under contract)
EFFEXOR®	Depression / Depressed state	Pfizer Japan Inc.	March 2018	Approved	Japan
imeglimin	Type 2 diabetes	Poxel SA	October 2017	Completed Phase 2	Japan, China, 11 Asian countries
UTIBRON®					
SEEBRI®	Chronic obstructive pulmonary disease (COPD)	Novartis (Switzerland)	December 2016	Approved	U.S.
ARCAPTA®					
Trulicity®	Type 2 diabetes	Eli Lilly Japan K.K.	July 2015	Approved	Japan
REMITCH®	Pruritus in chronic liver disease patients	Torii Pharmaceutical Co. Ltd.	May 2015	Approved	Japan
SB623	Chronic stroke (cellular medicine)	SanBio, Inc. (U.S.)	September 2014	Completed Phase 1/2	U.S., Canada
vatiquinone (EPI-743)	Mitochondrial disease	BioElectron Technology Corporation	March 2013	Phase 2 (U.S.)	Japan
EPI-589	Neurodegenerative diseases	(formerly Edison Pharmaceuticals, Inc.) (U.S.)		Preclinical	Japan

#### **Medical Science**

Generation, provision, and communication of medical information based on robust scientific evidence in order to address current unmet medical needs.



#### Medical Needs Are Learned On Site Offering True Value with Our Pharmaceutical Products

Sumitomo Dainippon Pharma's Medical Information and Medical Affairs Departments work in close coordination as the Company's Medical Science framework, with the same Executive Officer responsible for both departments. Their objective is 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.

By communicating the efficacy and safety of our pharmaceuticals from a scientific perspective, our Medical Science framework meets the needs of patients and healthcare professionals, while presenting the true value of our products. Furthermore, our Medical Science Liaisons (MSLs) work 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.

#### Promoting the Provision of Accurate Product Information Based on Scientific Evidence

In providing accurate information to healthcare professionals, we create appropriate material on our products, support Medical Representatives' (MRs) provision of safety and quality information, review promotional materials and other materials directed to external parties, and check slides presented at lecture meetings.

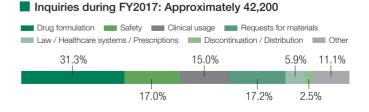
We also provide documents such as "Kusuri-no-shiori" and "Instructional Leaflets" which are used by healthcare professionals in explaining to patients about dosing schedules, precautions for use, possible adverse reactions, and so on. In order to be able to offer 24-hour support for regional healthcare, we will utilize various media, including our website, and continue to deliver and communicate easy-to-understand information to patients and families, while addressing the on-site needs of healthcare institutions.

Basic Activities of Medical Science Framework



#### Further Utilizing Customer Input as an Information Hub

Sumitomo Dainippon Pharma established the Product Information Center within our Medical Information Department as a customer support contact center for inquiries about our products from patients and their families, in addition to healthcare professionals. Going forward, we will continue to contribute to the health of patients by swiftly and politely providing accurate information on the proper use of pharmaceuticals, while pursuing appropriate internal feedback on content learned from external requests, and using this to strengthen improvements of our products and materials.



Corporate Regulatory Compliance & Quality Assurance

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



# Establishment of a Global Quality Assurance System for delivering "A-N-SHI-N"\*1

The Sumitomo Dainippon Pharma Group is developing new drugs in Japan, the U.S., Europe, China, and other countries, and, after receiving approval from each regulatory authority, delivering products to patients and healthcare professionals globally. 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.

#### Global Quality Policy DSP Group Quality Policy

Sumitomo Dainippon Pharma Co., Ltd. ("DSP") and all of DSP's affiliates and subsidiaries worldwide who signed below (collectively the "DSP Group Companies"), are fully committed to quality assurance as a primary objective in all aspects of operation. As responsible pharmaceutical companies, we, the DSP Group Companies, shall work to produce and supply customers with high-quality products.

- 1. We, the DSP Group Companies, shall provide satisfactory quality products to customers based upon consistent monitoring of customer needs.
- We, the DSP Group Companies, shall develop and apply practices leading to high-quality products, beginning with the start of product development and continuing throughout all stages of production and commercialization.
- We, the DSP Group Companies, shall establish and maintain a consistent quality system for all phases of operation from procurement of raw materials through product manufacturing, distribution, and sales.
- 4. We, the DSP Group Companies, shall act in accordance with the relevant legal and regulatory requirements, and establish and comply with quality standards at the global level based on current scientific and technological knowledge.
- We, the DSP Group Companies, shall have all our executives and employees involved in quality raise and strive to retain a high level of awareness and knowledge on the quality.

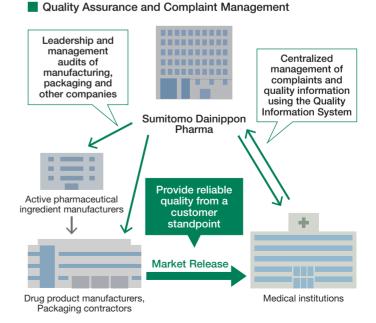
Furthermore, we supervise all manufacturing and packaging contractors for our pharmaceutical products in their various countries to assure quality across the entire supply chain. This approach to quality assurance activities, from development to post-marketing services, is implemented under a framework unifying our Group.

\*1 A-N-SHI-N: Trustworthiness, reliability, peace of mind, making people feel reassured and safe.

# Efficient Complaint Management with Our Quality Information System

In Japan, Sumitomo Dainippon Pharma's Quality Information System is designed to ensure efficient complaint management. We use this system in conformity to Good Quality Practices (GQP)\*<sup>2</sup>. When a complaint or quality issue is raised at a medical institution, it is reported to our Quality Information System by our MRs. The plant at which the product was manufactured begins investigation immediately, checking retained samples from the same lot, and verifying manufacturing records to confirm the quality of the product in question. The root cause of the quality issue is also investigated, and when necessary, the plant implements corrective and preventive actions.

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 carry tablet terminals that have answers to many expected inquiries, which facilitates a quick response to quality issues.

\*2 Good Quality Practice: A standard for managing the quality of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (manufacturing and marketing quality assurance standard).

#### Centralized Management of Safety Information from Development to Post-marketing

Adverse reactions that were unexpected during the development stage can occur once pharmaceuticals have started to be used by a large number of patients under various conditions after manufacturing and marketing approval. Because of this, we collect safety information generated at the early development stages, in addition to a wide range of post-marketing information from medical institutions, partner companies, and regulatory authorities in each country.

Similarly, a centralized database manages development stage and post-marketing safety information gathered in multiple countries, with that information then evaluated and promptly utilized for carrying out safety measures.

Inside Japan as well, we use a database to ensure the safety of our pharmaceuticals and propose and finalize policies necessary for proper use. We implement safety management activities of this nature as part of product safety oversight in compliance with the Pharmaceuticals, Medical devices and Other Therapeutic Products Act and Good Vigilance Practice (GVP).\*<sup>3</sup>

\*3 Good Vigilance Practice: A standard for managing the post-marketing safety of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (post-marketing safety management standard).



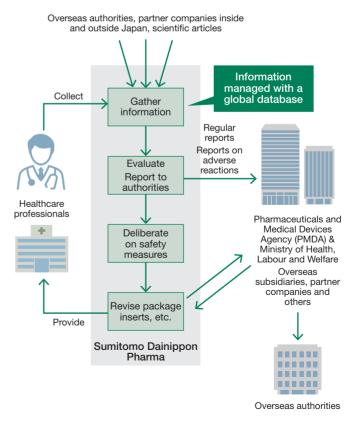
# Providing Easy-to-Understand Information to Support Proper Use

While pharmaceutical products are effective when used properly, their improper use can not only negate their effects, but can also lead to creating wayward effects.

Sumitomo Dainippon Pharma promptly and accurately provides healthcare professionals with information on the proper use of pharmaceuticals in order to ensure that the benefits of each pharmaceutical can be utilized more safely. Furthermore, we strive for ways to ensure that healthcare professionals can convey necessary information to patients in an easy-to-understand manner.

For example, when new adverse reactions are added to precautions on package inserts, a "Notice of Revisions to Precautions" is promptly provided to prescribing physicians and pharmacists by MRs and via our website. Moreover, in order to minimize the risks for patients, the tablet terminals carried by MRs are equipped with information on additional adverse reactions, including symptoms to notice in order to assist with early detection, types of patients likely to develop symptoms, and approaches to handling such occurrences, making it possible for MRs to communicate to healthcare professionals accurately.

#### Collecting and Providing Safety Information



# 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 released.

We have built a stable supply structure for products, which are manufactured mainly at our own plants in Japan 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 continuously work on cost reduction activities, 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.

#### **Restructuring Production Sites**

In order to build a stable and efficient production system that is able to flexibly respond to changes in the business environment, we are integrating the production functions of the Ibaraki Plant with the Suzuka Plant at the end of fiscal 2018. Similarly, we are closing the Ehime Plant and, from fiscal 2019, will shift to a two-plant structure: Suzuka and Oita. Steady progress is being made in transferring the production of products from the Ibaraki to Suzuka Plant, and products being made at the Ehime Plant will be made at contract manufacturers.

We aim to streamline and strengthen the production system through reduction of fixed costs with these restructuring steps. Additionally, in order to build a highly efficient operating structure within Japan going forward, we offered early retirement for employees in the Manufacturing Division in fiscal 2017.

#### Strengthening the Global Supply Chain

To further strengthen our stable supply system, we will continue to reinforce our global supply chain while keeping our sights focused on 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 2017, accompanying the expansion of the overseas sales territories for our mainstay products, we built a new supply chain suited for global growth, including incorporating overseas subcontractors in our product manufacturing and supply framework.

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

For domestic distribution, we have distribution centers in the west (Kobe, Hyogo Prefecture) and in the east (Kazo, Saitama Prefecture). 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).

In fiscal 2017, based on our corporate GDP\*<sup>2</sup> Guidelines, and targeting our domestic product distribution, we established standard procedures to assure product quality during storage

and transportation, while also building and launching a new organization scheme for our quality management system. \*2 Good Distribution Practice: A standard for proper distribution of pharmaceuticals.

#### **CSR** Procurement

We consistently conduct "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 unplanned evaluations 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 Reassuring Products

The production of pharmaceuticals requires a high level of quality assurance. Consequently, rigorous GMPs (Good Manufacturing Practices) have been established in each country. Sumitomo Dainippon Pharma's products are supplied around the world with the approval of the Health Authorities 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 GMPs of Europe and the U.S. have become the operational standards 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 to meet future standards—these include the solid dosage form facility and the installation of a RABS system that increases the level of sterility assurance. We are focusing our efforts on strengthening our supply system to continue providing pharmaceuticals with higher quality.

#### **Prevention of Medical Malpractice**

Since packaging and label designs for pharmaceuticals are highly regulated, including the provision of information, is stipulated by law, the appearance of 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, with aim of preventing drug mix-ups. When it seems likely that mix-ups will occur, we respond promptly, such as by considering changing the name and design, so that mix-ups do not occur based on consultation with the company marketing the other product.

We also continue to make improvements in order to meet the needs of medical institutions and patients. These include printing the product name on the tops of bottles, to increase ease of use for medical institutions, and, to facilitate ease of use for patients, improving blister sheets and printing product names on tablets.

# Initiatives for Environment Conservation and Occupational Safety and Health

Our 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.

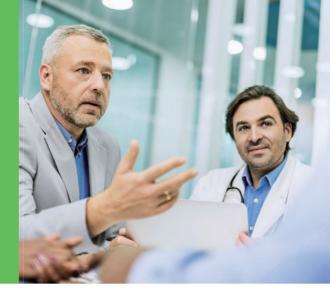
We also operate an occupational safety and health management system in order to operate without accidents and disasters based on the thorough observation of compliance.

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

#### Acquisition of ISO 14001 Certification

#### Marketing

We have made the Psychiatry & Neurology area a global focus area. Additionally, we have sales platforms in each specialty area in each of our business regions.



#### **Japanese Market**

Become the most trusted company in our focus areas

Carry responsibility for part of the local healthcare system and contribute to society

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



**TRERIEF®** 

Indications Parkinson's disease



Features Parkinson's disease drug with levodopaenhancing 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®

#### ndications Schizophrenia



Features Dopamine D2 receptors and serotonin 5-HT<sub>2A</sub> receptors blocker

 Approx. 770,000 patients in Japan. About target

. Ongoing 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.

#### **Diabetes Area**

disease

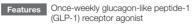
About target

diseas



#### **Trulicity**®

Indications Type 2 diabetes



 An estimated 10 million patients in Japan have diabetes, with the majority of them having type 2 diabetes About target Basic treatment is through exercise and dietary approaches; however, when blood glucose disease levels are not adequately controlled, oral hypoglycemic agents, insulin injections, or GLP-1 receptor agonists are administered.

# Global

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

In all of our research, development, and sales, we have built a growth platform with Psychiatry & Neurology as a focus area.

# Japan

In addition to the Psychiatry & Neurology area...

#### **Diabetes Area**

Provide varieties of type 2 diabetes therapeutic agents with different mechanisms of action.

#### **Specialty Areas**

Provide therapeutic agents for Anderson-Fabry disease, systemic fungal infections, and pruritus in chronic liver disease patients.



#### North American Market

- Further growth for atypical antipsychotic agent LATUDA<sup>®</sup> and antiepileptic APTIOM<sup>®</sup>
   Expand sales in the Chronic Obstructive Pulmonary Disease (COPD) area through
  - 5 products including LONHALA® MAGNAIR®
- Obtain approval and prepare for sale of products under application (dasotraline, apomorphine)

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



the U.S.

#### LATUDA®

Indications Schizophrenia, bipolar I depression

An atypical antipsychotic with affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2</sub>A and serotonin 5-HT<sub>7</sub> receptors where it has antagonist effects

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 2.4 million adults in the U.S.
 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

#### **APTIOM®**

 
 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

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

in adults.

#### **Respiratory Area**



COPD is responsible for over 1.2 million deaths per year, making it the third leading cause of

China

In addition to the Psychiatry & Neurology area...

#### **Infectious Diseases Area**

Expand business for mainstay products treating bacterial infectious diseases.

### Chinese Market

Maximize profit from existing products and establish highly efficient business foundation
 Quick penetration of the new product LONASEN<sup>®</sup> into the market



death in the U.S.

#### MEROPEN<sup>®</sup> (brand name in China: MEPEM<sup>®</sup>)

Indications General infections, febrile neutropenia

Features Standard therapy for severe infections, used in many countries

## North America

North American

Market

In addition to the Psychiatry & Neurology area...

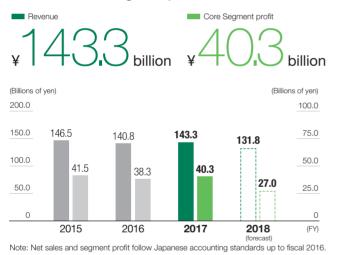
#### **Respiratory Therapeutic Area**

Market and sell multiple therapeutic agents for chronic obstructive pulmonary disease (COPD).

# **Japanese Market**



#### Revenue / Core Segment profit



Key Measures

- Become the most trusted company in our focus areas
- Carry responsibility for part of the local healthcare system and contribute to society.

#### Focus areas

Psychiatry & Neurology, Diabetes, Specialty

#### **Promoted Products**

Psychiatry & Neurology: TRERIEF®, LONASEN®, and EFFEXOR® Diabetes: Trulicity®, SUREPOST®, and METGLUCO® Specialty: REPLAGAL®, AmBisome®, and REMITCH®

Number of MRs (Fiscal 2017)

Revenue per MR (Fiscal 2017)



# ¥127 million

#### Fiscal 2017 Main Initiatives and Business Results

As initiatives toward reform in fiscal 2017, we transitioned to an MR system with strengthened specialization. We placed dedicated CNS MRs, focusing on TRERIEF® and LONASEN®, and MRs dedicated exclusively to REPLAGAL®, while also establishing a framework able to concentrate resources on each MR's promoted products.

On top of this, we implemented a new training program focused on the diabetes area and strove to improve both the quality of activities as well as productivity. In terms of performance, while long-listed drugs saw lower sales, gains in AIMIX<sup>®</sup> and Trulicity® contributed to revenue of 143.3 billion yen (up 1.8% year-on-year) and core segment profit of 40.3 billion yen (up 6.2% year-on-year).

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

Regarding Trulicity®, growth was robust due to a favorable reception for its ease of use (once a week administration), device features (single-use, pre-filled auto injector pen), and excellent blood glucose lowering effect. Furthermore, there was solid performance for AIMIX®, TRERIEF®, and REPLAGAL®, which compensated for the impact of generics for AVAPRO® and lower income from long-listed drugs.

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

Brand Name	Therapeutic Indication	FY 2016	FY 2017	Rate of change (%)	FY 2018 forecast
AIMIX®	Therapeutic agent for hypertension	17.1	18.8	9.6	10.4
TRERIEF®	Therapeutic agent for Parkinson's disease	15.1	16.1	6.2	14.5
Trulicity®*	Therapeutic agent for type 2 diabetes	6.8	15.9	135.1	22.8
LONASEN®	Atypical antipsychotic	12.8	12.6	(1.3)	12.5
REPLAGAL®	Anderson-Fabry disease	10.7	11.7	9.7	12.2
METGLUCO®	Therapeutic agent for type 2 diabetes	11.2	10.9	(2.8)	11.1
AVAPRO®	Therapeutic agent for hypertension	10.3	8.4	(18.9)	4.0
SUREPOST®	Therapeutic agent for type 2 diabetes	4.3	5.0	15.9	5.9
AmBisome®	Therapeutic agent for systemic fungal infection	4.4	4.3	(1.8)	4.3

\* Revenue of Trulicity® is shown on NHI price basis.

#### Fiscal 2018 Business Plan and Outlook

In fiscal 2018, we established the Japan Business Unit\* as a virtual organization. Having this unit clarifies strategic and investment allocations for our Japan Business for which we aim to strengthen earnings through integrated business operations.

Under the Japan Business Unit in fiscal 2018, we will strive to maximize product value in our focus areas, pursue an efficient sales organization, promote in-licensing and partnerships, and build an efficient production framework.

In the Psychiatry & Neurology area, we launched a co-promotion in Japan in April 2018 for the antidepressant EFFEXOR® being manufactured and sold by Pfizer Japan Inc. With a group of approximately 300 MRs, we will enhance activities to provide information for TRERIEF®, LONASEN®, and EFFEXOR®. Also, with regard to a TRERIEF® Parkinsonism in dementia with Lewy bodies, in June 2018 we became the first in the world to receive approval as a treatment targeting this indication.

In the Diabetes area, we will dedicate effort to Trulicity®,

SUREPOST<sup>®</sup>, and METGLUCO<sup>®</sup>. Where Trulicity<sub>®</sub> is concerned, we will expand the GLP-1 receptor agonist market in order to grow and further deliver this treatment to the many patients with insufficient blood glucose control.

In the Specialty area, we will strive to maximize product value for REPLAGAL<sup>®</sup>, AmBisome<sup>®</sup>, and REMITCH<sup>®</sup>.

While the NHI drug price revisions and the entry of generics for AIMIX<sup>®</sup> are factors impacting fiscal 2018, we will strive for more efficient sales through business operations with the newly established Japan Business Unit and enhanced training to continue improving the quality of our MRs. At the same time, we will endeavor to further expand sales of promoted products and maintain the level of domestic revenue.

\* The Japan Business Unit is composed of the following organizations and consolidated subsidiaries:

Sales and Marketing Division (including DS Pharma Promo Co., Ltd.), Drug Development Division, Manufacturing Division, Corporate Regulatory Compliance & Quality Assurance Division, International Business Management, Regulatory Affairs, External Affairs, Medical Information, Medical Affairs

### FOCUS

## Strengthening Human Resources Development for Highly Efficient and High Quality Marketing

With the objective of promoting high-quality activities for the provision of information, we have implemented a new training program and have launched initiatives toward strengthening the sales capacities of domestic MRs.

#### MR enhancement program: implementing MR Camp

In each of the therapeutic areas covered by MRs (the Psychiatry & Neurology area and general areas mainly focusing on the Diabetes area), we are fostering advanced knowledge and high-level skills in order to put in place a problem-solving sales approach that enables treatment proposals that meet physician needs and garners high acceptance from customers. On top of this, we are striving to develop what we call "professional human resources."

In the Psychiatry & Neurology area, where our approximately 300 dedicated CNS MRs work, we have been holding an MR Camp since the second half of fiscal 2016. The camp is a two-day overnight experience with practical training closely matched to clinical settings. In fiscal 2017, the far-ranging curriculum included presentations, written exams, role playing, oral exams, and more. In the role play training, for example, participants faced the rigorous requirement of having to repeat the scenario as many times as needed until they cleared a fixed proficiency level. In fiscal 2018, we will add new training matched to different MR levels when we hold the camp.

MRs covering the general therapeutic area receive oral exams (800 participants) that call on them to use their network in order to improve their ability to convey information in the diabetes area. In the Specialty area, we are carrying out enhanced role plays using fungal infection training modules with the objective of boosting interview communication skills.

#### Strengthening Regionally Focused Strategic Proposal Skills at Each Sales Office

From fiscal 2017, we retired the video-based training that we had been conducting uniformly across Japan and adopted Product Training that tasks sales offices with finding their own issues and systematically working to solve them. We are striving at the group level in each region to address local issues in a more hands-on fashion.

# North American Market



#### Revenue Core Segment profit billion billion (Billions of yen) (Billions of yen) 280.0 200.0 260.8 240.8 210.0 150.0 197.9 184.9 117.8 109.5 140.0 100.0 83.3 65.2 70.0 50.0 0 0 2015 2016 2017 2018 (FY)

**Revenue / Core Segment profit** 

Note: Net sales and segment profit follow Japanese accounting standards up to fiscal 2016.

#### **Key Measures**

- Further growth for atypical antipsychotic agent LATUDA® and antiepileptic APTIOM®.
- Expand sales in the Chronic Obstructive Pulmonary Disease (COPD) area through 5 products including LONHALA® MAGNAIR®
- Obtain approval and prepare for sale of products under application (dasotraline, apomorphine)

#### Number of MRs (Fiscal 2017)

Revenue per MR (Fiscal 2017)

\* MR: Medical Representative

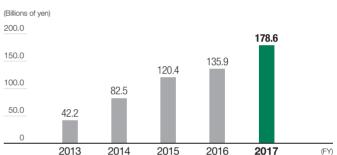




#### Fiscal 2017 Main Initiatives and Business Results

In FY2017, Sunovion achieved 240.8 billion yen in total revenue, up 23.7% year on year, while launching two new products. Core segment profit reached 109.5 billion yen, up 18.3% year on year. We continued to maximize growth of our leading product, LATUDA®, exceeding 170 billion yen in sales, an increase of 31.4% year on year. APTIOM® sales of 15.7 billion yen increased 35.5% year on year.

Our COPD franchise generated 33.6 million in sales, led by BROVANA®, which was complemented by the April 2017 launch of UTIBRON® and the October 2017 launch of SEEBRI®, both in-licensed from Novartis. Market rights to three ciclesonide products (for asthma and allergic rhinitis) were divested to Covis Pharma in July 2017.



#### Revenue of LATUDA<sup>®</sup> in North America

#### **Revenue of Major Products** (Billions of yen)

Brand Name	Therapeutic Indication	FY 2016	FY 2017	Rate of change (%)	FY 2018 forecast
LATUDA®	Atypical antipsychotic	135.9	178.6	31.4	184.7
BROVANA®	Therapeutic agent for COPD	33.1	33.1	0.3	34.2
<b>APTIOM®</b>	Antiepileptic	11.6	15.7	35.5	22.1
XOPENEX®	Therapeutic agent for asthma	5.1	4.0	(22.1)	3.6
In-licensed 3 products*	Therapeutic agent for COPD	-	0.5	-	2.9
LONHALA® MAGNAIR®	Therapeutic agent for COPD	-	_	-	5.0

\* UTIBRON®, SEEBRI®, ARCAPTA®

#### FY2018 Business Expansion and Outlook

In the Psychiatry & Neurology area, we will continue to drive the growth of LATUDA<sup>®</sup> and APTIOM<sup>®</sup> in FY2018, while planning for the approval of dasotraline and sublingual apomorphine.

With regard to LATUDA®, which is a pillar of Company earnings, we plan to increase fiscal 2018 promotional investment, including TV advertising, above last year's levels and will work to boost brand awareness as we strive for further gains in revenue. Also in fiscal 2018, our psychiatry Medical Representatives (MRs) will be utilized to efficiently cover LATUDA® and dasotraline upon its approval. We are planning a similar efficient neurology sales team structure, leveraging our APTIOM® MRs to support apomorphine upon its approval.

As for LATUDA®, we hold numerous patents and have filed patent infringement lawsuits against multiple pharmaceutical companies regarding their submissions of Abbreviated New Drug Applications for generic copies in the U.S.

In the COPD area, we are focused on the successful launch of LONHALA® MAGNAIR®, introduced in April 2018.

This product is the first long-acting muscarinic antagonist (LAMA) in the U.S. administered using a nebulizer system, which allows for quick absorption and easy portability. We have expectations for it to grow robustly, reaching the level of 50 billion yen in the future. Emphasis is being placed on early market penetration for this product and we will efficiently deploy resources to grow sales for BROVANA® and three in-licensed products (including UTIBRON® and SEEBRI®).



TV advertising of LATUDA®

## FOCUS

#### 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 that encourage the discovery of important, new medicines for patients by biopharmaceutical research companies.

Since 2002, PhRMA has had in place the PhRMA Code on Interactions with Healthcare Professionals (the PhRMA Code), which is a voluntary set of standards for communicating ethically with U.S. healthcare professionals and institutions. Sunovion is a signatory company of the PhRMA Code and has formulated policies and guidelines in order to comply with the PhRMA Code in its U.S. promotional activities.

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

#### **Implementing Patient Support**

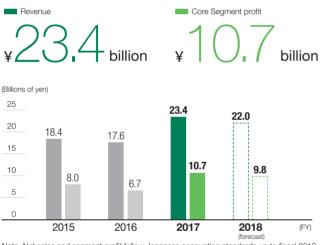
Sunovion partners with patient advocacy organizations across the U.S., while also developing and assisting premier advocacy programs in order to advance education and awareness across the psychiatry & neurology and respiratory therapeutic areas. Employees participate in various events that raise awareness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



# **Chinese Market**



#### Revenue / Core Segment profit



Note: Net sales and segment profit follow Japanese accounting standards up to fiscal 2016.

#### **Key Measures**

- Maximize profit from existing products
- Establish highly efficient business foundation
- Quick penetration of the new product LONASEN® into the market

Number of MRs (Fiscal 2017) Revenue per MR (Fiscal 2017)

#### \* MR: Medical Representative





#### Fiscal 2017 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 330 MRs at our subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. cover 30 provinces and cities (major cities, provinces, and autonomous regions).

In fiscal 2017, 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 28.1% over the previous fiscal year.

Additionally, we launched LONASEN®, an atypical antipsychotic agent, in February 2018.

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

Brand Name	Therapeutic Indication	FY 2016	FY 2017	Rate of change (%)	FY 2017 forecast
MEROPEN®	Carbapenem antibiotic	15.4	20.4	32.6	19.0

#### Fiscal 2018 Business Expansion and Outlook

Although growth has lagged due to impacts of ongoing factors, including the bidding system, we are dedicating effort to our mainstay product MEROPEN<sup>®</sup>, along with LONASEN<sup>®</sup> (launched in February 2018) as we expand the market in the Psychiatry & Neurology area.

Currently, we have approximately 30 specialist MRs dedicated to the Psychiatry & Neurology area in the Chinese market. With the launch of LONASEN® and lurasidone (planned for fiscal 2019), we expect this number to gradually rise to approximately 100 around 2022.

Furthermore, we will continue 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.

## Marketing **Related 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-guality foods. Products include polysaccharides, primarily GLYLOID® (tamarind seed gum), the first product of its kind successfully produced by the company 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 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 medicines and other products for companion animals, primarily dogs and cats, as well as for livestock such as cattle, swine, poultry, horses and aquacultured fish.

For the companion animal business, DS Pharma Animal Health launched MYFREE-GUARD (topical solution for exterminating ectoparasites) in March and MYFREE-GUARD  $\alpha$ in April, 2017. Also, in November of the same year, we launched the PETKISS® VET'S DOCTOR SPEC series of oral care products.

For the livestock business, DS Pharma Animal Health provides VICTAS® Soluble Powder 25%, a fluoroquinolone antibiotic for swine, URSO<sup>®</sup>, a bile acid product for cattle, EQVALAN® paste, an oral anthelmintic for horses, and other products. In April 2017, we started a co-promotion campaign with ASKA Animal Health Co., Ltd. for animal health products in the livestock field. Furthermore, in April 2018, we started selling MITOCHON POWER, a mixed feed with liquid photosynthetic bacteria culture.

For the aquaculture business, we provide vaccines and other products including anesthetics for fish and crustaceans and synthetic antibacterial drugs, contributing to the security and safety of food. In addition, we deal 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 2016. We started a clinical trial for cellular medicine in dogs using allogeneic mesenchymal stem cells in April 2018. In addition, since 2017, we have been running its New Business Program Supporting Animal Health.



PETKISS series (Lion products)

#### **Diagnostics and Ethical Drugs** DS Pharma Biomedical Co., Ltd. http://www.dsp-bio.com/

We develop, market and sell products such as point-of-care testing (POCT) diagnostics for infectious diseases (influenza, streptococcus, etc.), acute myocardial infarction, etc.; diagnostics to measure bone and calcium metabolism markers; diagnostics to measure drug concentration levels in the blood; high sensitivity products combining small immunofluorescence analyzers and special reagents.

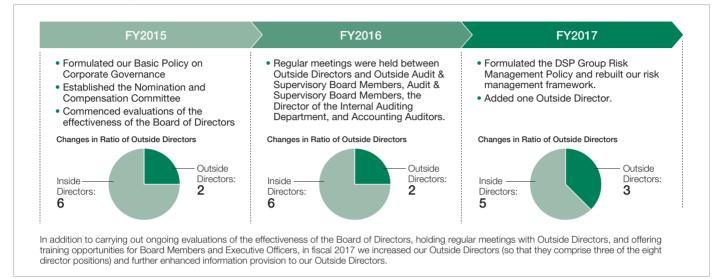
In July 2017, we launched "Influenza A+B FIA for Sofia® Analyzer," an influenza reagent specialized for a fluorescence detector "Sofia® Analyzer J." Also, we started co-promotion for Osteolinks® TRAP-5b (IVD to measure a bone absorption marker) with Teikoku Seiyaku Co., Ltd. in January 2017, and for Rapid SP® Chlamydia (POCT IVD for infectious diseases) with ASKA Pharmaceutical Co., Ltd. in February 2018.

Furthermore, we commenced manufacturing and selling of authorized generic (AG) pharmaceuticals in FY 2017. In December 2017, we launched IRBESARTAN Tablets DSPB, an AG for AVAPRO® Tablets, and, in June 2018, we launched ILUAMIX® Combination Tablets LD/HD DSPB, an AG for AIMIX® Combination Tablets LD/HD.



Sofia series

#### Measures to Strengthen Governance in Recent Years



### **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**

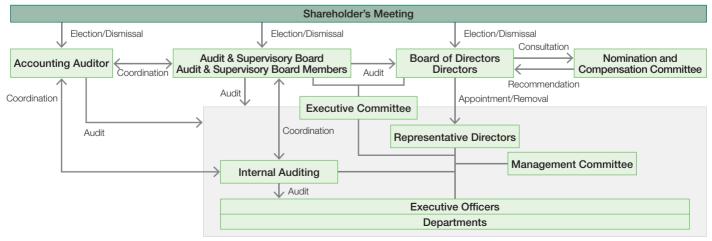
Sumitomo Dainippon Pharma commits itself to continuously pursuing the establishment of a corporate governance system which is highly effective, aiming for the fuller realization of our Corporate Mission and Management Mission.

#### **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.

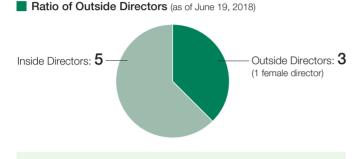
The Board of Directors consists of eight members, including three Independent Outside Directors. The Board of Directors holds a meeting once a month, in principle, and resolves and reports on material business matters.

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.



#### Corporate Governance Structure

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 are Independent Outside Directors, and the Chairperson is appointed from among the three Independent Outside Directors.

#### 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 (FY2017)

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)	
. , , ,	132
Total amount of fees to be paid in cash or otherwise by the Company or Subsidiaries of the Company	132

Notes: 1. The Audit & Supervisory Board of the Company has determined to consent to the amount of 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 remuneration.

- 2. Under the Audit Agreement between the Company and the Accounting Auditor, there is no distinction between 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. Note that this amount includes audit compensation pertaining to application of the International Financial Reporting Standards (IFRS).
- 3. Significant subsidiaries located overseas were audited by auditing firms other than the Accounting Auditor of the Company.

Organizational Body	Composition	Frequency of convocation	Purpose
The Board of Directors	The Board of Directors The Directors 8 members, (including three Outside Directors)		Resolving and reporting important management matters The Board of Directors Met 14 times in fiscal 2017
The Audit &The Audit & Supervisory Board 5 members, (including three outside Audit & Supervisory Board members)Once a month as a ruleDiscussing and resolving important audit-rel Met 13 times in fiscal 2017		Discussing and resolving important audit-related matters Met 13 times in fiscal 2017	
Nomination and Compensation Committee	The Directors 4 members, (includes three 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	Management Committee The members of the Board of Directors, and Executive Officers 12 members		As a consultative body to 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 23 times in fiscal 2017
Executive Committee	Executives, including the members of the Board of Directors, the Audit & Supervisory Board, and Executive Officers 23 members (including three 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 2017

#### Status of Convocation of the Meeting of the Board of Directors (FY2017)

#### 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 criteria for the independence of 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.

#### 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.

The members satisfy the Company's criteria for independence, and, having determined that there is no possibility of conflict of interest with ordinary shareholders, the Company has designated two of the three Outside Audit & Supervisory Board Members as Independent Outside Directors.

The Principal A	ctivities of	t the Outside	Directors and	Outside Al	idit & Supervis	ory Board Membe	<b>rs</b> (FY2017)

Category	Name	Name Principal Activities
	Hidehiko Sato	Of the fourteen (14) meetings during the fiscal year under review, he attended thirteen (13) meetings held by the Board of Directors. 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.
Outside Director	Hiroshi Sato	Of the fourteen (14) meetings during the fiscal year under review, he attended thirteen (13) meetings held by the Board of Directors. He made statements at those meetings as necessary, primarily based on his extensive experience and broad perspective as a corporate executive.
	Yutaka Atomi	Of the fourteen (14) meetings held by the Board of Directors during the fiscal year under review, he attended all eleven (11) meetings held after his appointment. He made statements at those meetings as necessary, primarily from the professional standpoint of a medical doctor.
Outside Audit & Supervisory Board Members	Harumichi Uchida	He attended all fourteen (14) meetings held by the Board of Directors and all thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review, and he made statements at those meetings as necessary, primarily from the professional standpoint of an attorney.
	Kazuto Nishikawa	He attended all fourteen (14) meetings held by the Board of Directors and all thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review, and he made statements at those meetings as necessary, primarily from the professional standpoint of an expert in the fields of finance and accounting.
	Junsuke Fujii	Of the fourteen (14) meetings held by the Board of Directors and the thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review, he attended all eleven (11) Board of Directors meetings after his appointment and nine (9) of the ten (10) Audit & Supervisory Board meetings. He made statements at those meetings, primarily based on his extensive experience and broad perspective as a corporate executive.

#### 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.

#### 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.

#### Saeko Arai

Saeko Arai has extensive experience as a corporate executive, having engaged in business management at multiple companies, and expertise as a certified public accountant. She has been appointed as an Outside Director in the hope that she will be able to contribute to the management of the Company with her experience and expertise.

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

#### 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.

#### Yoshio Iteya

Yoshio Iteya has extensive experience and expertise 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.

#### **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.

#### Messages from Outside Directors

At Sumitomo Dainippon Pharma, Outside Directors are provided with effective material and information from the Corporate Governance Department and Audit & Supervisory Board members, while we also coordinate with Audit & Supervisory Board members to exchange opinions in a timely manner. I believe that this system is extremely effective for the execution of work as an Outside Director.

Additionally, since being appointed in 2013, I feel that responses from management to the guestions and suggestions of Outside Directors have become more candid year by year. As a result, this has enhanced the depth of opinion exchanges with management. Reports on the results of these questions and suggestions have become more substantial and are being put to use in governance across the board.

One year has passed since I was appointed Outside Director in 2017. At present, Sumitomo Dainippon Pharma has three focus research areas: Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy (all areas where unmet medical needs are high). From my perspective as a medical doctor, I have spent the last year asking questions and providing suggestions to assist Company proposals.

Moreover, as a mid- to long-term growth strategy, Sumitomo Dainippon Pharma must strive to explore the potential for new business in frontier fields of healthcare in areas other than pharmaceuticals. We must build a second earnings pillar to succeed our pharmaceutical products business in the future and I would like to continue making suggestions going forward.

I was appointed as a new Outside Director for Sumitomo Dainippon Pharma on June 19, 2018. I would like to utilize my specialized knowledge as a certified public accountant to contribute to corporate governance and internal control from the perspective of accounting and finance. While serving as the first female Outside Director, I also plan to continue offering suggestions about hiring a varied work force through diversity promotion.

After my appointment, I would like to brace myself, in a positive sense, as I work with the managers and employees who are tackling human life issues in order to fight for the health and fuller lives of people on a daily basis. It is my hope to expend energy and devote myself to improvement and progress in order to increase the corporate value of Sumitomo Dainippon Pharma.





Hidehiko Sato





#### Amount of Executive Remuneration (FY2017)

Category	Number	Amount of Remuneration (Millions of Yen)
Directors	10	350
Audit & Supervisory Board Members	7	90

Notes: 1. The above includes the amount of remuneration and the like for Outside Directors and Outside Audit & Supervisory Board Members, six persons in total, which is 72 million yen in total.

- The above includes two Directors and two Audit & Supervisory Board members who reached the end of their tenure at the conclusion of the 197th Ordinary General Meeting of Shareholders held on June 22, 2017.
- 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.
- 4. The amount of compensation for Directors includes 35 million yen in Director bonuses scheduled to be paid at the conclusion of the 198th Ordinary General Meeting of Shareholders held on June 19, 2018.

# 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 2018 to March 2018 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 2018; and (ii) matters to be discussed for the further enhancement of the effectiveness of the Board of Directors. Based on analysis of the survey results, an exchange of opinions was held at the Board of Directors meeting in April 2018.

#### **Major Survey Categories**

- 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
- 7) Roles of Audit & Supervisory Board Members and the expectations for the Audit & Supervisory Board Members
- 8) Relationship with stakeholders
- 9) Improvements over last fiscal year

#### **Evaluation Overview**

- Overall, the Board of Directors demonstrates effectiveness.
- Improvement has been made with regard to FY2016 issues.
- The Board is aware of FY2018 issues, as follows.

#### FY2018 Issues

- To give sufficient prior explanations to the Outside Directors and the Outside Audit & Supervisory Board Members at an early time regarding highly-specialized matters that are specific to the pharmaceutical industry
- To secure adequate time to discuss important matters by organizing the time for discussion depending on the importance of matters to be discussed
- To share opinions and comments made at the Management Committee at meetings of the Board of Directors

#### 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 51.58% share of voting rights (as of March 31, 2018). 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.

#### 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 several 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. In March 2018, a gathering was held to tour the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT)

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 2017 held five such meetings.

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

#### Information Disclosure

Based on the recognition that transparency is vital to being a company 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 disclosure of information (the Disclosure Policy\*), 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.

\* Information on our information disclosure policies and criteria are posted on our website.

# 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.

### **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 2017, 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 management of each specific risk. The status of operations in each system to promote risk management is periodically reported to the Board of Directors. 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. 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

"Information" is an essential asset in our corporate activities, and how it is utilized and protected is of particular importance to Sumitomo Dainippon Pharma. We have established global policies for records and information management as well as various rules for information management and IT security to minimize risks.

#### Management of confidential information

In accordance with the internal rules, we manage confidential information in an appropriate manner according to the degree of importance. We have the information management system such as executive officer who is in charge of information management and the Information Management Committee. In order to prevent insider trading, we have internal rules which specify matters that all officers and employees must comply with, and we educate all officers and employees about these rules.

#### Information Security

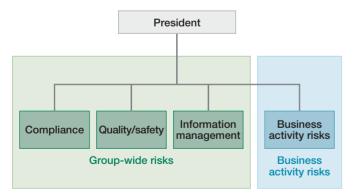
With respect to our information security efforts, we continue to update technical measures, rules and procedures according to change of social environment or progress of information technology. We also strive to strengthen information security in our group companies.

In addition, we focus on education with the aim that officers and employees strongly recognize the importance of information security and ensure full compliance with rules and regulations. Moreover, we provide them with periodic training to maintain high awareness about information security.

#### Managing Personal Information

Sumitomo Dainippon Pharma has a privacy policy in place, and in accordance with its internal rules, properly handles and protects personal information acquired through its business activities from medical professionals, product users, business partners, shareholders, employees and other persons. In addition, Sumitomo Dainippon Pharma actively promotes protection of personal information by building a solid management system that includes an executive officer in charge of personal information management and a personal information hotline, and educating and training its officers and employees.





## Board Members and Executive Officers (As of July 1, 2018)

#### Directors



#### Masayo Tada Representative Director, Chairman

1968: Joined Sumitomo Chemical Co., Ltd. 2005: Managing Executive Officer of the former Sumitomo Pharmaceuticals Co., Ltd.
 2005: Director and Managing Executive Officer of the former Sumitomo Pharmaceuticals Co., 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
 2018: Representative Director and Chairman of the Company (for the present)

Company (to the present)





#### Hiroshi Nomura **Representative Director.** President and Chief Executive Officer

1981: Joined Sumitomo Chemical Co., Ltd.

- 2008: Joined the Company 2008: Joined the Company 2008: Executive Officer of the Company 2012: Member of the Board of Directors and Senior 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
- 2018: 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 Deputy Head of Japan Business Unit

1981: Joined Sumitomo Chemical Co., Ltd. 1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd. 2012: Executive Officer of the Company

2017: Member of the Board of Directors and Executive Officer 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
- 2011: Outside Director of Scrupp Corporation (currently, LIXIL Group Corporation)
   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 Head of Japan Business Unit

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 2016: Member of the Board of Directors and Senior 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 2010: President of Kyorin University 2013: Outside Audit & Supervisory Board Member of the
- 2013: President Emeritus of Kyorin University
- (to the present)



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

Senior Executive Research Director. Drug Research Division Regenerative & Cellular Medicine Office; Regenerative & Cellular Medicine Kobe Center; Regenerative & Cellular Medicine Manufacturing Plant

1989: Joined Sumitomo Chemical Co., Ltd. 1992: Joined the former Sumitomo Pharmaceuticals Co., Ltd. 2015: Executive Officer of the Company

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



#### Saeko Arai Member, Board of Directors (Outside)

1987: Joined Eiwa Audit Corporation (currently, KPMG AZSA LLC) 2002: Established Gratia, Inc. (currently, Acuray, Inc.)

- and assumed the position of President thereof (to the present) 2017: Outside Audit & Supervisory Board Member of
- 2017: Outside Audit & Supervisory Board Member of AEON Credit Service Co., Ltd. (to the present)
   2018: Professor at the Faculty of Global Business of
- Showa Women's University (to the present) 2018: Outside Member of the Board of Directors of Tokyu Fudosan Holdings Corporation
- 2018: Outside Member of the Board of Directors of the Company (to the present)

#### Audit & Supervisory Board Members



#### 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)



#### Takashi Kutsunai Audit & Supervisory Board Member

- 1981: Joined Sumitomo Chemical Co., Ltd.
   1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
   1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
   2006: Director of Personnel of the Company
   2008: Director of Strategic Marketing & Planning (Asia), International Business Management of the Company
   2009: Director of International Business Strategic Marketing and Planning of the Company
   2010: Director of Global Business Planning and
   2011: Director of Global Business Planning and

- 2011. Director of oliobal blasmess relatining and Development, and Director of Global Sales and Marketing of the Company 2012: Director of Internal Auditing of the Company 2018: Audit & Supervisory Board Member of the Company (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
- 2014: Nonmember Inspector of the Hyogo Prefectural Credit Federation of Agricultural Cooperatives (to the present)



#### Junsuke Fujii Audit & Supervisory Board Member (Outside)

- 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

- Institute, Limited 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 Company (to the present)



#### Yoshio Iteya Audit & Supervisory Board Member (Outside)

1983: Admitted to the Bar (Japan) 1989: Admitted to the Bar (New York) 1992: Partner at Mori Hamada & Matsumoto (to the

- present)
- 2000: Lecturer at the Graduate School of International Corporate Strategy of Hitotsubashi University (currently, the Graduate School of Law of
- Hitotsubashi University) (to the present) 2004: Adjunct Professor at Hitotsubashi University School of Law (to the present) 2018: Outside Audit & Supervisory Board Member of the
- Company (to the present)

#### Executive Officers

#### Nobuhiko Tamura

Senior Executive Officer Chairman and Chief Executive Officer, Sunovion Pharmaceuticals Inc.

#### Yoshiharu Ikeda

Senior Executive Officer Executive Director, Manufacturing Division; Technology Research & Development Division Deputy Head of Japan Business Unit

#### Kazuo Koshiya

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

#### Hiroyuki Baba

#### Executive Officer

Global Corporate Planning; Legal Affairs; Intellectual Property; IT Management & Digital Transformation

#### Hidevuki Harada

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

#### Mitsuyuki Taniguchi

Executive Officer Deputy Executive Director, Sales & Marketing Division

#### Atsuko Higuchi

Executive Officer Executive Communication Officer; Human Resources

#### Shigeyuki Nishinaka

#### **Executive Officer**

Global Business Development; International Business Management

#### Kazuhiro Takada

**Executive Officer** Senior Director, Corporate Governance

#### 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**

Chief Executive Officer, Boston Biomedical, Inc.

# Materiality Assessment to Deepen 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. Alongside providing pharmaceutical products that are truly needed, we strive as a company to fulfill our social responsibilities by pursuing an effective corporate governance structure and highly transparent management,



Kazuhiro Takada Executive Officer Senior Director, Corporate Governance

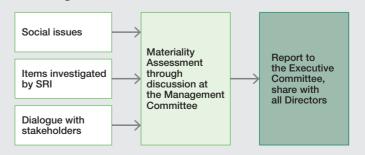
ensuring thorough compliance, maintaining communication with a wide range of stakeholders, reducing our environmental impact, enacting "Work Style Innovation", promoting diversity and inclusion starting with support for the active participation of women, and implementing other activities that contribute to society both in Japan and overseas.

In promoting CSR-based management, we are making a conscious effort to contribute to the achievement of the Sustainable Development Goals (SDGs) adopted by the United Nations in September 2015. The Company's main focus is on participating in the achievement of each of the goals through a wide range of activities. For example, based on the approach specified by Goal 17, "Partnership for the Goals," we collaborate in a variety of programs with academic, governmental, and international organizations. Furthermore, with Goal 12, "Responsible consumption and production" in mind, we are promoting the proper use of pharmaceutical products, and in regard to Goal 8, "Decent work and economic growth," we are proactively implementing "Work Style Innovation". We also 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.

#### Materiality Assessment as a Guideline of CSR-based Management

It is very important that companies strive to solve the various issues that face society through their business activities.

For Sumitomo Dainippon Pharma to continue growing sustainably with society, we have conducted an assessment to identify the material issues to guide our CSR-based management, and to be addressed through our business activities, based on verification of the opportunities and risks in our business.



#### Materiality Map

The material issues Sumitomo Dainippon Pharma should tackle have been classified in terms of their "Societal Significance (based on the expectations from various stakeholders and social demand)" and "Importance to Sumitomo Dainippon Pharma's Business," and prioritization of the issues from both perspectives. This materiality map guides our CSR-based management and gives focus to our efforts to solve these issues through our business activities. We will continuously review and verify these material issues. Other our CSR activities can be found on the Company website.

Societal Significance	<ul> <li>Climate change initiatives</li> <li>Improvement of healthcare infrastructure in developing countries</li> <li>Development of local communities</li> </ul>	provement of healthcare frastructure in developing pountries• Support for patients and their familiesinnovative products • Advancement of science • Product quality assurance • Product safety and side• Oncole • Regen Cell The • Intract			ases
High	<ul> <li>Effective use of water resources</li> <li>Prevention of air pollution</li> <li>Reduction of waste</li> </ul>	<ul> <li>Preventing environmental accidents</li> <li>Biodiversity</li> </ul>	<ul> <li>Stakeholder engagement</li> <li>Promoting diversity</li> <li>Health, safety, and welfare o</li> <li>Training and development of</li> <li>Utilizing external resources</li> </ul>		
	High Importance to Sumitomo Dainippon Pharma's Business				Very High

#### Current Status of Initiatives for Material Issues

Material Issues	Page
Development of innovative products	03-04, 17, 19-22
Advancement of science	19-22, 32
Product quality assurance	31-32
Product safety and side effects	21, 30-32
Responsibility for drug-induced suffering	21, 31-32
Stable supply	33-34
Fair marketing	37-41
Work Style Innovation	18, 55
Respecting human rights	21, 34
Strengthening corporate governance	43-50
Ensuring compliance	34, 49
Ensuring business activities are ethical and transparent	21, 33-34, 49

Material Issues	Page
Stakeholder engagement	05-06
Promoting diversity	60
Health, safety, and welfare of employees	59
Training and development of employees	59
Utilizing external resources	21
Access to healthcare	56
Support for patients and their families	57
Fair pricing	33-34
Development of innovation beyond medicine	17, 19
Responding to counterfeit medicines	58
Prevention of bribery and corruption	05, 33
CSR procurement	34
Proactive disclosure	48
Information security	50
Support education of the next generation	58

## Work Style Innovation

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 it is important to achieve work-life balance if we are to have an active, diverse work force.

We designated 2017 as Year One for "Work Style Innovation" and have promoted a variety of initiatives, including holding seminars to facilitate implementing "Work Style Innovation" and starting Work Style Innovation Meetings for employees to discuss and review work styles at each work site. Additionally, we set up a Work Style Innovations microsite on our intranet in order to share each department's goals and case studies of initiatives, which helps galvanize work style innovation efforts.

With regard to our work from home initiative, in June 2016 we launched a system to support employees involved in childcare or nursing care and we expanded the system in October 2017 so that, in principle, all employees are able to work from home. Furthermore, as part of our office environment reforms, we introduced open, unassigned desk space at some business sites and we are promoting initiatives that lead to employee productivity improvements.

Our ongoing initiatives for remedying long working hours include no overtime days and other measures, while we are also encouraging employees to take their annual paid leave.

Going forward, we aim to continue to create workplace environments where employees can exercise their full capabilities and achieve a work-life balance.

#### Main Initiatives in FY2017

Established a Senior Governance Officer - Work style reforms

- Held panel seminars Work Style Innovation
- Ikuboss'
- · Balancing work with childcare/nursing care Supporting women's active participation

Joined the *Ikuboss* Corporate Alliance and formulated an *Ikuboss* Declaration

Set up a Work Style Innovation microsite (DSP intranet)

Expanded the work from home system

Established a staggered work hours system (starting April 2018)

Office environment reforms (trial implementation of unassigned desk space in fiscal 2017, with adoption planned in fiscal 2018)

Curb long working hours •Started Work Style Innovation Meetings at each work site for taking inventories of work tasks and reassessing work styles

Thoroughly managing work hours

Encouraged improvement of the usage rate for paid leave

 Achieved a 65% utilization rate for paid leave in fiscal 2017

 Encouraged employees to consistently take their paid leave

Formulated the Declaration of Health Innovation

\* Leaders who encourage employees to utilize child care/nursing care leave and who facilitate an environment conducive to both work and childrearing.







Access Accelerated https://www.accessaccelerated.org/





## Access to Healthcare

Contributing to 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 Goal 17, "Partnerships for the Goals." While establishing a sustainable framework, we are working towards solutions by collaborating with government agencies, international institutions, research institutions, and civil society.

Main Initiatives in FY	2017
Participation in Access Accelerated	Since January 2017, we have participated in Access Accelerated, which is a partnership initiative with 24 global pharmaceutical companies, and also includes international organizations such as the World Bank and the Union for International Cancer Control. Through this involvement, we are striving to improve access to care for non-communicable diseases in low- to low-middle-income countries, focusing on Africa and Asia. In fiscal 2017, 62 Access Accelerated programs at different companies were promoted targeting 88 low- to low-middle-income countries in Africa and Asia, while pharmaceutical regulatory easing initiatives were started in 5 countries.
Initiatives for Safe Delivery and Sound Child Growth	From July 2016, we have worked with NPOs, local governments, and the community to provide a health improvement program for mothers and children in Cambodia's Kampong Cham Province. In fiscal 2017, this program trained 19 Community Care volunteers for Mothers and New-borns (CCMN) and visited the homes of 122 antenatal women and 119 postnatal women. Through the home visits, CCMN encouraged antenatal, postnatal, and neonatal checkups, and also provided education on nutrition and hygiene. This program is registered as one of Access Accelerated's individual company programs so the expertise and outcomes can be shared with partner companies and organizations, while a mutual measurement framework has been established in collaboration with Boston University to evaluate the effects of those programs.



A Child Life Specialist explains disease to a child



Website of the Japan Epilepsy Research Foundation



Sunovion employees who participated in the NAMI Walk in Boston

# Support for Patients and Their Families

Implementing Support through Donations In the spirit of our global slogan "Innovation today, healthier tomorrows," Sumitomo Dainippon Pharma promotes social contribution activities in the hope that all patients and their families can lead healthier and more fulfilling lives.

As we focus on support for patients and their families, global health, and educating the next generation, voluntary financial contributions by our officers and employees are matched by a corresponding Sumitomo Dainippon Pharma donation and presented to organizations that promote such causes. In fiscal 2017, Sumitomo Dainippon Pharma provided donations in the form of funds to assist with activities to the Japan Association of Certified Child Life Specialists, the Japan Mental Health Peer Support Specialists Training Organization, and the Japan Association of Medical Translation for Cancer.

## 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 running on contributions from Sumitomo Dainippon Pharma and other donors. The Foundation provides grants and commendations related to epilepsy. In fiscal 2017, JERF provided 12 research grants, two overseas study grants, and one Japan Epilepsy Research Grant 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.

#### **Implementing Patient Support**

Our U.S. subsidiary Sunovion Pharmaceuticals Inc. 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. In fiscal 2017, Sunovion continued efforts from the previous fiscal year to support walking events by the U.S. National Alliance on Mental Illness (NAMI), while also supporting Be Vocal, a campaign promoting mental health in the U.S.

# Support Education of the Next Generation

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

Since fiscal 2012, we have been providing visiting lectures at junior high and high schools as part of activities for supporting the next generation. 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.

As medical technology continues to progress, we believe that bioethics is important in junior high and high school education as a discipline that does not offer simple right or wrong answers. Using an original program on bioethics and incorporating the particular perspective that a biology-related corporation can offer, Sumitomo Dainippon Pharma employees deliver visiting lectures. As a program that fosters young learners' abilities to think, feel, and empathize, the program has been highly praised by the Ministry of Economy, Trade and Industry and by classroom teachers.

In fiscal 2017, participating students numbered approximately 2,800 at 29 schools, with 40 of our employees serving as instructors.

Additionally, we added SUKOYAKA Compass as a part of our company website for students to access. SUKOYAKA Compass conveys information on the importance of understanding and using medicines correctly, encourages students to take an interest in medicine, offers explanations of pharmaceutical products, and presents details on what employees do at pharmaceutical companies.

## Responding to Counterfeit Medicines

There have been increases in the volume of ethical pharmaceuticals illegally manufactured and distributed (i.e., counterfeit drugs), in addition to the number of countries and regions targeted by these drugs, which creates a global threat hindering access to pharmaceutical products. Furthermore, since the distribution of these drugs can easily become a source of funds for criminal and terror organizations, international coordination for solving the issue is crucial.

In order to ensure the safety and security of products, Sumitomo Dainippon Pharma is working with other pharmaceutical companies to take part in the initiatives of industry associations and international organizations, while also striving to collect and share the most up to date information. More specifically, we have joined the Pharmaceutical Security Institute (PSI) and we are sharing information such as response measures, etc. with global pharmaceutical companies inside and outside Japan.

Additionally, we are taking anticounterfeiting measures, such as using multiple and complicated steps for product packaging, for drugs distributed in particularly high-risk countries/regions, as well as drugs that can be easy targets for counterfeiting, and also drugs that could cause critical harm to health if counterfeit versions were manufactured. We are establishing a global protocol in order to take measures promptly for patients' health, in the event that a counterfeit product is detected, or a suspicious case arises.

No. of employees teaching courses



Schools using DSP visiting lectures / No. of attendees





# Training and Development of Employees

#### DSP Academy, for Training Selected Employees, and Overseas Training with Open Recruitment

As part of our employee training, we established the DSP Academy in July 2016, which is a career grade-specific training program. The Academy provides extensive learning opportunities to highly talented students, from young employees to mid-career employees as well as managers. Chairman Masayo Tada serves as the Academy principal, leading various management courses and other modules aimed at fostering future top-level managers. In the five years from fiscal 2016, 400 students are expected to complete the program.

In addition, in fiscal 2017, we started an overseas training program with open recruitment. The program's objective is to place promising young employees in environments with different industries and cultures, and provide them with early experience in overcoming challenges through their own efforts, thereby instilling resilient courage. In fiscal 2017, three talented young employees were dispatched overseas.

#### Talent Management for Strategically Placing Employees and Promoting Human Resource Development

In April 2018, we adopted a talent management system for maximizing the performance of our employees (talents) and systematically understanding and supervising which employees possess which skills, assets, and capacities. Utilizing the talent management system, we encourage employees to take steps toward independent career planning and autonomous self-improvement. We also have superiors and subordinates work together to design customized development plans in order to realize human resources development and the proper placement of personnel, while striving to maximize results.

## Health, Safety, and Welfare of Employees

#### Striving for a Company in Which Employees Can Be Healthy and Vibrantly Active

We have announced a 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 order to achieve this mission, we believe that it is important to create workplaces where each and every employee can enjoy both mental and physical health while vibrantly engaging in their jobs. Hence, we are vigorously striving to ensure health management and safety as we offer our employee programs and systems.

In October 2017, we formulated our Declaration of Health Innovation in order to implement ever stronger promotion of health maintenance and improvement activities for employees and their families.

Also, in February 2018, Sumitomo Dainippon Pharma was recognized under the "Certified Health & Productivity Management Outstanding Organizations 2018 Recognition Program 'White 500,'" promoted by the Ministry of Economy, Trade and Industry and the Nippon Kenko Kaigi, for our excellent health management as a large enterprise in coordination with health insurance societies. Following on 2017's selection, this was our second year of receiving this recognition.

Going forward, we will continue to work together as an organization to realize healthy and full lives for all employees and their families, so that we can contribute to the betterment of healthcare and fuller lives of people worldwide.

Number of participants in the DSP Academy Expected number over 5 years:



An employee who took part in the open recruitment overseas training program (Front row, second from the right, in India)





#### Main Initiatives in FY2017

Held training for managers, addressing the long-term inclusion and development of female employees

Held training for female employees, aiming at developing them into managerial staff

Worked to create an environment of meaningful work, where both men and women enjoy a positive balance between their jobs and private lives

Implemented support measures for returning to work, and pursuing a career, after child-care leave

## **Promoting Diversity**

#### Achieving Work-Life Balance

In order for employees to independently pursue transformation and to generate innovative ideas, we believe that it is necessary to create an environment conducive to exercising one's full capacities while effecting a positive cycle connecting work and personal lifestyles for every employee. We also believe that the presence of "*lkuboss*"\* supervisors is important for encouraging rank and file employees in both their careers and their broader lives. In August 2017, we joined the "*lkuboss* Corporate Alliance," run by the NPO Fathering Japan, and formulated an "*lkuboss* Declaration."

For the company's efforts to promote child support, we received the "Kurumin"

Certification twice, in 2010 and 2013, and "Platinum *Kurumin*" in July 2017. In each workplace, we promote a mindset of understanding and assistance for employees facing diverse life events who require flexible work styles.

We will continue to aim to create workplace environments where employees can exercise their full capacities and achieve a work-life balance.

\* Leaders who encourage employees to utilize child care/nursing care leave and who facilitate an environment conducive to both work and childrearing.

#### Supporting Women's Active Participation

Sumitomo Dainippon Pharma has vigorously strived for active participation by women as one focus of our efforts on diversity and inclusion. We have formulated a Voluntary Action Plan on Promotion of Women to Managerial and Board Positions, 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 April 2018, women accounted for 8.4% of managerial staff at Sumitomo Dainippon Pharma.

In November 2017, we received the highest "*Eruboshi*" certification (three stars) as a company making excellent progress implementing initiatives for the active involvement of female employees.

## **Environment**

#### **Environmental Management**

Sumitomo Dainippon Pharma recognizes its environmental responsibility 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 served 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 issues of special importance and objectives for three years.

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

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

#### **Results in Fiscal 2017 for Mid-term Environmental Plan**

As part of our efforts to build a low-carbon society, which is one of our most important topics, we have set a target of reducing CO<sub>2</sub> emissions by 23% by FY2020, compared to FY2005. In fiscal 2017, our CO<sub>2</sub> emissions were 20.2% lower than in fiscal 2005 due to the significant contribution of energy reduction measures, such as optimizing the operation of air conditioners for the reorganization of production sites, in addition to the use of cogeneration systems and solar power generation facilities that were introduced in the past. 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**

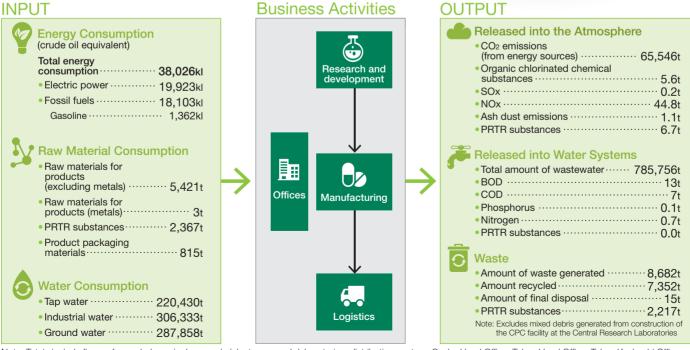
To formulate a Mid-term Environmental Plan comprising specific measures for implementing the basic environmental policies

 $\uparrow$ 

#### **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

#### Overview of Environmental Impact (FY2017)



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

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102-4	Ownership and legal form	[WEB] Corporate Profile
102-5	Markets served	[WEB] Corporate Profile
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102-21	environmental, and social topics	System, Compliance, Environmental Management
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## Financial Section Ten-Year Summary of Selected Financial Data

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

Japanese GAAP	2009	2010	2011	2012	2013	2014	2015
RESULTS OF OPERATIONS:							
Net sales	¥264,037	¥296,262	¥379,513	¥350,396	¥347,724	¥387,693	¥371,371
Overseas sales revenue	22,051	53,015	152,226	130,243	133,125	174,286	174,911
Ratio to net sales	8.4%	17.9%	40.1%	37.2%	38.3%	45.0%	47.1%
Cost of sales	103,741	112,263	110,030	98,857	101,686	104,100	101,228
Selling, general and administrative expenses	129,130	148,374	238,531	231,137	220,994	241,450	246,868
(Research and development costs)	52,819	51,371	68,160	56,891	59,844	69,804	71,304
(Ratio to net sales)	20.0%	17.3%	18.0%	16.2%	17.2%	18.0%	19.2%
Operating income	31,166	35,625	30,952	20,402	25,044	42,143	23,275
Operating margin	11.8%	12.0%	8.2%	5.8%	7.2%	10.9%	6.3%
Net income attributable to owners of the parent	19,988	20,958	16,796	8,630	10,044	20,061	15,448
FINANCIAL POSITION:							
Total assets	¥391,295	¥626,743	¥589,868	¥559,410	¥607,219	¥659,033	¥711,584
Net assets	324,496	343,483	323,983	319,227	349,248	398,540	451,021
OTHER STATISTICS:							
Capital expenditures	¥10,569	¥6,471	¥8,663	¥8,742	¥12,384	¥23,421	¥10,676
Depreciation and amortization	11,455	18,650	44,628	40,232	35,085	26,777	19,226
PER SHARE OF COMMON STOCK	:						
Basic net income	¥ 50.30	¥ 52.75	¥ 42.27	¥ 21.72	¥ 25.28	¥ 50.49	¥ 38.88
Net assets	816.49	864.51	815.44	803.47	879.03	1,003.11	1,135.21
Cash dividends applicable to the year	18.00	18.00	18.00	18.00	18.00	18.00	18.00
FINANCIAL INDICATORS:							
ROE	6.2%	6.3%	5.0%	2.7%	3.0%	5.4%	3.6%
ROA	5.1%	4.1%	2.8%	1.5%	1.7%	3.2%	2.3%
Equity ratio	82.9%	54.8%	54.9%	57.1%	57.5%	60.5%	63.4%
Dividend payout ratio	35.8%	34.1%	42.6%	82.9%	71.2%	35.7%	46.3%

Notes 1. 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).

2. Because provisional accounting treatment for business combinations conducted during the fiscal year ended March 31, 2017 was fixed during the fiscal year ended March 31, 2018, the allocation of acquisition costs was reviewed. Consequently, the figures for the year ended March 31, 2017 were adjusted retroactively.

Millio	ns of yen		
2	016	2017	2018
¥40	)3,206	¥411,639	¥477,966
21	5,055	227,495	290,321
	53.3%	55.3%	% <b>60.7%</b>
10	)4,471	100,071	119,852
26	61,805	259,066	292,291
8	32,034	80,819	91,397
	20.3%	19.6%	% <b>19.1%</b>
3	36,930	52,501	65,823
	9.2%	12.8%	% <b>13.8%</b>
2	24,697	28,733	37,525
¥70	)7,717	¥783,640	¥801,425
44	6,473	460,389	483,050
À	9,785	¥10,619	¥10,060
2	20,267	18,649	19,909
	Yen		
¥	62.16	¥ 72.32	¥ 94.45
1,1	23.76	1,158.80	1,215.84
	18.00	20.00	28.00
	5.5%	6.39	% <b>8.0%</b>
	3.5%	3.9%	% <b>4.7%</b>
	63.1%	58.89	% <b>60.3%</b>
	29.0%	27.79	% <b>29.6%</b>

	Millions of yen	
IFRS (Core Basis)	2017	2018
RESULTS OF OPERATIONS:		
Revenue	¥408,357	¥466,838
Overseas sales revenue	224,234	281,434
Ratio to revenue	54.9%	60.3%
Cost of sales	94,523	112,345
Selling, general and administrative expenses	171,385	186,176
Research and development expenses	81,373	86,881
Ratio of R&D expenses to revenue	19.9%	18.6%
Core operating profit	64,372	90,604
Ratio of core operating profit to revenue	15.8%	19.4%
Net profit attributable to owners of the parent	31,316	53,448
FINANCIAL POSITION:		
Total assets	¥779,072	¥809,684
Total equity	412,268	452,723
OTHER STATISTICS:		
Capital expenditures	¥7,835	¥10,184
Depreciation and amortization	13,352	13,518
PER SHARE OF COMMON STOCK:	Yen	
Basic net profit	¥ 78.82	¥ 134.53
Equity attributable to owners of the parent	1,037.68	1,139.50
Cash dividends applicable to the year	20.00	28.00
FINANCIAL INDICATORS:		
ROE	7.8%	12.4%
ROA	4.2%	6.7%
Ratio of equity attributable to owners of the parent to total assets	52.9%	55.9%
Dividend payout ratio	25.4%	20.8%
To coincide with the adoption of the IFRS, the Group has set "core ope	rating profit" as an earnir	has indicator showing the

To coincide with the adoption of the IFRS, the Group has set "core operating profit" as an earnings indicator showing the Company's recurring profitability.

Core operating profit is calculated by deducting from operating profit any gains and losses resulting from nonrecurring factors (hereinafter, "non-recurring items") designated by the Group, and expense figures ("core basis") are reported after adjusting for non-recurring items. Capital expenditures have typically shown the acquisition costs of property, plant and equipment and intangible assets. However, the figures under IFRS for the fiscal year ended March 31, 2017 and after show the acquisition costs of property, plant and equipment and intangible assets.

plant and equipment and software.

## Financial Section Operating Results and Financial Condition

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

During the fiscal year ended March 31, 2018, the Japanese economy was continuing a mild recovery track as consumer spending picked up, capital expenditures and production gradually increased, and corporate earnings and business sentiments improved. Overseas, the U.S. economy steadily recovered and the Chinese economy continued to rally. Regarding the Japanese economy, while employment and income environments continue to improve, it is expected that these mild recovery trends should be sustained, in part due to government economic packages. Nevertheless, uncertainties in overseas business situations and fluctuations in financial and capital markets still warrant attention.

In the pharmaceutical sector, the Japanese authorities are undertaking a drastic reform of the National Health Insurance (NHI) drug price scheme and authorities around the world are taking further steps to curb prices of brand-name drugs and promote use of generics in a bid to put the brakes on ever-expanding social security benefit expenditures. Amid these circumstances, the increasing difficulty of developing new drugs, rising R&D expenses, and other factors serve to lower business predictability and add to business risks.

Against this backdrop, in an attempt to bolster sales of TRERIEF<sup>®</sup>, LONASEN<sup>®</sup>, Trulicity<sub>®</sub>, and other drugs in Japan, the Group has focused its management resources to provide scientific information on these key offerings.

In North America, the Company's U.S. subsidiary, Sunovion Pharmaceuticals Inc., continued to direct its resources into expanding the sales of global strategic product LATUDA® and other mainstay products. The Company possesses multiple patents for LATUDA®, which is one of the primary sources of revenue of the Group. As counter-measures against application submissions for generic products, the Company and Sunovion filed patent infringement lawsuits in the U.S. against those submissions in January 2015 based on the compound patent, and further filed patent infringement lawsuits against those submissions in February 2018 based on a method of use patent issued in November 2017.

In China, Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. pursued business opportunities in a bid to expand sales of MEROPEN<sup>®</sup> and other products in the Chinese market.

In Europe, the Company signed a partnership agreement with Angelini S.p.A. with the aim of expanding sales of LATUDA®.

#### **Operating Results**

#### Revenue: ¥466.8 billion (up 14.3% year-on-year)

The increase is attributable to sales growth of Trulicity® in the Japan segment and MEROPEN® and other products in the China segment, as well as a substantial sales expansion of LATUDA® in the North America segment.

#### Core operating profit: ¥90.6 billion (up 40.8% year-on-year)

Despite the increase in selling, general, and administrative expenses in the North America segment and R&D expense, core operating profit rose as gross profit grew in tandem with the increase in revenue.

#### Operating profit: ¥88.2 billion (up 118.9% year-on-year)

The substantial increase is attributable to a reversal of expenses resulting from a decline in the fair value of contingent consideration following the Company's decision, in June 2017, to unblind a Phase 3 global study of napabucasin, which is under development by Boston Biomedical, for gastric and gastro-esophageal junction cancer patients, in addition to a decline in business structure improvement expenses.

# Net profit attributable to owners of the parent: ¥53.4 billion (up 70.7% year-on-year)

The ratio of net profit attributable to owners of the parent to revenue was 11.4%.

#### **Financial Condition**

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

Non-current assets decreased by 10.4 billion yen over the previous fiscal year-end. This is because deferred tax assets dropped significantly due to the U.S. tax reform, and goodwill and intangible assets decreased owing primarily to the impact of foreign currency translations, while other financial assets increased with the fair value measurement of marketable securities. For current assets, income taxes receivable decreased, but cash and cash equivalents and other financial assets increased, resulting in an increase of 41.0 billion yen over the previous fiscal year-end.

As a result, total assets increased by 30.6 billion yen from the previous fiscal year-end, to 809.7 billion yen.

#### -Liabilities

Total liabilities decreased by 9.8 billion yen from the previous fiscal year-end, to 357.0 billion yen. This was due primarily to decreases in bonds and borrowings despite increases in trade and other payables, including accounts payable-other.

#### -Equity

Equity amounted to 452.7 billion yen, due primarily to an increase in retained earnings.

Ratio of equity attributable to owners of the parent to total assets as of the end of the fiscal year under review was 55.9%.

#### Status of cash flows

#### -Net cash provided by operating activities

Cash flows provided by operating activities increased by 74.3 billion yen from the previous fiscal year, to 93.4 billion yen, owing primarily to a major increase in profit before taxes, as well as a major decrease in income taxes paid.

#### -Net cash used in investing activities

Despite the acquisition of intangible assets following in-licensing and investment securities, cash flows used in investing activities decreased by 39.6 billion yen from the previous fiscal year, to 16.5 billion yen, due to the absence of the high expenditures for acquisition control over subsidiaries that were recorded in the previous fiscal year.

#### -Net cash provided by financing activities

Cash flows used in financial activities amounted to 29.6 billion yen, due primarily to redemption of bonds and repayment of loans, while net cash was generated overall during the corresponding period of the previous fiscal year due to fundraising.

#### -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, 2018 amounted to 147.8 billion yen, which represents an increase of 42.2 billion yen from the end of the previous fiscal year.

#### Allocation of the Company's Profits

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

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

In addition to placing high importance on distribution of surplus in a manner reflecting 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 consistently allocate profits to its shareholders.

In the fiscal year ended March 31, 2018, the Company achieved a record-high operating income, greatly exceeding the target for the fiscal year ended March 31, 2018 that was laid out in the 3rd Mid-Term Business Plan (MTBP), so we issued a special dividend. Given the aforementioned basic policy on profit distribution to shareholders and earnings results of the fiscal year under review, the Company paid a year-end dividend of 19 yen per share, which comprises an ordinary dividend of 9 yen and a special dividend of 10 yen, thus making the annual dividend for the fiscal year under review 28 yen per share.

#### Forecasts for the Year Ending March 31, 2019

In Japan, revenue is expected to decrease due to the difficulty of offsetting the impacts of AIMIX<sup>®</sup> generic entries, NHI drug price revisions, and declines in sales of long-listed products, despite the continued focus on expanding sales of TRERIEF<sup>®</sup> and Trulicity<sub>®</sub>. In North America, meanwhile, revenue is expected to grow due to sales expansion of LATUDA<sup>®</sup> and APTIOM<sup>®</sup> and the launch of LONHALA<sup>®</sup> MAGNAIR<sup>®</sup> (therapeutic agent for COPD), despite the impact of the strong yen. Consolidated revenue is expected to reach 467.0 billion yen (up by 0.2 billion yen year-on-year).

Core operating profit is expected to be 77.0 billion yen, which represents a decrease of 13.6 billion yen from the previous year, after taking into account the impact of the strong yen on selling, general, and administrative expenses and an increase in selling expenses in North America, where a new launch is scheduled. In the fiscal year ended March 31, 2018, the Company reported a reversal of expenses resulting from changes in fair value of contingent consideration related to an acquisition, but expects to incur expenses in the fiscal year ending March 31, 2019. As a result, the Company expects operating profit of 53.0 billion yen (down by 35.2 billion yen year-on-year) and net profit attributable to owners of the parent of 35.0 billion yen (down by 18.4 billion yen year-on-year).

Note: Foreign currency exchange rates used for the forecasts are: 1 USD = 105 JPY (JPY110.9 in the fiscal year under review),

1 RMB = 16.5 JPY (JPY16.7 in the fiscal year under review)

## 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, 2018.

#### 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 product development may not proceed as planned or attain approval and market launch because of the growing difficulty of development of new drugs. It is possible that some development projects, from the standpoint of efficacy, safety, etc., may be delayed or abandoned. Such cases could have a significant and negative impact on the Group's operating results and financial position.

# Risk relating to specific products comprising a large proportion of consolidated revenue

In the fiscal year under review, the revenue in North America for atypical antipsychotic LATUDA® (lurasidone hydrochloride), which is a pillar of Group earnings, comprised 38% of Sumitomo Dainippon Pharma's consolidated revenue. If LATUDA® revenue falls due to patent infringement litigation, the emergence of other strong competing products, or through other unexpected events, it 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, there is the possibility, that some use might be deemed an infringement of the intellectual property rights of a third party unknown to the Group. Furthermore, the Group's business is safeguarded by a large quantity of intellectual property. Consequently, if the Group's intellectual property were infringed by a third party, or if legal disputes pertaining to the validity and ownership of intellectual property rights were to arise, it 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 administrative measures overseas.

#### 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.

#### 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

Regarding the atypical antipsychotic LATUDA<sup>®</sup>, which is one of the Group's mainstay products, in the fiscal year under review, Sumitomo Dainippon Pharma obtained a new method of use patent and formulation patent. However, at the end of the fiscal year under review, Sumitomo Dainippon Pharma and subsidiaries filed a patent infringement lawsuit against multiple generic drug manufacturers. Additionally, 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. Such patent infringement lawsuits and other lawsuits involve inherent uncertainties. 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 non-financial assets

The Group owns various types of net property, plant and equipment and intangible 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 Statement of Profit or Loss

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

		Million	
	Note	2017	2018
Revenue	4	¥ 408,357	¥ 466,838
Cost of sales		94,625	112,345
Gross profit		313,732	354,493
Selling, general and administrative expenses	5	181,668	183,651
Research and development expenses		81,373	86,928
Other income	6	3,554	9,417
Other expenses	7	13,959	5,158
Operating profit		40,286	88,173
Finance income	8	3,182	2,430
Finance costs	8	687	5,737
Profit before taxes		42,781	84,866
Income tax expenses	9	11,465	31,418
Net profit		31,316	53,448
Net profit attributable to:			
Owners of the parent		31,316	53,448
Net profit total		31,316	53,448
Earnings per share (yen)			
Basic earnings per share	10	78.82	134.53

## Consolidated Statement of Comprehensive Income

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries		Millions	of yen
Years Ended March 31, 2018 and 2017	Note	2017	2018
Net profit		¥ 31,316	¥ 53,448
Other comprehensive income			
Items that will not be reclassified to profit or loss:			
Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income	11	(2,886)	8,527
Remeasurements of defined benefit liability (asset)	11	3,277	(2,824)
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	11	(1,871)	(10,748)
Cash flow hedges	11	(7)	(1)
Total other comprehensive income		(1,487)	(5,046)
Total comprehensive income		29,829	48,402
Total comprehensive income attributable to:			
Owners of the parent		29,829	48,402
Total comprehensive income		29,829	48,402

## Financial Section Consolidated Statement of Financial Position

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Transition Date (April 1, 2016), March 31, 2018 and 2017

			Millions of yen	
	Note	Transition Date (As of April 1, 2016)	2017	2018
Assets				
Non-current assets				
Property, plant and equipment	12, 15	¥ 63,665	¥ 61,121	¥ 58,204
Goodwill	13	76,950	100,194	95,097
Intangible assets	14	78,821	197,114	189,681
Other financial assets	16	65,232	52,681	70,993
Income taxes receivables		—	—	2,453
Other non-current assets		3,862	3,313	3,067
Deferred tax assets	9	73,580	57,089	41,608
Total non-current assets		362,110	471,512	461,103
Current assets				
Inventories	17	44,511	60,286	60,169
Trade and other receivables	18, 26	108,656	112,732	112,982
Other financial assets	16	49,377	17,494	22,066
Income taxes receivables		_	6,234	419
Other current assets		5,261	5,211	5,170
Cash and cash equivalents	19	135,572	105,603	147,775
Total current assets		343,377	307,560	348,581
Fotal assets		705,487	779,072	809,684
iabilities and equity				
Liabilities				
Non-current liabilities				
Bonds and borrowings	20, 26	28,000	10,000	30,940
Trade and other payables	21	156	_	_
Other financial liabilities	22	69,874	100,873	88,427
Retirement benefit liabilities	24	21,909	16,374	20,700
Other non-current liabilities		6,174	7,352	6,551
Deferred tax liabilities	9	4,061	72	95
Total non-current liabilities		130,174	134,671	146,713
Current liabilities		,	,	
Bonds and borrowings	20, 26	23.010	58,000	16,460
Trade and other payables	21	43,528	47,394	58,708
Other financial liabilities	22	6,648	13,917	6,278
Income taxes payable		28,456	10,001	14,368
Provisions	23	57,757	76,905	84,433
Other current liabilities		26,320	25,916	30,001
Total current liabilities		185,719	232,133	210,248
Fotal liabilities		315,893	366,804	356,961
Equity		0.0,000	000,001	,
Share capital	25	22,400	22,400	22,400
Capital surplus	25	15,860	15,860	15,860
Treasury shares	25	(663)	(667)	(669)
Retained earnings	25	326,358	357,769	396,037
Other components of equity	25	25,639	16,906	19,095
Equity attributable to owners of the parent	20	389,594	412,268	452,723
Fotal equity		389,594	412,208	452,723

## Financial Section Consolidated Statement of Changes in Equity

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

Tears Ended March 31, 2010 and 2017				1	Villions of yen				
		Equity attributable to owners of the parent							
						Other components of equity			
	Note	Share capital	Capital surplus	Treasury shares	Retained earnings	Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit liability (asset)		
Balance as of April 1, 2016		¥ 22,400	¥ 15,860	¥ (663)	¥ 326,358	¥ 25,652	¥ —		
Net profit		_	_	_	31,316	_	_		
Other comprehensive income	11	_	_	_	_	(2,886)	3,277		
Total comprehensive income		—	_	_	31,316	(2,886)	3,277		
Purchase of treasury shares	25	_	_	(4)	_	_	_		
Disposal of treasury shares	25	—	_	_	_	—	—		
Dividends	25	—	_	_	(7,151)	_	—		
Reclassification from other components of equity to retained earnings		_	_	_	7,246	(3,969)	(3,277)		
Other increase (decrease)		_	_	_	_	_	_		
Total transactions with owners		_	_	(4)	95	(3,969)	(3,277)		
Balance as of March 31, 2017		¥ 22,400	¥ 15,860	¥ (667)	¥ 357,769	¥ 18,797	¥ —		
Net profit		—	—	—	53,448	-	_		
Other comprehensive income	11	_	_	_	_	8,527	(2,824)		
Total comprehensive income		_	_	_	53,448	8,527	(2,824)		
Purchase of treasury shares	25	—	—	(2)	—	-	_		
Disposal of treasury shares	25	—	—	—	—	_	—		
Dividends	25	—	—	—	(7,945)	_	-		
Reclassification from other components of equity to retained earnings		-	-	-	(7,235)	4,411	2,824		
Other increase (decrease)		_	—	—	_	—	—		
Total transactions with owners		_	—	(2)	(15,180)	4,411	2,824		
Balance as of March 31, 2018		¥ 22,400	¥ 15,860	¥ (669)	¥ 396,037	¥ 31,735	¥ —		

				Millions of yen		
	NULL	Othe	er components of equit			
	Note	Exchange differences on translation of foreign operations	Cash flow hedges	Total	Total	Total equity
Balance as of April 1, 2016		¥ —	¥ (13)	¥ 25,639	¥ 389,594	¥ 389,594
Net profit		_	_	_	31,316	31,316
Other comprehensive income	11	(1,871)	(7)	(1,487)	(1,487)	(1,487)
Total comprehensive income		(1,871)	(7)	(1,487)	29,829	29,829
Purchase of treasury shares	25	_	_	_	(4)	(4)
Disposal of treasury shares	25	_	_	_	_	_
Dividends	25	_	_	_	(7,151)	(7,151)
Reclassification from other components of equity to retained earnings		_	_	(7,246)	_	_
Other increase (decrease)		_	_	_	_	_
Total transactions with owners		_	_	(7,246)	(7,155)	(7,155)
Balance as of March 31, 2017		¥ (1,871)	¥ (20)	¥ 16,906	¥ 412,268	¥ 412,268
Net profit		_	-	-	53,448	53,448
Other comprehensive income	11	(10,748)	(1)	(5,046)	(5,046)	(5,046)
Total comprehensive income		(10,748)	(1)	(5,046)	48,402	48,402
Purchase of treasury shares	25	_	_	_	(2)	(2)
Disposal of treasury shares	25	_	_	-	_	_
Dividends	25	_	-	-	(7,945)	(7,945)
Reclassification from other components of equity to retained earnings		-	_	7,235	-	-
Other increase (decrease)		_	_	_	-	_
Total transactions with owners		_	_	7,235	(7,947)	(7,947)
Balance as of March 31, 2018		¥ (12,619)	¥ (21)	¥ 19,095	¥ 452,723	¥ 452,723

# Financial Section Consolidated Statement of Cash Flows

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

		ns of yen	
	Note	2017	2018
Cash flows from operating activities			
Net profit		¥ 31,316	¥ 53,448
Depreciation and amortization		12,713	12,887
Impairment losses		2,254	2,147
Changes in fair value of contingent consideration		8,131	(8,608)
Interest and dividend income		(1,945)	(2,430)
Interest expenses		662	394
Income tax expenses		11,465	31,418
(Increase) decrease in trade and other receivables		(4,065)	(2,934)
(Increase) decrease in inventories		(15,295)	(4,382)
Increase (decrease) in trade and other payables		7,103	10,493
Increase (decrease) in retirement benefits liabilities		(829)	276
Increase (decrease) in provisions		18,713	12,067
Others, net		(7,201)	442
Subtotal		63,022	105,218
Interest received		801	1,058
Dividends received		1,198	1,246
Interest paid		(374)	(338)
Income taxes paid		(45,504)	(13,764)
Net cash provided by operating activities		19,143	93,420
Cash flows from investing activities		-, -	
Purchase of property, plant and equipment		(8,131)	(5,129)
Proceeds from sales of property, plant and equipment		631	960
Purchase of intangible assets		(5,328)	(7,225)
Purchase of investments		(356)	(6,226)
Proceeds from sales and redemption of investments		8,935	31
Acquisitions of control over subsidiaries		(84,348)	_
Net decrease (increase) in short-term loan receivables		29,855	(5,468)
Proceeds from business transfer			9,423
Others, net		2,613	(2,889)
Net cash used in investing activities		(56,129)	(16,523)
Cash flows from financing activities		(	(
Net increase (decrease) in short-term borrowings	20	39,036	(36,500)
Proceeds from long-term borrowings	20		35,300
Repayments of long-term borrowings	20	(12,000)	(9,400)
Redemption of bonds	20	(10,000)	(10,000)
Repayments of finance lease obligations	20	(1,117)	(1,064)
Dividends paid	_0	(7,151)	(7,944)
Others, net		(4)	(1,544)
Net cash provided by (used in) financing activities		8,764	(29,610)
Net increase (decrease) in cash and cash equivalents		(28,222)	47,287
Cash and cash equivalents at beginning of year	19	135,572	105,603
Effect of exchange rate changes on cash and cash equivalents	10	(1,747)	(5,115)
Cash and cash equivalents at end of year	19	¥ 105,603	¥ 147,775
	13	+ 100,000	+ 1+1,115

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

# 1. Reporting Entity

2. Basis of Preparation Sumitomo Dainippon Pharma Co., Ltd (the "Company") is a company domiciled in Japan. The closing date of the Company's Consolidated Financial Statements is March 31, 2018. The Company's Consolidated Financial Statements comprise the Company and its subsidiaries (the "Group"), its interests in associates. The Group is primarily involved in pharmaceutical business. The details of the main business are presented in Note 4 Operating Segments. The registered address of the Company's Head Office and its main places of business are presented on the Company's website (URL https://www.ds-pharma.co.jp/).

# (1) Compliance with IFRS and matters concerning First-time Adoption

The Group's consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") issued by the international Accounting Standards Board. The provision of Article 93 of the Ordinance on Terminology, Forms, and Preparation Methods of Consolidated Financial Statements applies, as the Company meets the requirements for a "Specified Company Applying Designated International Accounting Standards" prescribed in Article 1 (2) of said ordinance.

The consolidated financial statements for the fiscal year ended March 31, 2018 are the first IFRS consolidated financial statements the Company has prepared in accordance with IFRS. The date of transition to IFRS (the "transition date") was April 1, 2016. And the Company applies IFRS 1 First-time Adoption of International Financial Reporting Standards ("IFRS 1"). The effects of the transition to IFRS on the Group's financial position, results of operations, and cash flows are presented in Note 32 First-time Adoption of IFRS.

The Group's consolidated financial statements were approved on June 19, 2018 by the Board of Directors.

# (2) Basis of Measurement

The Group's consolidated financial statements are prepared on the historical cost basis, except for certain financial instruments presented in Note 3 Significant Accounting Policies.

### (3) Functional Currency and Presentation Currency

The Group's consolidated financial statements are presented in Japanese yen, which is the Company's functional currency, rounded to the nearest million yen.

### (4) Significant Accounting Estimates, Judgments and Assumptions

In preparing the consolidated financial statements, management has made estimates, judgments and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, revenues and expenses. However, due to the uncertainty of these estimates and assumptions, there are possibilities that material adjustments to the carrying amount of assets and liabilities are required in future periods.

Main estimates, judgments, and assumptions are summarized as follows:

- Significant assumptions used in calculating recoverable amounts when performing impairment test on goodwill and intangible assets (Note 13 and 14)
- Estimated useful lives of intangible assets (Note 3)
- Recoverability of deferred tax assets (Note 9)
- Measurement of defined benefit obligations (Note 24)
- Fair value of financial assets (Note 26)
- Accounting treatment and measurement of provisions (Note 23)
- Fair value of contingent consideration related to business combinations (Note 30)

### (5) New Standards and Interpretations Issued but Not Yet Applied

The new and amended standards and interpretations issued but not yet early applied by the Group are as follows:

IFRS		Mandatory application (Hereafter, Starting Year)	Application by the Group	Overview of introduction or Revision	
IFRS 15	Revenue from Contracts with Customers	January 1, 2018	Fiscal year ending March 31, 2019	New revenue recognition standards, replacing IAS 18, IAS 11, and related interpretations	
IFRS 16	Lease	January 1, 2019	Fiscal year ending March 31, 2020	Revised accounting standards for recognition of leases	

The effect on the Group's consolidated financial statements from applying IFRS 15 Revenue from Contracts with Customers is immaterial. The Group is currently evaluating the effect of applying IFRS 16 Lease.

#### (6) Early application of the new standard

The Group early applied IFRS 9 Financial Instruments (final version issued in July 2014) at the IFRS transition date (April 1, 2016).

### 3. Significant Accounting Policies

The significant accounting policies adopted by the Group are continuously applied to all the reporting periods presented in the consolidated financial statements (including the consolidated statement of financial position as of the Transition Date).

### (1) Basis of consolidation

1. Subsidiaries

Subsidiaries are entities controlled by the Group.

The Group controls an entity when the Group is exposed to, or has rights to variable returns from its involvement with the investee and has the ability to use its power to affect its returns.

The Group consolidates the financial statements of subsidiaries from the date when the Group controls the investees, and excludes them from the scope of consolidation from the date when the Group loses control over the investees.

When the closing date of subsidiary is different from that of the Group, the financial statements of subsidiary, on which a provisional financial closing has been performed as of the Group's closing date, are used for consolidation purpose.

In preparing the consolidated financial statements, all intergroup balances and transactions, and unrealized gains and losses arising from intergroup transactions are eliminated.

### 2. Associates

Associates are those entities in which the Group has significant influence over the financial and operating policies but does not have control or joint control. Significant influence is the power to participate in the financial and operating policy decisions of the investee, but does not have control over those policies.

Investment in associate is accounted for by using the equity method.

The closing date of the associates accounted for using the equity method is same as that of the Group.

3. Business combinations

Business combinations are accounted for using the acquisition method.

The identifiable assets and liabilities of the acquired company are measured at acquisition-date fair value.

The fair value of all the assets and liabilities arising from contingent consideration contract is included in the consideration transferred.

Goodwill is measured at the excess of the aggregate of the consideration transferred and the amount of any non-controlling interests in the acquired company over the net of acquisition-date amounts of the identifiable assets acquired and liabilities assumed. If it is a deficit, the deficit is recognized immediately in profit or loss.

Acquisition-related costs are recognized in the profit or loss when incurred.

The Group elects to adopt the exemption prescribed in IFRS 1 and does not apply retrospectively IFRS 3 Business Combinations ("IFRS 3") to the business combinations that occurred before the date of transition.

### (2) Foreign currency translations

1. Foreign currency transactions

Foreign currency transactions are translated into the functional currency at the spot exchange rate at the date of transactions or at the foreign exchange rate that approximates the spot exchange rate at the date of the translation.

Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated into the functional currency using the exchange rate at the reporting date. Non-monetary assets and liabilities measured at fair value that are denominated in foreign currency are translated into the functional currency at the exchange rates prevailing at the date when the fair value was measured.

Exchange differences arising from foreign currency translations and settlements are recognized in the profit or loss. However, exchange differences arising from financial assets measured at fair value through other comprehensive income and the effective portion of cash flow hedges are recognized in other comprehensive income.

### 2. Foreign operations

The assets and liabilities (including any goodwill arising on the acquisition and fair value adjustments) of the Group's foreign operations are translated into Japanese yen at the spot exchange rate at the reporting date. Income and expenses are translated into Japanese yen at the average exchange rate for the period except for the case that the exchange rate fluctuates significantly.

Exchange differences arising from translation of financial statements of the foreign operations are recognized in other comprehensive income. The cumulative amount of such exchange differences is recognized as other components of equity in the consolidated statements of financial position.

On the disposal of a foreign operation, the cumulative amount of the exchange differences relating to the foreign operation is reclassified to profit or loss during the period in which the foreign operation is disposed.

The Group elects to apply the exemption prescribed in IFRS 1 and deems the cumulative translation differences for all foreign operations as zero and reclassifies the total amount to retained earnings at the date of transition.

### (3) Revenue

### 1. Sale of goods

Revenue is measured at the fair value of a consideration received or receivable after deducting the amount of trade discounts and volume rebates.

Revenue from sales of goods is recognized when Group has transferred the significant risks and

rewards of the goods to the customer, the Group retains neither continuing managerial involvement nor effective control over the goods sold, it is probable that the economic benefits associated with the transaction will flow to the Group, and the amount of revenue and associated cost can be measured reliably.

#### 2. Revenue arising from intellectual property rights

Revenue arising from Intellectual property is recognized on an accrual basis in accordance with the substance of the relevant agreement. Revenue associated with milestone agreements is recognized upon achievement of the milestone defined in the respective agreements.

#### (4) Income taxes

Income taxes are presented as the aggregate amount of current taxes and deferred taxes, and recognized in the profit or loss, except for those related to business combinations and items that are recognized directly in equity or in other comprehensive income.

Current taxes are measured by the statutory tax rate and tax laws that have been enacted or substantively enacted at the reporting date and the amount expected to be paid to or recovered from the taxation authorities.

Deferred tax assets and liabilities are recognized for temporary differences arising from the difference between the carrying amount of assets or liabilities in the consolidated statement of financial position at the reporting date and its tax base, tax loss carryforwards and tax credit carryforwards. However, the deferred tax assets and liabilities are not recognized for the following temporary differences:

- Temporary difference arising from initial recognition of goodwill;
- Temporary differences arising from the initial recognition of assets and liabilities in a transaction which is not a business combination, and at the time of the transaction, affects neither accounting profit nor taxable profit or loss;
- Deductible temporary differences associated with investments in subsidiaries and associates when it is not probable that the temporary difference will reverse in the foreseeable future; or there will not be taxable profits will be available against which the deductible temporary differences can be utilized; and
- Taxable temporary differences associated with investments in subsidiaries and associates, to the extent that the Group is able to control the timing of reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognized for deductible temporary differences, the carryforwards of unused tax losses and the carryforward of unused tax credits to the extent that it is probable that future taxable profits will be available against which they can be used. In principle, deferred tax liabilities are recognized for all taxable temporary differences.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realized or the liability is settled, based on statutory tax rates and tax laws that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and liabilities are offset if the Group has a legally enforceable right to set off current tax assets against current tax liabilities and income taxes are levied by the same taxation authority on the same taxable entity.

### (5) Earnings per share

Basic earnings per share are calculated by dividing net profit attributable to owners of the parent by the weighted average number of ordinary shares outstanding during the period, excluding treasury shares held. Diluted earnings per share are not calculated because no dilutive shares are outstanding.

### (6) Property, plant and equipment

Cost model is applied for measurement of property, plant and equipment after initial recognition.

Property, plant and equipment are carried at cost less accumulated depreciation and accumulated impairment losses.

The acquisition cost includes direct costs of acquisition, estimated costs of dismantlement, removal and restoration, and borrowing costs eligible for capitalization requirements.

Property, plant and equipment other than land and construction in progress is depreciated by using straight-line method over each asset's useful life. Depreciation of such asset begins when it is available for use.

The estimated useful lives of major categories of property, plant and equipment are as follows:

- Buildings and structures 3~60 years
- Machineryand vehicle 2~17 years
- Tools, furniture and fixtures 2~20 years

The depreciation method, the residual value and the estimated useful life are reviewed at each reporting date and adjusted if appropriate.

### (7) Lease

The Group classifies a lease as a finance lease if it transfers substantially all the risks and rewards of ownership to the lessee. An operating lease is a lease other than a finance lease.

In finance lease transactions, leased assets and lease liabilities are recognized at the lower of the fair value of the leased property and the present value of the minimum lease payments, each determined at the inception of the lease. Leased assets are depreciated on a straight-line basis over the shorter of their estimated useful lives and lease term. Lease payments are apportioned between the finance cost and the reduction of the lease obligations. The finance cost allocated to each period during the lease term is the amount that produces a constant rate of interest on the remaining balance of the lease liabilities.

Operating lease payments are recognized as an expense on a straight-line basis over the lease term.

### (8) Goodwill

Initial measurement of goodwill is stated in (1) Basis of consolidation 3. Business Combinations. Goodwill is carried at cost less any accumulated impairment losses.

Goodwill is not amortized and is allocated to cash-generating units or group of cash-generating units. Goodwill is tested for impairment annually and whenever there is an indication that it may be impaired. Impairment loss on goodwill is recognized in profit or loss and is not reversed in subsequent periods.

### (9) Intangible assets

Intangible assets are non-monetary assets without physical substance, other than goodwill, including patents, technologies, marketing rights and in-process research and development acquired separately or acquired in a business combination.

Separately acquired intangible assets are measured initially at cost. Intangible assets acquired in a business combination are measured at fair value at the acquisition date.

Cost model is applied for measurement of intangible assets after initial recognition. Intangible assets are carried at its cost less accumulated amortization and accumulated impairment losses.

Research expenditures of an internal project are recognized as expenses when they are incurred. Development expenditures of an internal project that satisfy all the recognition criteria are recognized as intangible assets. However, internally generated development expenditures incurred before acquisition of marketing approval, including clinical trial expenditures, etc. are recognized as expenses when they are incurred, because such expenditures are considered not meeting the criteria for recognition of intangible assets due to the uncertainties related to the length of period and the development.

Acquisition costs and development expenditures of software for internal use purpose are recognized as intangible assets if future economic benefits are expected to flow to the Group.

Intangible assets other than in-process research and development project are amortized using straight-line method over each asset's useful life. Amortization of such asset begins when it is available for use.

The estimated useful lives of major categories of intangible assets are as follows:

- Intangible assets related to products 3~20 years
- Software 3~5 years

The amortization method, the residual value and the estimated useful life are reviewed at each reporting date and adjusted if appropriated.

In-process research and development project recognized as intangible asset is not amortized because it is not available for use. Impairment test is performed annually and whenever there is an indication that the in-process research and development project may be impaired.

In-process research and development expenditures are reclassified to patents, marketing rights or other related accounts when marketing approval from regulatory authorities is obtained and are amortized when they are available for use.

### (10) Impairment of non-financial assets

The Group assesses whether there is any indication that non-financial assets other than inventories, retirement benefit assets and deferred tax assets may be impaired.

If there is an indication of impairment or annual impairment test is required, the recoverable amount of each asset is measured. Goodwill, intangible assets with indefinite useful lives and an intangible asset not yet available for use are tested for impairment annually or whenever there is an indication of impairment.

Recoverable amount of an asset or a cash-generating unit ("CGU") is measured at the higher of its fair value less disposal costs and its value in use. The value in use of an asset is measured at the present value of estimated future cash flows by applying a pre-tax discount rate that reflects current assessments of the time value of money and the risk specific to the asset. An impairment loss is recognized if the carrying amount of an asset or CGU exceeds its recoverable amount impairment are recognized in profit or loss.

A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or group of assets.

The impairment loss recognized for a CGU is first allocated to reduce the carrying amount of goodwill allocated to the unit, and subsequently reduce the carrying amounts of the other assets in the CGU on a pro rate basis.

Impairment losses on goodwill are not reversed.

The Group assesses at each reporting date whether there is any indication that reversal of impairment loss recognized in prior periods for an asset other than goodwill may exist. An impairment loss recognized in prior periods for an asset other than goodwill is reversed if there has been a change in the estimates used to determine the asset's recoverable amount.

The reversal of an impairment loss does not exceed the carrying amount (net of amortization or depreciation) that would have been determined if no impairment loss had been recognized for the asset in prior periods.

### (11) Financial instruments

The Group early applied IFRS 9 Financial Instruments (final version issued in July 2014) to account for its financial instruments.

1. Financial assets

(i) Initial recognition and measurement

The Group initially recognizes financial assets on transaction date and classifies as financial assets measured at amortized cost and financial assets measured at fair value at the initial

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recognition. Financial assets are classified as financial asset measured at amortized cost if the following conditions are met. Otherwise, financial assets are classified as financial assets measured at fair value.

- The financial asset is held within a business model whose objective is to hold assets in order to collect contractual cash flows; and
- Contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principals and interests.
- (ii) Subsequent measurement

After initial recognition, financial assets are measured as follows:

- (a) Financial assets measured at amortized cost
- Financial assests are measured at amortized costs using the effective interest method.
- (b) Financial assets measured at fair value through profit or loss

Financial assets are measured at fair value and subsequent changes in fair value are recognized in profit or loss.

(c) Financial assets measured at fair value through other comprehensive income Among the financial assets measured at fair value, an entity may make an irrevocable election at initial recognition for an investment in an equity instrument that is not held for trading purpose to present subsequent changes in the fair value in other comprehensive income. Therefore, the Group makes such election for each financial instrument.

Financial assets are measured at fair value, and subsequent changes in fair value are recognized in other comprehensive income. The cumulative amount recognized in other comprehensive income is reclassified to retained earnings, but not profit or loss, when equity instruments are derecognized or when the fair value of equity instruments declines significantly. However, dividends are recognized in profit or loss.

### (iii) Derecognition

- A financial asset is derecognized when it meets one of the following conditions:
- the contractual rights to the cash flows from the financial assets expire; or
- the Group transfers the financial assets and substantially all the risks and rewards related to the ownership of the financial assets.
- (iv) Impairment

Financial assets measured at amortized cost are presented at the carrying amount reduced by a loss allowance recognized for expected credit losses to be incurred in the future. The Group assesses whether a credit risk on a financial asset measured at amortized cost has increased significantly since initial recognition and considers all reasonable and supportable information in addition to delinquency information when assessing the credit risk.

The Group estimates expected credit losses for each individual financial asset measured at amortized cost at an amount equal to the lifetime expected credit losses if the credit risk on that financial asset has increased significantly since initial recognition. If not, the Group estimates expected credit losses for that financial asset at an amount equal to expected credit losses for 12 months after the reporting date.

Among the financial assets measured at amortized cost, the Group estimates expected credit losses at an amount equal to lifetime expected credit losses for trade receivables, independently by each type of similar receivables.

2. Financial liabilities

(i) Initial recognition and measurement

The Group initially recognizes financial liabilities when the Group becomes a contractual party and classifies financial liabilities as follows:

(a) Financial liabilities measured at fair value through profit or loss

Financial liabilities which were designated to be measured at fair value through profit or loss.

(b) Financial liabilities measured at amortized cost

Financial liabilities other than financial liabilities measured at fair value through profit or loss. Financial liabilities are measured at fair value at initial recognition. However, financial liabilities measured at amortized cost are measured at fair value after deducting transaction costs that are directly attributable to the financial liabilities.

- (ii) Subsequent measurement
- After the initial recognition, financial liabilities are measured as follows:
  - (a) Financial liabilities measured at fair value through profit or loss

Financial liabilities are measured at fair value and subsequent changes are recognized in profit or loss.

(b) Financial liabilities measured at amortized cost

Financial liabilities are measured at amortized cost using the effective interest method.

(iii) Derecognition

A financial liability is derecognized only when the obligation specified in the contract is fulfilled, discharged, cancelled or expires.

3. Derivatives

The Group uses derivatives to hedge foreign currency risk exposures. Such derivatives used by the Group are foreign currency forward contracts. However, the Group does not use derivatives for speculative purpose. Derivatives are initially recognized at fair value and the related transaction costs are recognized as expenses when incurred. Derivatives not qualified for hedge accounting are measured at fair value after initial recognition and the change in fair value is recognized in profit or loss.

4. Hedge accounting

Certain derivatives are designated as hedging instruments in cash flow hedges and if they meet certain hedging criteria, the effective portion of fair value changes of derivatives is recognized in other comprehensive income and is cumulated in accumulated other comprehensive income.

At the inception of the designation of hedge, the Group has a formal documentation of the relationship between hedging instruments and hedged items, including risk management objective, strategy for undertaking the hedge and method for assessing whether the hedge effectiveness requirements are met. At the inception of the hedge and on an ongoing basis, the Group assesses whether the Group can forecast if the hedging instrument is effective in offsetting changes in fair value or cash flows of the hedged item attributable to the hedged risk throughout the period for which the hedge is designated.

The other components of equity are reclassified to profit or loss, in the hedged item related account in the consolidated statement of profit or loss, during the same period in which the expected cash flows of hedged item affect profit or loss. If a hedged forecasted transaction subsequently results in the recognition of a non-financial asset or non-financial liability, the cumulative amount previously recognized in other components of equity are reclassified to and included in the initial amount of the cost of the non-financial asset or the non-financial liability. In the changes in the fair value of derivatives, the portion of hedging ineffectiveness is immediately recognized in profit or loss.

Hedge accounting is discontinued when the Group revokes the designation of hedge, when the hedging instrument expires or is sold, terminated or executed or when the hedge no longer meets the criteria for hedge accounting.

#### (12) Inventories

Inventories mainly comprise merchandise and finished goods, work-in-process, raw materials and supplies.

Inventories are measured at the lower of acquisition cost and net realizable value. The cost of inventories is calculated by the average method and comprises purchase costs, processing costs and

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other related production costs. Finished goods and work-in-process include a proper allocation of production overheads that are based on the expected capacity of the production facilities. Net realizable value is the estimated selling price in the ordinary course of business, less the estimated costs of completion and the estimated costs necessary to make the sale.

### (13) Cash and cash equivalents

Cash and cash equivalents comprise cash on hand, demand deposits, and short-term investments that are readily convertible to cash and are subjected to insignificant risks of changes in value, and whose maturities are three months or less from the date of acquisition.

### (14) Employee benefits

1. Post-retirement benefits

The Group has both defined benefit plans and defined contribution plans as employee post-retirement benefits.

(i) Defined benefit plan

The present value of the defined benefit obligations arising from a defined benefit plan and the related current service cost and past service cost are measured by using the projected unit credit method by each plan. The discount rates are determined by reference to market yields at the fiscal year-end on high quality corporate bonds for the corresponding periods in which the retirement benefits are to be paid. The amount of the net defined benefit liability (asset) is calculated by deducting the fair value of plan assets from the present value of the defined benefit obligation. Service cost and net interest on the net defined benefit liability (asset) are recognized as post-retirement benefit expense in profit or loss. Remeasurement of the net defined benefit liability (asset) are recognized in other comprehensive income and immediately reclassified to retained earnings in the period in which they occur.

(ii) Defined contribution plan

The expense related to post-retirement arising from a defined contribution plan is recognized as post-retirement benefit expense in profit or loss in the period which the employee renders service to the Group.

2. Other long-term employee benefits

Long-term employee benefit obligations other than post-retirement benefit plan are measured at the present value of the future benefit payments by the Group in exchange for the services rendered by employees up to the reporting date.

3. Short-term employee benefits

Short-term employee benefits are recognized as an expense on an undiscounted basis at the time when the service is rendered by employee.

Bonuses are recognized as liabilities, when the Group has a present legal or constructive obligation to pay for service rendered as a result of the service rendered by employees in the past.

### (15) Provisions

Provisions are recognized when the Group has a present legal or constructive obligation arising as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

When the effect of the time value of money is material, the amount of a provision is the present value of the expenditures expected to be required to settle the obligation. The discount rate is generally a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability.

### (16) Government grants

Government grants are measured at fair value when the grant will be received and there is reasonable assurance that the Group will comply with the conditions attached to grants, and are recognized.

Government grants related to assets are being deducted from acquisition cost of the asset and are recognized in profit or loss over the useful life of the depreciable asset as a reduced depreciation expense. Also, government grants related to income are recognized in profit or loss on a systematic basis over the periods in which the Group recognizes as expenses the related costs for which the grants are intended to compensate.

### (17) Capital

#### 1. Ordinary share

With regard to ordinary shares issued by the Company, the issuance value is recorded in share capital and capital surplus, and the costs directly attributable to the issue of ordinary shares (after tax effect) are recognized as a deduction from capital surplus.

### 2. Treasury share

When treasury shares are acquired, they are recognized at cost and presented as a deduction from equity. In addition, directly attributable costs arising from the acquisition of treasury shares are deducted from capital surplus.

When treasury shares are sold, the difference between carrying amount and consideration received is recognized in capital surplus.

### 4. Operating Segments

The Group sets core operating profit, which is an indicator showing the Company's profitability from ordinary income, as its own business performance management indicator.

Core operating profit is operating profit after deducting gains and losses arising from extraordinary items prescribed by the Group. The amount deducted as extraordinary items mainly represents impairment losses, business structure improvement expenses, litigation related expenses, the changes in fair values of contingent considerations arising from business combinations and etc.

### (1) Reportable segments

The Group is mainly engaged in manufacture, purchase and sales of pharmaceuticals for medical treatment and manages the performance of pharmaceutical business by market in Japan, North America, China and etc. Therefore, the Group has four reportable segments: Japan, North America, China, and Other Regions.

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

### (2) Revenues and operating results of the reportable segments

Revenues, profit or loss and other items by each of the Group's reportable segments are shown below.

The accounting policies of reportable segments are identical to those set forth in the Note 3 Significant Accounting Policies.

The Group sets core segment profit, which is an indicator showing the segment's profitability from ordinary income, as its own indicator of segment business performance management.

Core segment profit is calculated by deducting research and development expenses, gains and losses on sales of operations and etc. which are not allocated to operating segments because such expenses are managed on a global basis from core operating profit, and presented as segment profit.

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# 1. Year ended March 31, 2017

		Millions of yen					
		2017					
		Repo	ortable segments				
	Pharmaceutical business C			Other Business (Note)	Total		
	Japan	North America	China	Other Regions	Subtotal		
Revenues from external customers	¥ 140,849	¥ 194,652	¥ 17,625	¥ 11,543	¥ 364,669	¥ 43,688	¥ 408,357
Inter-segment revenues	50	_	_	—	50	75	125
Total	140,899	194,652	17,625	11,543	364,719	43,763	408,482
Segment profit (Core segment profit)	37,936	92,552	6,728	2,831	140,047	2,376	142,423
Other items							
Depreciation and amortization	4,404	3,690	327	440	8,861	99	8,960
Impairment losses	2,161	_	93	_	2,254	_	2,254

(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.

# 2. Year ended March 31, 2018

	Millions of yen						
				2018			
		Repo	rtable segments				
		Pharmaceutical business				Other Business (Note)	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenues from external customers	¥ 143,325	¥ 240,791	¥ 23,444	¥ 16,468	¥ 424,028	¥ 42,810	¥ 466,838
Inter-segment revenues	75	_	-	_	75	68	143
Total	143,400	240,791	23,444	16,468	424,103	42,878	466,981
Segment profit (Core segment profit)	40,271	109,527	10,715	5,127	165,640	2,650	168,290
Other items							
Depreciation and amortization	3,068	4,944	583	909	9,504	93	9,597
Impairment losses	2,147	_	_	_	2,147	_	2,147

(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.

# (3) Reconciliations between the total amounts of reportable segments and the amounts in the consolidated financial statements (reconciliation items)

The details of reconciliation are as follows:

	Millions of yen				
Revenue	Year ended March 31, 2017	Year ended March 31, 2018			
Total of reportable segments	¥ 364,719	¥ 424,103			
Revenue of Other Business	43,763	42,878			
Elimination of inter-segment revenue	(125)	(143)			
Revenue on the consolidated financial statements	¥ 408,357	¥ 466,838			

	Millions of yen		
Profit	Year ended March 31, 2017	Year ended March 31, 2018	
Total of reportable segments	¥ 140,047	¥ 165,640	
Segment profit of Other Business	2,376	2,650	
Elimination of inter-segment profit	26	27	
Research and development expenses (Note)	(81,373)	(86,881)	
Gains on business transfers	3,249	9,178	
Others	47	(10)	
Core operating profit	64,372	90,604	
Change in fair value of contingent consideration	(8,131)	6,371	
Impairment losses	(2,254)	(2,147)	
Litigation related expenses	_	(1,746)	
Other income	258	249	
Other expenses	(13,959)	(5,158)	
Operating profit in the consolidated financial statements	¥ 40,286	¥ 88,173	

(Note) The Group does not allocate research and development expenses to the operating segments because such expenses are managed on a global basis.

		Millions of yen						
	Total of reportable segments Other Business Adjustments				Amount in the consolidated financial statements			
Other items	Year ended March 31, 2017	Year ended March 31, 2018	Year ended March 31, 2017	Year ended March 31, 2018	Year ended March 31, 2017	Year ended March 31, 2018	Year ended March 31, 2017	Year ended March 31, 2018
Depreciation and amortization	¥ 8,861	¥ 9,504	¥ 99	¥ 93	¥ 3,753	¥ 3,290	¥ 12,713	¥ 12,887

### (4) Revenues

The details of revenues from external customers are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Sale of goods	¥ 404,880	¥ 462,117	
Revenue arising from intellectual property rights	2,555	3,548	
Other	922	1,173	
Total	¥ 408,357	¥ 466,838	

# (5) Information by product and service

The details of sales from external customer by product and service are as follows:

	Million	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018		
Pharmaceuticals	¥ 364,669	¥ 424,028		
Others	43,688	42,810		
Total	¥ 408,357	¥ 466,838		

### (6) Geographic information

The Group's geographic revenues are classified by country and region, based on the location of customers.

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Japan	¥ 186,333	¥ 188,806	
North America	194,481	239,615	
U.S.A.in North America	190,471	235,207	
Others	27,543	38,417	
Total	¥ 408,357	¥ 466,838	

The details of the breakdown of carrying amounts of the Group's non-current assets (except for financial assets, deferred tax assets and retirement benefit assets) by location are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Japan	¥ 77,667	¥ 71,705	¥ 74,221	
North America	143,870	288,537	272,882	
U.S.A. in North America	143,615	287,016	271,575	
Others	1,761	1,500	1,399	
Total	¥ 223,298	¥ 361,742	¥ 348,502	

### (7) Information of major customers

Revenue from major customer which individually accounts for greater than 10% of the total Group's revenue are as -follows:

		Millions of yen			
	Reportable segment	Year ended March 31, 2017	Year ended March 31, 2018		
McKesson Corporation	North America	¥ 70,003	¥ 82,506		
Cardinal Health Inc.	North America	49,594	64,301		
AmerisourceBergen Corporation	North America	45,784	59,783		

# 5. Selling, General and Administrative Expenses

The details of selling, general and administrative expenses are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Salaries and bonuses	¥ 60,981	¥ 63,321	
Retirement benefit expenses	5,204	4,740	
Advertising and promotion expenses	37,016	38,212	
Depreciation and amortization	5,821	6,538	
Impairment losses	2,152	2,100	
Change in fair value of contingent consideration (Note)	8,131	(6,371)	
Others	62,363	75,111	
Total	¥ 181,668	¥ 183,651	

(Note) Contingent considerations are future payments to the former shareholder when milestones specified at the time of acquisition are achieved. The details are presented in Note 26 Financial Instruments and Note 30 Business Combinations.

### 6. Other Income

The details of other operating income are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Gain on business transfers (Note)	¥ —	¥ 8,895	
Gain on sale of intangible assets	3,249	283	
Others	305	239	
Total	¥ 3,554	¥ 9,417	

(Note) Gain on business transfers is recorded due to the transfers of business related to three ciclesonide products (asthma and allergic rhinitis) in North America during the year ended March 31, 2018.

# 7. Other Expenses

The details of other operating expenses are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Donation	¥ 741	¥ 788	
Business structure improvement expenses (Note)	10,872	3,723	
Loss on discontinued research and development	2,006	_	
Others	340	647	
Total	¥ 13,959	¥ 5,158	

(Note) Business structure improvement expenses are expenses for reformation of organizations and operations, including special retirement payments which were incurred as a result of the Company's voluntary early retirement program, etc. for the years ended March 31, 2017 and 2018.

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# 8. Finance Income and Finance Expenses

## (1) Finance Income

The details of finance income are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Interest income			
Financial assets at amortized cost	¥ 747	¥ 1,184	
Dividend income			
Financial asset at fair value through other comprehensive income	1,198	1,246	
Exchange gain (net)	1,237	_	
Total	¥ 3,182	¥ 2,430	

# (2) Finance costs

The details of finance costs are as follows:

	Million	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018		
Interest expenses				
Financial liabilities at amortized cost	¥ 662	¥ 394		
Exchange loss (net)	—	5,207		
Other	25	136		
Total	¥ 687	¥ 5,737		

9. Deferred Income Taxes and Income Tax Expenses

## (1) Deferred Income Taxes

 Deferred tax assets and liabilities on the consolidated statement of financial position. The details of deferred tax assets and liabilities on the consolidated statement of financial position are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Deferred tax assets	¥ 73,580	¥ 57,089	¥ 41,608	
Deferred tax liabilities	4,061	72	95	
Net deferred tax assets	¥ 69,519	¥ 57,017	¥ 41,513	

### 2. Details and movement in deferred tax assets and liabilities

The details of originations of deferred tax assets and liabilities by major reasons and movements are as follows:

			Millions of yen		
	Transition Date (As of April 1, 2016)	Recognized in profit or loss	Recognized in other comprehensive income	Others (Note)	As of March 31, 2017
Outsourced research expenses	¥ 7,642	¥ 925	¥ —	¥ 20	¥ 8,587
Inventories	38,226	669	_	(195)	38,700
Property, plant and equipment	2,129	(161)	_	(6)	1,962
Intangible assets	(9,897)	(2,297)	_	(16,616)	(28,810)
Other financial assets	(11,930)	(16)	1,292	1,702	(8,952)
Accrued expenses and provisions	24,763	(5,289)	—	(218)	19,256
Retirement benefits	7,536	(212)	(1,443)	6	5,887
Tax loss carryforwards	7,976	5,708	_	171	13,855
Tax credits	_	2,488	_	87	2,575
Undistributed profits of foreign subsidiaries	(308)	(172)	_	_	(480)
Others	3,382	502	_	553	4,437
Total	¥ 69,519	¥ 2,145	¥ (151)	¥ (14,496)	¥ 57,017

(Note) 1. Others include exchange differences on translation of foreign operations.

2. Others in Intangible assets include deferred tax liabilities of ¥ (15,061) million arising from business combinations. The details are presented in Note 30 Business Combinations.

3. Others in Other financial assets include decrease in deferred tax liabilities amounting to ¥1,769 million which is reclassified to Retained earnings due to the disposal during the year ended March 31, 2017.

			Millions of yen		
	As of April 1, 2017	Recognized in profit or loss	Recognized in other comprehensive income	Others (Note)	As of March 31, 2018
Outsourced research expenses	¥ 8,587	¥ 2,506	¥ —	¥ 6	¥ 11,099
Inventories	38,700	(16,175)	_	(140)	22,385
Property, plant and equipment	1,962	5	—	(38)	1,929
Intangible assets	(28,810)	8,366	_	1,251	(19,193)
Other financial assets	(8,952)	(4)	(3,658)	(40)	(12,654)
Accrued expenses and provisions	19,256	(5,088)	—	(617)	13,551
Retirement benefits	5,887	26	1,251	(6)	7,158
Tax loss carryforwards	13,855	(2,511)	—	(629)	10,715
Tax credits	2,575	561	_	(159)	2,977
Undistributed earnings of foreign subsidiaries	(480)	(146)	_	—	(626)
Others	4,437	2,469	_	(2,734)	4,172
Total	¥ 57,017	¥ (9,991)	¥ (2,407)	¥ (3,106)	¥ 41,513

(Note) Others include exchange differences on translation of foreign operations.

## 3. Unrecognized deferred tax assets

Tax loss carryforwards, tax credit carryforwards and deductible temporary differences for which deferred tax assets are not recognized are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Tax loss carryforwards	¥ 441	¥ 893	¥ 1,478	
Tax credit carryforwards	2,140	3,294	5,089	
Deductible temporary differences	127	947	91	

### 4. Unrecognized deferred tax assets and expiry schedule

(i) Expiry schedule of the tax loss carryforwards for which deferred tax assets are not recognized The expiry schedule of tax losses carryforwards for which deferred tax assets are not recognized are as follows:

	Millions of yen				
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018		
Not later than 1 year	¥ —	¥ —	¥ —		
Later than 1 year and not later than 2 years	_	_	_		
Later than 2 years and not later than 3 years	_	—	-		
Later than 3 years and not later than 4 years	_	_	_		
Later than 4 years	441	893	1,478		
Total	¥ 441	¥ 893	¥ 1,478		

(ii) Expiry schedule of the tax credit carryforward for which deferred tax assets are not recognized The expiry schedule of tax credit carryforwards for which deferred tax assets are not recognized are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Not later than 1 year	¥ 61	¥ 149	¥ 274	
Later than 1 year and not later than 2 years	237	263	318	
Later than 2 years and not later than 3 years	264	306	271	
Later than 3 years and not later than 4 years	307	260	144	
Later than 4 years	1,271	2,316	4,082	
Total	¥ 2,140	¥ 3,294	¥ 5,089	

5. Recoverability of deferred tax assets

Deferred tax assets as of March 31, 2018 was ¥78,835 million. Recoverability of deferred tax assets depends upon the future taxable income and future taxable temporary differences, and deferred tax assets are recognized to the extent that future taxable income and future taxable temporary differences will be available.

### 6. Unrecognized deferred tax liabilities

There are no taxable temporary differences in respect of investments in subsidiaries, etc. for which unrecognized deferred tax liabilities were not recognized as of the Transition Date, March 31, 2017 and 2018.

### (2) Income Tax Expenses

1. Income tax expenses

The details of income tax expenses are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Current tax expenses	¥ 13,610	¥ 21,427	
Deferred tax expense			
Origination and reversal of temporary Differences	(2,145)	(3,586)	
Change in income tax rate (Note)	—	13,577	
Subtotal	(2,145)	9,991	
Total	¥ 11,465	¥ 31,418	

(Note) "The Tax Cuts and Jobs Act of 2017" was enacted on December 22, 2017. The effective statutory tax rate used for calculating the deferred tax assets and deferred tax liabilities as of March 31, 2018 of the consolidated subsidiaries located in the United States was changed from 37.0% as of March 31, 2017 to 22.7%. As a result, deferred income tax expenses for the year ended March 31, 2018 increased by ¥13,577 million.

## 2. Reconciliation of income tax rate

The reconciliation between the normal statutory tax rate and the effective tax rate is as follows: The Group is mainly subject to corporate tax, inhabitant tax and enterprise tax for the years ended March 31, 2017 and 2018. The normal statutory tax rate based on these taxes is 30.8%. However, overseas subsidiaries are subject to income taxes in their respective countries of domicile.

	Year ended March 31, 2017	Year ended March 31, 2018
Normal statutory tax rate	30.8%	30.8%
Permanent non-deductible expenses such as entertainment expenses	3.8%	2.4%
Permanent non-taxable income such as dividend received	(0.4%)	(0.1%)
Tax credit for research and development expenses	(12.1%)	(6.6%)
Changes in unrecognized deferred tax assets	3.2%	(0.9%)
Difference of subsidiaries' applicable income tax rates	(5.0%)	(2.5%)
Changes in tax effect of undistributed earnings of subsidiaries	0.4%	0.2%
Effect of change in fair value of contingent consideration	5.8%	(2.1%)
Effect of change in tax rate	_	16.0%
Others	0.3%	(0.2%)
Effective tax rate	26.8%	37.0%

### 10. Earnings per Share

The basis for calculation and the amount of basic earnings per share are as follows:

	Year ended March 31, 2017	Year ended March 31, 2018
The basis for calculation of basic earnings per share Net profit attributable to owners of the parent (Millions of yen)	¥ 31,316	¥ 53,448
Amounts not attributable to ordinary shareholders of the parent (Millions of yen)	_	_
Net profit used to calculate basic earnings per share (Millions of yer	) 31,316	53,448
Weighted average number of ordinary shares (Thousands of shares	) 397,300	397,299
Earnings per share Basic earnings per share (Yen)	78.82	134.53

(Note) Dilutive earnings per share is not disclosed as there are no shares with dilutive effect.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

11. Other	The movement of other comprehensive income is as follows:			
Comprehensive		Millions of yen		
Income		Year ended March 31, 2017	Year ended March 31, 2018	
	Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income			
	Amounts arising during the year	¥ (4,174)	¥ 12,186	
	Tax effect	1,288	(3,659)	
	Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income	(2,886)	8,527	
	Remeasurements of defined benefit liability (asset)			
	Amounts arising during the year	4,720	(4,075)	
	Tax effect	(1,443)	1,251	
	Remeasurements of defined benefit liability (asset)	3,277	(2,824)	
	Exchange differences on translation of foreign operations			
	Amounts arising during the year	(1,871)	(10,748)	
	Exchange differences on translation of foreign operations	(1,871)	(10,748)	
	Cash flow hedges			
	Amounts arising during the year	(11)	(2)	
	Tax effect	4	1	
	Cash flow hedges	(7)	(1)	
	Total	¥ (1,487)	¥ (5,046)	

# 12. Property, Plant and Equipment

# (1) Movements in acquisition cost, accumulated depreciation and accumulated impairment losses and carrying amount

Movements in acquisition cost, accumulated depreciation and accumulated impairment losses and carrying amount of property, plant and equipment are as follows: 1. Acquisition cost

Millions of yen

Buildings Machinery Tools, Construction and and furniture and structures vehicles fixtures Land in progress Total ¥94,771 Balance as of April 1, 2016 ¥83,966 ¥ 33,497 ¥ 6,333 ¥ 1,550 ¥ 220,117 Additions 239 1,486 318 3 4.276 6,322 Transfer from construction in progress 673 1.025 976 (2.674)Sales and disposals (365) (2, 529)(2, 433)(6) (5,333) \_\_\_\_ Foreign currency translation differences (121)(71)(69)(2) 4 (259) Other 20 64 102 18 Balance as of March 31, 2017 95,217 83,895 32,353 6,328 3,156 220,949 Additions 628 1,222 552 6,068 8,470 \_\_\_\_ Transfer from construction in progress 2,013 2,864 1,578 (6, 455)(8,517)Sales and disposals (519)(3, 473)(4, 525)Foreign currency translation differences (365)(211)(197)(22)(45)(840) Other (296)295 (16)(17)¥ 30,056 ¥96,974 ¥ 6,306 ¥ 2,708 ¥ 220,045 Balance as of March 31, 2018 ¥ 84,001

## 2. Accumulated depreciation and accumulated impairment losses

	Millions of yen					
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Total
Balance as of April 1, 2016	¥ (55,073)	¥ (73,690)	¥ (27,573)	¥ (64)	¥ (52)	¥ (156,452)
Depreciation	(2,611)	(2,773)	(2,638)	—	—	(8,022)
Impairment losses	(8)	(92)	(2)	—	_	(102)
Sales and disposals	351	1,901	2,404	_	—	4,656
Foreign currency translation						
differences	32	53	49	—	—	134
Other	(7)	(11)	(33)	—	9	(42)
Balance as of March 31, 2017	(57,316)	(74,612)	(27,793)	(64)	(43)	(159,828)
Depreciation	(2,616)	(2,762)	(2,265)	—	—	(7,643)
Impairment losses	(955)	(1)	(32)	(1,159)	_	(2,147)
Sales and disposals	461	2,769	4,173	_	_	7,403
Foreign currency translation differences	103	93	161	_	_	357
Other	_	185	(184)	_	16	17
Balance as of March 31, 2018	¥ (60,323)	¥ (74,328)	¥ (25,940)	¥ (1,223)	¥ (27)	¥ (161,841)

# 3. Carrying amount

		Millions of yen				
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Total
Balance as of April 1, 2016	¥ 39,698	¥ 10,276	¥ 5,924	¥ 6,269	¥ 1,498	¥ 63,665
Balance as of March 31, 2017	37,901	9,283	4,560	6,264	3,113	61,121
Balance as of March 31, 2018	36,651	9,673	4,116	5,083	2,681	58,204

(Note) 1. There is no capitalized borrowing cost for property, plant and equipment for the years ended March 31, 2018 and 2017.

2. Details of commitment in respect of acquisitions of property, plant and equipment are presented in Note 27 Commitment.

3. Property, plant and equipment under construction is presented as Construction in progress.

### (2) Lease assets classified as finance leases

The carrying amounts of lease assets classified as finance leases, included in property, plant and equipment are as follows:

		Millions of yen			
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Total
Balance as of April 1, 2016	¥ —	¥ 2,480	¥ —	¥ —	¥ 2,480
Balance as of March 31, 2017	_	2,519	_	_	2,519
Balance as of March 31, 2018	—	2,225	—	—	2,225

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

### (3) Impairment losses

Impairment losses recognized for the year ended March 31, 2017 and 2018 were ¥102 million and ¥2,147 million, respectively. Impairment loss was recognized in Cost of sales, Selling, general and administrative expenses, and research and development expenses in the consolidated statement of profit or loss.

Impairment losses recognized for the year ended March 31, 2017 amounting to ¥102 million mainly resulted from the idle property, plant and equipment of Japan segment in pharmaceutical business after evaluating the recoverability. The carrying amounts of such assets were reduced to the extent of the recoverable amount. The recoverable value was measured at fair value less disposal costs. As it is not expected to have future cash flows due to the low possibility of convert to a different use and sale of such assets, the recoverable amount was estimated as zero.

Impairment losses amounting to ¥2,147 million were recognized in the current fiscal year, which was mainly led by the assessment result of recoverable amounts of certain closed welfare benefit facilities of Japan segment in pharmaceutical business. The recoverable amounts were measured at fair value less cost of disposal. The fair value was measured by the real estate appraisal value which was assessed using the market approach by a third party. It is classified as level 3 of the fair value hierarchy.

# 13. Goodwill

# (1) Movements in acquisition cost and accumulated impairment losses and carrying amount of goodwill

Movements in acquisition cost and accumulated impairment losses and carrying amount of goodwill are as follows:

1. Acquisition cost

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Beginning balance	¥ 76,950	¥ 100,194	
Acquisitions through business combinations	23,752	-	
Foreign currency translation differences	(508)	(5,097)	
Ending balance	¥ 100,194	¥ 95,097	

### 2. Accumulated impairment losses

	Millions	s of yen
	Year ended March 31, 2017	Year ended March 31, 2018
Beginning balance	¥ —	¥ —
Impairment losses	—	—
Foreign currency translation differences	—	—
Ending balance	¥ —	¥ —

Milliono of von

### 3. Carrying amount

	IVIIIIONS OF yen
Balance as of April 1, 2016	¥ 76,950
Balance as of March 31, 2017	100,194
Balance as of March 31, 2018	¥ 95,097

### (2) Significant goodwill

Significant goodwill recognized in the consolidated statement of financial position arose from the acquisition of Sepracor Inc. (currently known as Sunovion Pharmaceuticals Inc.) and Tolero Pharmaceuticals, Inc. by the Group. The carrying amounts of significant goodwill are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Sunovion Pharmaceuticals Inc.	¥ 70,911	¥ 70,640	¥ 66,900	
Tolero Pharmaceuticals, Inc.	¥ —	¥ 22,185	¥ 21,010	

### (3) Impairment test of goodwill

In principle, the geographical business segments managed for internal reporting purposes are identified as a cash generating unit by the Group. In the North America segment of the pharmaceutical business, 'excluding oncology area' and 'oncology area' are identified as a CGU respectively. The carrying amounts of Goodwill allocated to the North America segment of the pharmaceutical business recognized as of March 31, 2017, 2018 and the Transition Date, are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
North America (excluding oncology area)	¥ 74,787	¥ 75,852	¥ 71,836	
North America (oncology area)	2,163	24,342	23,261	
Total	¥ 76,950	¥ 100,194	¥ 95,097	

Impairment losses are recognized when any indication that recoverable amount is less than carrying amount exits, and the carrying amount of goodwill is reduced to the extent of the recoverable amount. The recoverable amount is determined based on value in use.

As the recoverable value of CGU is greater than the carrying amount as a result of the impairment tests as of the Transition Date, March 31, 2017 and 2018, impairment losses are not recognized. Value in use is determined by the present value of estimated future cash flows based on the past experience and external information.

The discount rate used in the impairment test for goodwill is the weighted average cost of capital, etc. set by each region. The discount rate used in the impairment test of goodwill were 9.0% - 14.0%, 8.5% - 15.0% and 9.0% - 17.0% as of the Transition Date, March 31, 2017 and 2018, respectively.

Value in use is sufficiently greater than carrying amount of a CGU, even if key assumptions used in measuring value in use change within a reasonable range, the Group considers the possibility that a significant impairment loss occurs low.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

# 14. Intangible Assets (1) Movements in acquisition cost, accumulated amortization and accumulated impairment losses and carrying amount

Movements in acquisition cost, accumulated amortization and accumulated impairment losses and carrying amount of intangible assets are as follows:

1. Acquisition cost

	Millions of yen			
	Intangible assets related to products	Software	Other	Total
Balance as of April 1, 2016	¥ 90,469	¥ 13,249	¥ 165	¥ 103,883
Individual acquisitions	3,885	1,511	55	5,451
Acquisitions through business combinations	115,194	_	—	115,194
Sales and disposals	(396)	(1,625)	(1)	(2,022)
Foreign currency translation differences	4,538	(42)	(2)	4,494
Balance as of March 31, 2017	213,690	13,093	217	227,000
Individual acquisition	5,800	1,706	21	7,527
Sales and disposals	(1,146)	(1,442)	—	(2,588)
Foreign currency translation differences	(10,434)	(307)	_	(10,741)
Balance as of March 31, 2018	¥ 207,910	¥ 13,050	¥ 238	¥ 221,198

2. Accumulated amortization and accumulated impairment losses

	Millions of yen				
	Intangible assets related to products	Software	Other	Total	
Balance as of April 1, 2016	¥ (17,176)	¥ (7,753)	¥ (133)	¥ (25,062)	
Amortization	(2,821)	(1,860)	(10)	(4,691)	
Impairment losses	(2,152)	_	—	(2,152)	
Sales and disposals	386	1,598	1	1,985	
Foreign currency translation differences	14	20	_	34	
Balance as of March 31, 2017	(21,749)	(7,995)	(142)	(29,886)	
Amortization	(3,434)	(1,789)	(21)	(5,244)	
Impairment losses	—	_	—	—	
Sales and disposals	1,146	1,347	—	2,493	
Foreign currency translation differences	877	243		1,120	
Balance as of March 31, 2018	¥ (23,160)	¥ (8,194)	¥ (163)	¥ (31,517)	

### 3. Carrying amount

		Millions of yen			
	Intangible assets related to products	Software	Other	Total	
Balance as of April 1, 2016	¥ 73,293	¥ 5,496	¥ 32	¥ 78,821	
Balance as of March 31, 2017	191,941	5,098	75	197,114	
Balance as of March 31, 2018	184,750	4,856	75	189,681	

(Note) 1. The amortization of intangible assets is recognized in Cost of sales, Selling, general and administrative expenses, and Research and development expenses of the consolidated statement of profit or loss.

2. There are no internally generated intangible assets.

3. There are no interest expenses capitalized as intangible assets.

4. Intangible assets related to products include expenditures incurred in the research and development phase, of which the approval for sales by regulatory authorities has not been obtained. As they are not yet available for use, it is determined that the period for which future economic benefits will inflow to the Group is unforeseeable. Therefore, such assets are classified as intangible assets with indefinite useful lives. The carrying amounts of such intangible assets as of the Transition Date, March 31, 2017 and 2018 were ¥58,268, ¥177,991 million, and ¥153,930 million, respectively.

#### (2) Significant intangible assets

Significant intangible assets recognized in the consolidated statement of financial position are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Cynapsus Therapeutics Inc.				
APL-130277 (Apomorphine hydrochloride)	¥ —	¥ 75,044	¥ 71,071	
Tolero Pharmaceuticals, Inc.				
DSP-2033 (alvocidib)	—	26,926	25,500	
TP-0903	_	17,053	16,150	
Boston Biomedical, Inc.				
BBI608 (Napabucasin)	28,605	28,496	26,988	

The above table mainly represent the intangible assets related to products that are not yet available for use arising from the acquisition of Cynapsus Therapeutics Inc. (currently known as Sunovion CNS Development Canada ULC), Tolero Pharmaceuticals, Inc. and Boston Biomedical, Inc., by the Group. The activities of research and development are described in page 19.

The intangible assets related to products that are not yet available for use are in-process research and development assets. Due to the inherent uncertainties in the research and development processes, there exist a risk of incurring impairment losses due to failure in product commercialization. Intangible assets related to products includes expenditures incurred in the research and development phase, of which the approval for sales by regulatory authorities has not been obtained. As they are not yet available for use, it is determined that the period for which future economic benefits will inflow to the Group is unforeseeable. Therefore, such assets are classified as intangible asset with indefinite useful lives.

### (3) Impairment losses

Intangible assets are grouped into CGU that is the smallest group of assets independently generating cash flows. As for the intangible assets related to products, any individual assets of each finished goods and developed products are classified as a CGU.

Impairment losses of intangible assets are recognized when any indication that recoverable amount is less than carrying amount exits, and the carrying amount of intangible assets is reduced to the extent of the recoverable amount. The recoverable amount is determined based on value in use. Value in use is determined by the present value of estimated future cash flows based on the past experience and external information.

The discount rate used in the impairment test for intangible assets is the weighted average cost of capital, etc. set by each cash generating units. The discount rate used in the impairment test of intangible assets were 6.3% - 15.0%, 6.3% - 15.0% and 6.0% - 18.5% as of the Transition Date, March 31, 2017 and 2018, respectively

As a result of impairment test, impairment losses amounting to ¥2,152 million was recognized for the year ended March 31, 2017, which are recognized in selling, general and administrative expenses in the consolidated statement of profit or loss.

There are no impairment losses recognized for the year ended March 31, 2018.

Impairment losses for the year ended March 31, 2017 are mainly attributable to the product marketing rights in Japan. As the profitability is expected to be declining and the discounted future cash flows were lower than the carrying amount of the assets, impairment losses were recognized. In addition, the recoverable amount is measured based on value in use, using the pre-tax discount rate of 6.3%. The impairment loss was recognized in the Japan segment of the pharmaceutical business.

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# 15. Lease

# (1) Finance lease

The details of finance lease obligations are as follows:

		Millions of yen				
	Total mi	nimum lease pa	yments	Present value of	f total minimum	lease payments
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018
Within 1 year	¥ 728	¥ 749	¥ 726	¥ 702	¥ 722	¥ 702
Over 1 year, Within 5 years	1,479	1,646	1,467	1,449	1,617	1,445
Over 5 years	280	132	5	277	131	5
Total	¥ 2,487	¥ 2,527	¥ 2,198	¥ 2,428	¥ 2,470	¥ 2,152
Less: finance expenses	59	57	46			
Present value of total minimum						
lease payments	2,428	2,470	2,152			
Finance lease obligations (non-curren	t) 1,726	1,748	1,450			
Finance lease obligations (current)	702	722	702			

The assets recorded related to lease transactions classified as finance leases of the Group mainly comprise of machinery equipment and vehicles. Certain lease contracts contain renewal option after termination of lease terms. There are no variable lease payments, escalation clauses, and any significant restrictions provided in the lease contracts.

# (2) Operating lease

The total future minimum lease payments of non-cancellable operating lease are as follows:

	Millions of yen		
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018
Within 1 year	¥ 1,010	¥ 949	¥ 1,001
After 1 year, Within 5 years	2,590	2,365	2,586
After 5 years	4,063	3,503	3,022
Total	¥ 7,663	¥ 6,817	¥ 6,609

The Group uses many offices, warehouses, plants and equipment under operating lease contacts. Certain lease contracts contain renewal options after termination of lease terms. There are no variable lease payments, escalation clauses, and any significant restrictions provided in the lease contracts.

The total minimum lease payments under operating lease contracts recognized as expenses are as follows:

	Millions	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018		
Total minimum lease payments	¥ 8,621	¥ 8,200		

# 16. Other Financial Assets

## (1) Details of other financial assets

The details of other financial assets are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Financial assets at amortized cost				
Loan receivables	¥ 48,481	¥ 16,782	¥ 21,300	
Others	2,516	2,757	2,716	
Financial assets at fair value through profit or loss				
Derivative assets	201	—	79	
Financial assets at fair value through other comprehensive income				
Equity securities, etc.	63,411	50,636	68,964	
Total	¥ 114,609	¥ 70,175	¥ 93,059	
Other financial assets(non-current)	65,232	52,681	70,993	
Other financial assets(current)	49,377	17,494	22,066	
Total	¥ 114,609	¥ 70,175	¥ 93,059	

### (2) Financial assets measured at fair value through other comprehensive income

All equity securities, etc. held by the Group are designated as financial assets measured at fair value through other comprehensive income.

1. Details of fair value

The fair values of major investees are as follows:

	Millions of yen		
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018
SanBio Company Limited	¥ 4,231	¥ 3,323	¥ 10,027
Medipal Holdings Corporation	5,753	5,643	7,051
Ono Pharmaceutical Co., Ltd.	7,934	3,837	5,485
JCR Pharmaceuticals Co., Ltd.	2,136	2,099	5,160
BioElectron Technology Corporation	3,966	3,344	4,422
Suzuken Co., Ltd.	3,535	3,374	4,062
Alfresa Holdings Corporation	3,543	3,166	3,886
Healios K.K.	2,330	2,699	2,985
ANTEROGEN CO., LTD.	848	479	2,462
Mochida Pharmaceutical Co., Ltd.	2,264	2,237	2,026
Others	26,871	20,435	21,398
Total	¥ 63,411	¥ 50,636	¥ 68,964

### 2. Others

The dividend income derived from the financial assets measured at fair value through other comprehensive income held by the Group are ¥1,198 million and ¥1,246 million for the years ended March 31, 2017 and 2018, respectively. The details of "Other financial assets" under financial assets measured at fair value through other comprehensive income which were disposed in the years ended March 31, 2017 and 2018 are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Fair value at the time of disposal	¥ 8,953	¥ 31	
Accumulated gains (losses)	5,754	21	
Dividend income	125	107	

These were disposed as a result of the revision of business strategies, etc. The accumulated gains (net of tax) reclassified from other components of equity to retained earnings at the disposal are ¥3,981 million and ¥15 million for the years ended March 31, 2017 and 2018, respectively.

The accumulated losses (net of tax) of those financial assets measured at fair value through other comprehensive income of which the significant decline in fair value compared with acquisition cost is other-than-temporary, amounting to ¥ (12) million and ¥ (4,426) million for the years ended March 31, 2017 and 2018, respectively, are reclassified from Other components of equity to Retained earnings in the respective period.

### 17. Inventories

The details of Inventories are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Merchandise and finished goods	¥ 33,969	¥ 47,222	¥ 46,674	
Work-in-process	3,205	3,359	3,345	
Raw materials and supplies	7,337	9,705	10,150	
Total	¥ 44,511	¥ 60,286	¥ 60,169	

Certain inventories included in raw materials and supplies are expected to be consumed over more than 12 months from each fiscal year-end. However, these are included in Inventories as they are held within the normal operating cycle.

The amount of write-downs of inventories recognized as cost of sales in profit or loss are ¥318 million and ¥863 million for the years ended March 31, 2017 and 2018, respectively.

### 18. Trade and Other Receivables

### (1) Details of trade and other receivables

The details of trade and other receivables are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Financial assets measured at amortized cost				
Accounts receivable and notes receivable	¥ 107,028	¥ 110,704	¥ 110,583	
Other receivables	1,702	2,032	2,400	
Allowance for credit losses	(74)	(4)	(1)	
Total	¥ 108,656	¥ 112,732	¥ 112,982	
Trade and other receivables (non-current)	_	—	_	
Trade and other receivables (current)	108,656	112,732	112,982	
Total	¥ 108,656	¥ 112,732	¥ 112,982	

### (2) Credit risk and market risk, and loss allowances

The exposures to credit risk and foreign currency risk, and the loss allowances for trade and other receivables are presented on Note 26 Financial Instruments.

# 19. Cash and Cash Equivalents

The details of cash and cash equivalents are as follows:

	Millions of yen			
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	
Financial assets measured at amortized cost				
Cash and deposits	¥ 54,533	¥ 71,408	¥ 113,428	
Short-term investments (cash equivalents)	81,039	34,195	34,347	
Total	¥ 135,572	¥ 105,603	¥ 147,775	

The details of "Acquisitions of control over subsidiaries" in the consolidated statement of cash flows are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Considerations paid in the form of cash and cash equivalents	¥ (85,401)	¥ —	
Less: cash and cash equivalents owned by subsidiaries acquired	1,053	_	
Net cash outflows arising from acquisition of control over subsidiaries	¥ (84,348)	¥ —	

(Note) The fair value of assets acquired and liabilities assumed of the acquisition of subsidiaries are presented on Note 30 Business Combination.

# 20. Bonds and Borrowings

# (1) Details of Bonds and borrowings

The details of Bonds and borrowings are as follows:

	Millions of yen					
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	Average interest rate	Repayment due date	
Bonds (other than current portion)	¥ 20,000	¥ 10,000	¥ —	_	_	
Current portion of bonds	10,000	10,000	10,000	0.82%	_	
Long-term borrowings (other than current portion)	8,000	_	30,940	0.18%	June 2019~ March 2023	
Current portion of long-term borrowings	12,000	8,000	2,960	0.20%	_	
Short-term borrowings	1,010	40,000	3,500	0.13%	_	
Total	¥ 51,010	¥ 68,000	¥ 47,400	—	_	
Bonds and borrowings (non-current)	28,000	10,000	30,940	—		
Bonds and borrowings (current)	23,010	58,000	16,460	—		
Total	¥ 51,010	¥ 68,000	¥ 47,400	_	_	

(Note) The average interest rate is the weighted average interest rate calculated based on the balance of the bonds and borrowings as of March 31, 2018.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

# (2) Bond issuance conditions

The bond issuance conditions are summarized as follows:

			Millions of yen					
Issuer	Bond name	Issuance date	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018	Interest rate	Collateral	Maturity date
Sumitomo Dainippon Pharma Co., Ltd.	3rd unsecured bonds	March 8, 2011	¥ 10,000	¥ 10,000	¥ —	1.11%	No	March 8, 2018
Sumitomo Dainippon Pharma Co., Ltd.	4th unsecured bonds	September 8, 2011	10,000	_	_	0.54%	No	September 8, 2016
Sumitomo Dainippon Pharma Co., Ltd.	5th unsecured bonds	September 8, 2011	10,000	10,000	10,000	0.82%	No	September 7, 2018
Total	_	_	¥ 30,000	¥ 20,000	¥ 10,000	_	_	_

## (3) Changes in liabilities associated with cash flows provided by financing activities

The changes in liabilities associated with cash flows provided by financing activities are as follows:

•			•	•		
	Millions of yen					
	Short-term borrowings	Long-term borrowings	Bonds	Lease obligations	Total	
Balance as of April 1, 2016	¥ 1,010	¥ 20,004	¥ 30,015	¥ 2,428	¥ 53,457	
Cash flows provided by financing activities	39,036	(12,000)	(10,000)	(1,117)	15,919	
Other changes						
Additions due to acquisition of leased assets	_	_	_	1,156	1,156	
Interest expenses	22	102	216	30	370	
Payment of interests	(22)	(106)	(219)	(30)	(377)	
Effect of foreign currency translation differences	(46)	_	_	2	(44)	
Others	_	_	_	1	1	
Balance as of March 31, 2017	40,000	8,000	20,012	2,470	70,482	
Cash flows provided by financing activities	(36,500)	25,900	(10,000)	(1,064)	(21,664)	
Other changes						
Additions due to acquisition of leased assets	_	_	_	829	829	
Interest expenses	38	72	186	30	326	
Payment of interests	(38)	(72)	(192)	(30)	(332)	
Effect of foreign currency translation differences	_	_	_	(83)	(83)	
Others	_	_	_			
Balance as of March 31, 2018	¥ 3,500	¥ 33,900	¥ 10,006	¥ 2,152	¥ 49,558	

# 21. Trade and Other

The details of trade and other payables are as follows:

**Payables** 

	Millions of yen				
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018		
Financial liabilities measured at amortized cost					
Accounts payable and notes payables	¥ 12,155	¥ 14,514	¥ 17,512		
Other payables	31,529	32,880	41,196		
Total	¥ 43,684	¥ 47,394	¥ 58,708		
Trade and other payables (non-current)	156	_	_		
Trade and other payables (current)	43,528	47,394	58,708		
Total	¥ 43,684	¥ 47,394	¥ 58,708		

# 22. Other Financial Liabilities

The details of other financial liabilities are as follows:

#### Millions of yen Transition Date As of As of (As of April 1, 2016) March 31, 2017 March 31, 2018 Financial liabilities at amortized cost Deposit received ¥ 6,409 ¥ 6,829 ¥ 4,146 Others 2,049 1,944 1,758 Financial liabilities at fair value through profit or loss 65,616 103.516 86.616 Contingent considerations Others 20 31 33 Lease obligations 2,428 2.470 2,152 ¥76,522 Total ¥ 114,790 ¥ 94,705 Other financial liabilities (non-current) 69,874 100,873 88,427 Other financial liabilities (current) 6,648 13,917 6,278 ¥ 94,705 Total ¥76,522 ¥ 114,790

# 23. Provisions

### (1) Movements of provisions

The movement of provisions is as follows: For the year ended March 31, 2018

	Millions of yen				
	Reserve for sales returns	Reserve for sales rebates	Total		
Balance at the beginning of the year	¥ 11,291	¥ 65,614	¥ 76,905		
Increase	5,130	74,955	80,085		
Decrease (utilization)	(3,172)	(64,845)	(68,017)		
Decrease (reversal)	_	—			
Foreign currency translation differences	(679)	(3,861)	(4,540)		
Balance at the end of the year	12,570	71,863	84,433		
Provision (non-current)	_	_	_		
Provision (current)	12,570	71,863	84,433		
Total	¥ 12,570	¥ 71,863	¥ 84,433		

## (2) Details of Provisions

The calculation of provisions is based on the best estimates of the outflow of future economic benefits as of reporting date. Significant adjustments to provisions are possible to be made in the consolidated financial statements for the fiscal years subsequent to the reporting date, in case the result that is different from the assumptions used for estimation occurs.

1. Reserve for sales returns

Reserve for sales returns is provided based on the estimated amount of sales return of products and goods. The future outflow of economic benefits is expected to be incurred within the normal operating cycle from the end of each reporting period.

2. Reserves for sales rebates

Reserve for sales rebates is provided based on the estimated amount to be paid for sales rebates related to public programs, wholesales and other contacts. The future outflow of economic benefits is expected to be incurred within the normal operating cycle from the end of each reporting period.

# 24. Employee Benefits

### (1) Summary of post-retirement benefit plans

The Company and certain consolidated subsidiaries adopt funded or unfunded defined benefit plans and defined contribution plans to pay for the employee post-retirement benefits.

Under the defined benefit corporate pension plans which are funded plan, lump-sum payments or pensions are mainly paid based on job position and length of service period. Certain defined benefit corporate pension plans are established by retirement benefit trusts.

Under the lump-sum payment retirement plans as post-retirement benefit, payments are paid based on job grade and length of service period.

## (2) Defined benefit plan

1. Details of defined benefit liabilities and assets

Net defined benefit liabilities and assets recognized in the consolidated statement of financial position are as follows:

	Millions of yen				
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018		
Present value of defined benefit obligations	¥ 100,232	¥ 95,378	¥ 101,380		
Fair value of the plan assets (including retirement benefit trusts)	78,323	79,004	80,680		
Net defined benefit (assets) liabilities	21,909	16,374	20,700		
Retirement benefit liabilities	21,909	16,374	20,700		
Retirement benefit assets	_	_	_		

### 2. Defined benefit obligations

Changes in the present value of defined benefit obligations are as follows:

	Millions of yen			
	Year ended March 31, 2017	Year ended March 31, 2018		
Balance at beginning of the year	¥ 100,232	¥ 95,378		
Current service cost	3,670	3,352		
Interest expense	610	725		
Remeasurement of net defined benefit liability (asset)				
Changes in demographic assumptions	451	4,344		
Changes in financial assumptions	(1,812)	1,406		
Experience adjustments	(1,421)	102		
Past service cost	377	_		
Benefits paid	(6,757)	(3,929)		
Foreign currency translation differences	14	(25)		
Others	14	27		
Balance at end of the year	¥ 95,378	¥ 101,380		

(Note) The weighted average number of payment years of defined benefit obligations are 15.2 years and 16.3 years as of March 31, 2017 and 2018, respectively.

### 3. Plan assets

Changes in the fair value of plan assets are as follows:

	Millions of yen		
	Year ended March 31, 2017	Year ended March 31, 2018	
Balance at beginning of the year	¥ 78,323	¥ 79,004	
Interest income	579	723	
Benefits paid	(4,097)	(2,889)	
Contributions by the employer	2,248	2,044	
Remeasurement of defined benefit plans			
Return on plan assets	1,938	1,777	
Others	13	21	
Balance at end of the year	¥ 79,004	¥ 80,680	

(Note) The Group is expected to pay contributions amounting to ¥4,813 million in the year ended March 31, 2019.

### 4. Components of plan assets

The details of plan assets by category are as follows:

					Millions of yen				
	Transitio	n Date (As of April	1, 2016)	A	s of March 31, 201	7	A	s of March 31, 2018	3
	With quoted prices in active markets	Without quoted prices in active markets	Total	With quoted prices in active markets	Without quoted prices in active markets	Total	With quoted prices in active markets	Without quoted prices in active markets	Total
Equity securities	¥ 11,477	¥ —	¥ 11,477	¥ 13,983	¥ —	¥ 13,983	¥ 14,988	¥ —	¥ 14,988
Debt securities	42,033	—	42,033	39,349	—	39,349	39,667	-	39,667
General accounts of life insurance companies	_	8,458	8,458	_	8,620	8,620	_	8,740	8,740
Cash and cash equivalents	3,940	_	3,940	3,790	_	3,790	3,827	_	3,827
Others	_	12,415	12,415	_	13,262	13,262	-	13,458	13,458
Total	¥ 57,450	¥ 20,873	¥ 78,323	¥ 57,122	¥ 21,882	¥ 79,004	¥ 58,482	¥ 22,198	¥ 80,680

(Note) The retirement benefit trusts set for defined benefit pension plans consist of 6.5%, 7.8%, and 8.1% in the total plan assets as of the Transition Date, March 31, 2017 and 2018 respectively. For general accounts of life insurance companies, a certain level of interest rate and principal are guaranteed by life insurance companies.

5. Significant actuarial assumptions

The key actuarial assumptions used for calculating the present value of defined benefit obligations are as follows:

	Transition Date	As of	As of
	(As of April 1, 2016)	March 31, 2017	March 31, 2018
Discount rate (%)	0.6	0.8	0.7

6. Sensitivity analysis

The effects of changes in the significant actuarial assumptions on the defined benefit obligations as of March 31, 2017 and 2018 are as follows:

The sensitivity analysis is performed under the assumption that other parameters remain unchanged. The analysis is performed on the same basis with calculation of defined benefit obligation recognized in the consolidated statement of financial position.

	Millions	s of yen
	As of March 31, 2017	As of March 31, 2018
In case that the discount rate increases by 0.5%	¥ (6,109)	¥ (6,890)
In case that the discount rate decreases by 0.5%	¥ 5,919	¥ 6,740

### 7. Investment strategy and operating policy of plan assets

The Company's basic policy of plan asset management is aimed to generate a required long-term comprehensive return within an acceptable range of risk exposure in order to provide sufficient funding for future pension payments and lump-sum payments that are stipulated in the Group's regulations on retirement benefits and regulations on corporate pension funds.

The targeted rate of return is the required return rate to operate and maintain a sound defined benefit plan in the future. Concretely, the objective is to achieve a mid-to-long term expected rate of return that exceeds the discount rate. In order to achieve the objective, the Group establishes the basic policy for plan asset management. Such policy is subject to change according to the changes of the Group's status and systems or operating environment surrounding the Group.

### 8. Impact of the defined benefit plan on future cash flows

In relation to the defined benefit corporate pension plan, the Group's funds revise the amounts of contributions every five years to ensure balanced finances for future periods. The funds also revise the amounts of contributions in the event that the balance of the fund reserve falls below the amount of the liability reserve following adjustment by the amount of deficit eligible for carry-forward as of the fund's reporting date.

### (3) Defined contribution plan

The expenses recognized for defined contribution plans were ¥2,894 million and ¥2,213 million for the years ended March 31, 2017 and 2018, respectively.

### (4) Other Employee benefit expenses

The employee benefit expenses for the years ended March 31, 2017 and 2018 are as follows:

	Million	Millions of yen			
	Year ended March 31, 2017	Year ended March 31, 2018			
Salaries	¥ 65,306	¥ 67,419			
Bonuses	20,053	21,852			
Retirement benefit expenses	7,212	7,416			
Business structure improvement expenses	10,722	3,686			
Others	12,629	12,923			
Total	¥ 115,922	¥ 113,296			

## 25. Share Capital and Other Equity Items

#### (1) Share capital

The numbers of shares authorized and the changes in shares issued are as follows:

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	Year ended March 31, 2017	Year ended March 31, 2018	
Number of shares authorized	1,500,000	1,500,000	
Number of issued shares			
Balance at the beginning of the year	397,900	397,900	
Changes during the year	_	_	
Balance at the end of the year	397,900	397,900	

(Note) All the shares issued by the Company are ordinary shares with no par value which have no limitations on any rights. The issued shares are fully paid.

### (2) Treasury shares

The changes of number of treasury shares are as follows:

	Thousands of shares		
	Year ended March 31, 2017	Year ended March 31, 2018	
Balance at the beginning of the year	598	600	
Changes during the year	2	1	
Balance at the end of the year	600	601	

(Note) The treasury shares held by the Company are all ordinary shares. The changes during the year mainly represents the increase due to the request for purchases of shares less than one unit, and the decrease due to the request for sales of shares less than one unit.

### (3) Surplus

1. Capital surplus

Out of the amount generated from the equity transactions, capital surplus consists of the amount which is not included in share capital.

2. Retained earnings

Retained earnings consist of net profit (loss) recognized in the current year and prior years, and the amount reclassified from other components of equity.

### (4) Other components of equity

1. Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income

It represents the cumulative amount of net gain (loss) arising from the changes in the fair value of financial assets measured at fair value through other comprehensive income.

2. Remeasurements of net defined benefit liability (asset)

It represents the effects of differences between the actuarial assumptions at the beginning of the year and actual result, and the effects of changes in actuarial assumptions, and the income derived from changes in fair value on plan assets other than interest income.

3. Foreign differences on translation of foreign operations

It represents the cumulative translation differences arising from consolidating financial statements of foreign operations prepared using foreign currencies.

Thousands of shares

4. Cash flow hedges

It represents the effective portion of the cumulative amount of net gain (loss) in fair value of cash flow hedges relating to hedge transactions that have not yet been realized.

### (5) Dividends

- 1. Dividends paid and dividends per share
  - The total dividends paid and dividends per share are as follows:
  - (i) For the year ended March 31, 2017

Date of resolution	Type of share	Total dividend amount (Millions of yen)	Dividend amount per share (Yen)	Declaration date	Effective date of distribution
Annual shareholders meeting (June 23, 2016)	Ordinary share	¥ 3,576	¥ 9.00	March 31, 2016	June 24, 2016
Meeting of the Board of directors (October 27, 2016)	Ordinary share	¥ 3,576	¥ 9.00	September 30, 2016	December 1, 2016

### (ii) For the year ended March 31, 2018

Date of resolution	Type of share	Total dividend amount (Millions of yen)	Dividend amount per share (Yen)	Declaration date	Effective date of distribution
Annual shareholders meeting (June 22, 2017)	Ordinary share	¥ 4,370	¥ 11.00	March 31, 2017	June 23, 2017
Meeting of the Board of directors (October 30, 2017)	Ordinary share	¥ 3,576	¥ 9.00	September 30, 2017	December 1 ,2017

2. Dividends with record date in the current fiscal year but whose effective date in the following years Dividends with record date in the current fiscal year but whose effective date in the following years are as follows:

(i) For the year ended March 31, 2017

Date of resolution	Type of share	Total dividend amount (Millions of yen)	Dividend amount per share (Yen)	Declaration date	Effective date of distribution
Annual shareholders meeting (June 22, 2017)	Ordinary share	¥ 4,370	¥ 11.00	March 31, 2017	June 23, 2017

(ii) For the year ended March 31, 2018

Date of resolution	Type of share	Total dividend amount (Millions of yen)	Dividend amount per share (Yen)	Declaration date	Effective date of distribution
Annual shareholders meeting (June 19, 2018)	Ordinary share	¥ 7,549	¥ 19.00	March 31, 2018	June 20, 2018

# 26. Financial Instruments

### (1) Capital management

In order to achieve sustainable and integrative increase of corporate value and shareholder value, the Group conducts capital management under the policy of introducing merchandise and developed products and making investments in domestic business, North America business, and new business, etc., and also positioning return on profits to shareholders as a key management priority. There are no significant capital restrictions applicable to the Group.

#### (2) Overview of financial risk management

Risk management policy

In order to reduce financial risks (such as credit risk, liquidity risk, and market risks, etc.) arising from business operations, the Group performs risk management. Derivatives are used to mitigate part of such risks and are not used for speculative purposes.

#### (3) Credit risk

1. Summary

Credit risk is the risk of financial loss to the Group if a customer or a counterparty of financial instrument fails to meet its contractual obligations. It mainly arises from the debtors, such as trade receivables due from the Group's customers.

As for the customers' credit risk arising from trade receivables and etc., the Group monitors the status of overdue balances, reviews outstanding balances of each customer according to the Group's internal credit management policies and assesses the credibility of major customers on a regular basis in order to reduce credit risks.

#### 2. Maximum credit risk exposures

The maximum exposures related to the credit risk of financial assets held by the Group are the carrying amount of financial assets presented in the consolidated statements of financial position.

3. Changes in allowance for doubtful accounts

An allowance for doubtful accounts is recognized for expected credit losses for trade receivables and other receivables.

(i) Trade receivables

Allowance for doubtful accounts related to trade receivables that do not contain a significant financing component is recognized at the amount equal to the lifetime expected credit loss by similar receivables.

(ii) Other receivables

For assets of which credit risk significantly increases, in principle, an allowance for doubtful accounts is recognized at the amount equal to the 12-month expected credit loss, and calculated by multiplying the carrying amount by the provision rate calculated by considering prospects of future economic conditions, etc. in addition to the historical rate of credit losses of similar assets. For assets of which credit risk is considered significantly increased, and credit-impaired financial assets, the allowance for doubtful accounts is recognized at an amount equal to the lifetime expected credit losses, and is calculated based on the difference between recoverable amount that is individually determined by considering the prospects of future economic conditions, in addition to the financial conditions of counterparty and total carrying amount.

Any financial asset will be treated as credit-impaired financial assets, if there is a request to change terms and conditions for repayment from the debtor, serious financial difficult of the debtor, or commencement of legal liquidation procedures due to bankruptcy and others of the debtor, etc. In addition, if a financial asset is impaired, the impairment loss is recognized in the account of allowance for doubtful accounts rather than deducted directly from the carrying amount of the asset.

#### Changes in the allowance for doubtful accounts are as follows:

	Million	s of yen
	Year ended March 31, 2017	Year ended March 31, 2018
Balance at the beginning of the year	¥ 6	¥ 4
Increase	—	_
Decrease (utilization)	(2)	_
Decrease (others)	—	_
Others (Note)		(3)
Balance at the end of the year	¥ 4	¥ 1

(Note) The analysis of changes in the allowance for doubtful accounts by credit risk category of financial instruments is not presented, as they are immaterial.

4. Total carrying amount of financial assets for which allowances for doubtful accounts are provided The aging analyses of trade and other receivables, etc. as of March 31, 2017 and 2018 are as follows:

	Millions of yen		
	As of March 31, 2017	As of March 31, 2018	
Not past due	¥ 129,170	¥ 133,150	
Within 30 days	233	1,034	
Over 30 days and within 60 days	76	43	
Over 60 days and within 90 days	38	36	
Over 90 days within 1 year	1	20	
Over 1 year		_	
Total	¥ 129,518	¥ 134,283	

(Note) The aging analysis by each credit risk category is not presented, because there are no financial assets for which material credit risk has increased significantly since initial recognition, and credit-impaired financial assets.

#### (4) Liquidity risk

1. Overview

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset.

The Group manages the liquidity risk by preparing monthly funding plan by each company and etc.

#### 2. Maturity analysis

The contractual maturity of financial liabilities including estimated interest payment are as follows: (i) As of April 1, 2016

		Millions of yen						
	Carrying amount	Total contractual cash flow	Due within one year or less	Due after one year within two years	Due after two years within three years	Due after three years within four years	Due after four years within five years	Due after five years
Borrowings	¥ 21,010	¥ 21,248	¥ 13,205	¥ 8,043	¥ —	¥ —	¥ —	¥ —
Bonds	30,000	30,439	10,217	10,186	10,036	—	—	—
Total	¥ 51,010	¥ 51,687	¥ 23,422	¥ 18,229	¥ 10,036	¥ —	¥ —	¥ —

#### (ii) As of March 31, 2017

		Millions of yen						
	Carrying amount	Total contractual cash flow	Due within one year or less	Due after one year within two years	Due after two years within three years	Due after three years within four years	Due after four years within five years	Due after five years
Borrowings	¥ 48,000	¥ 48,047	¥ 48,047	¥ —	¥ —	¥ —	¥ —	¥ —
Bonds	20,000	20,178	10,137	10,041	—	—	—	—
Total	¥ 68,000	¥ 68,225	¥ 58,184	¥ 10,041	¥ —	¥ —	¥ —	¥ —

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#### (iii) As of March 31, 2018

		Millions of yen						
	Carrying amount	Total contractual cash flow	Due within one year or less	Due after one year within two years	Due after two years within three years	Due after three years within four years	Due after four years within five years	Due after five years
Borrowings	¥ 37,400	¥ 37,492	¥ 6,495	¥ 2,985	¥ 2,978	¥ 4,971	¥ 20,063	¥ —
Bonds	10,000	10,041	10,041	—	—	—	—	—
Total	¥ 47,400	¥ 47,533	¥ 16,536	¥ 2,985	¥ 2,978	¥ 4,971	¥ 20,063	¥ —

The Group does not expect the cash flows included in the maturity analysis to occur much earlier than anticipated or to differ significantly from the anticipated monetary amounts.

#### (5) Market risk

1. Overview

Market risk is the risk that changes in market prices - such as foreign exchange rates, interest rates, and equity prices - will affect the Group's income or the value of its holdings of the financial instruments. The Group implements certain measures for each kind of risks.

2. Foreign exchange risk

(i) Foreign exchange risk exposure

A summary of the quantitative data regarding the Group's foreign exchange risk exposure provided to the Management of the Group which is prepared according to the risk management policy is as follows:

	Thousands of USD		
	As of March 31, 2017	As of March 31, 2018	
Receivables	\$ 631,157	\$ 1,133,520	
Payables	97,719	97,338	
Net exposures of the consolidated statement of financial position	533,438	1,036,182	
Forward foreign exchange contracts	_	(100,757)	
Net exposures	\$ 533,438	\$ 935,425	

Receivables are mainly foreign currency deposit, trade receivables and loan receivable. Payables are mainly trade payables and other payables.

Forward foreign exchange contracts are used for trade receivables recorded with a certain export transactions for the year ended March 31, 2018.

(ii) Foreign exchange sensitivity analysis

The Group is exposed mainly to the foreign exchange risks against US dollars.

If the Japanese yen depreciates by 5% against the US dollar, the impact on profit or loss arising from the financial instruments held by the Group would be ¥2,071 million and ¥3,437 million as of March 31, 2017 and 2018, respectively.

The analysis includes neither the impact arising from the translation of financial instruments denominated in functional currencies, nor the translation of assets, liabilities, revenue and expenses of foreign operations into Japanese yen.

It is assumed that other variable factors are constant.

3. Interest rate risk

Many of interest-bearing debts held by the Group are fixed interest rates. The impact of interest expenses on the Group's net profit or loss is not significant. Therefore, the sensitivity analysis of interest rate risk is not presented as it is immaterial.

#### (6) Fair value of financial instrument

1. Fair value hierarchy levels

When measuring the fair value of an asset or a liability, the group were observable market data as far as possible. Fair value based on the inputs used in the valuation techniques as follows: Level 1: Fair value measured at quoted prices in active markets for identical assets or liabilities. Level 2: Fair value measured using inputs other than guoted price included in Level 1 that are

observable price for the assets or liabilities, either directly or indirectly.

Level 3: Fair value measured using inputs that are not based on observable market data.

#### 2. Financial instruments at amortized cost

The carrying amount and fair value of financial instruments at amortized cost are as follows: The financial instruments of which the carrying amounts are reasonable approximation of their fair value or financial instrument that are not material, are not included in the below table.

Millions of ven

	Transition Date (As of April 1, 2016)		As o March 31		As of March 31, 2018		
	Carrying amount	Fair value	Carrying amount	Fair value	Carrying amount	Fair value	
Financial liabilities at amortized cost							
Bonds	¥ 30,000	¥ 30,390	¥ 20,000	¥ 20,209	¥ 10,000	¥ 10,032	
Borrowings	21,010	21,085	48,000	48,026	37,400	37,370	
Total	¥ 51,010	¥ 51,475	¥ 68,000	¥ 68,235	¥ 47,400	¥ 47,402	

The measurement techniques of fair value of the major financial instruments at amortized cost are as follows:

#### (i) Bonds

The fair value of bonds is measured based on the same bond's guoted price in an inactive market as of the reporting date, of which fair value hierarchy is classified as Level 2.

#### (ii) Borrowings

The fair value of the borrowings is measured at the present value of remaining principal and interest discounted using an interest rate that would be used for new borrowings. Fair value hierarchy of the borrowings is classified as Level 3.

3. Financial instruments at fair value in the consolidated statement of financial position The fair value hierarchy of financial instruments at fair value in the consolidated statement of financial position is as follows:

Transfers of financial instruments among levels of fair value hierarchy are recognized at each year-end. There are no transfers among levels occurred as of the Transition Date, March 31, 2017 and 2018.

#### (i) Transition date (April 1, 2016)

_	Millions of yen							
	Level	1	Level 2	2	Leve	3	Tot	tal
Financial assets at fair value through profit or loss								
Derivative assets	¥	_	¥	201	¥	_	¥	201
Financial assets at fair value through other comprehensive income								
Investment securities, etc.	51	,642		_	1	1,769	6	63,411
Total	¥ 51	,642	¥	201	¥ 1 <sup>.</sup>	1,769	¥θ	63,612
Financial liabilities at fair value through profit or loss								
Contingent consideration		_		_	65	5,616	6	65,616
Others		_		20		_		20
Total	¥	_	¥	20	¥ 6	5,616	¥θ	63636

(ii) As of March 31, 2017

	Millions of yen						
	Level 1	Level 2	Level 3	Total			
Financial assets at fair value through profit or loss							
Derivative assets	¥ -	– ¥ –	¥ —	¥ —			
Financial assets at fair value through other comprehensive income							
Investment securities, etc.	38,78	5 —	11,851	50,636			
Total	¥ 38,78	5 ¥ —	¥ 11,851	¥ 50,636			
Financial liabilities at fair value through profit or loss							
Contingent consideration	-		103,516	103,516			
Others	-	- 31	_	31			
Total	¥ -	– ¥ 31	¥ 103,516	¥ 103,547			

#### (iii) As of March 31, 2018

—	Level 1	Level 2	Level 3	Total
Financial assets at fair value through profit or loss				
Derivative assets	¥ —	¥ 79	¥ —	¥ 79
Financial assets at fair value through other comprehensive income				
Investment securities, etc.	55,572	_	13,392	68,964
Total	¥ 55,572	¥ 79	¥ 13,392	¥ 69,043
Financial liabilities at fair value through profit or loss				
Contingent consideration	_	_	86,616	86,616
Others	_	33	_	33
Total	¥ —	¥ 33	¥ 86,616	¥ 86,649

Millions of yen

> The movement of the financial instruments of which fair value is classified as Level 3 is as follows: (i) Financial assets

	Millions of yen		
	As of March 31, 2017	As of March 31, 2018	
Balance at the beginning of the year	¥ 11,769	¥ 11,851	
Purchase	334	6,205	
Changes in financial assets at fair value through other comprehensive income	(252)	(4,633)	
Sales/settlement	_	(31)	
Balance at the end of the year	¥ 11,851	¥ 13,392	

(ii) Financial liabilities

	Millions of yen		
	As of March 31, 2017	As of March 31, 2018	
Balance at the beginning of the year	¥ 65,616	¥ 103,516	
Addition arising from business combination	30,149	—	
Changes in fair value of contingent consideration (Note)	8,131	(6,371)	
Settlement	_	(5,543)	
Foreign currency translation differences	(380)	(4,986)	
Balance at the end of the year	¥ 103,516	¥ 86,616	

(Note) The changes in fair value of contingent consideration is recognized in selling, general and administrative expenses in the consolidated statement of profit or loss.

The financial assets classified as Level 3 of fair value hierarchy mainly consist of unlisted securities. Because these fair values are approximate to their net asset value, the fair value is mainly measured by valuation techniques based on net asset value.

The financial liabilities classified as Level 3 of fair value hierarchy mainly consist of contingent consideration arising from business combination. Contingent consideration is determined by development milestones for which payment will be required upon achievement of the development progress in a specific development product, and commercial milestones for which payment will be required based on revenue earned since commencement of sales, etc. The fair value of the contingent consideration is measured by taking account of possibility of achievement of milestones and time value of money.

These fair value measurements are determined in accordance with the Group's valuation policies and procedures. The valuation models are determined so that they most appropriately reflect each financial instrument's nature, characteristics and risks. The Group examines the changes in important metrics that could affect the changes in fair value, on an ongoing basis.

The Group considers there are no material changes in fair values of financial instruments classified as Level 3, in case the unobserved inputs are replaced by alternative assumptions that are considered reasonable.

#### 4. Contingent consideration

As for the acquisitions of Boston Biomedical, Inc. ("BBI"), Elevation Pharmaceuticals, Inc. (Currently: Sunovion Respiratory Development Inc.) ("Elevation"), and Tolero Pharmaceuticals, Inc. ("Tolero"), the contingent considerations are to be additionally paid to former shareholders upon the achievement of predetermined milestone.

As for the acquisition of BBI, consideration for acquisition amounting to USD 225 million (¥18,958 million) has been paid till March 31, 2018, and it is possible to pay a maximum amount of

USD 515 million (¥54,719 million), before considering time value of money on achievement of the development milestones of the chemical compounds under development by BBI. In addition, it is possible to pay a maximum amount of USD 1,890 million (¥200,813 million), before considering time value of money on achievement of the commercial milestones based on revenue earned after commencement of sales.

As for the acquisition of Elevation, consideration for acquisition amounting to USD 189 million (¥17,800 million) has been paid till March 31, 2018, and it is possible to pay a maximum amount of USD 210 million (¥22,313 million), before considering time value of money, on achievement of the commercial milestones determined based on revenue earned after commencement of sales.

As for the acquisition of Tolero, consideration for acquisition amounting to USD 195 million (¥22,165 million) has been paid till March 31, 2018, and it is possible to pay a maximum amount of USD 430 million (¥45,688 million) on achievement of the development milestones for chemical compounds under development by Tolero. In addition, it is possible to pay a maximum amount of USD 150 million (¥15,938 million), before considering time value of money, on achievement of the commercial milestones determined based on revenue earned after commencement of sales.

The Group recognize these contingent considerations in other financial liabilities in the consolidated statement of financial position after considering the time value of the money.

The fair value of contingent consideration is classified as Level 3 in the fair value hierarchy. The changes in the fair value are recognized in selling, general and administrative expenses in the consolidated statement of profit or loss.

The total amount of future payments that the Group may be required to make pursuant to contingent consideration contract is ¥367,429 million (undiscounted) and ¥342,661 million (undiscounted) as of March 31, 2017 and 2018, respectively.

The impact on fair value of contingent considerations due to changes in significant assumptions which affect the fair value of contingent considerations is as follows:

		Millions of yen		
		Year ended March 31, 2017	Year ended March 31, 2018	
Payapua	Increase by 5%	¥ 1,907	¥ 2,445	
Revenue	Decrease by 5%	(2,468)	(2,551)	
Discount rate	Increase by 0.5%	(1,986)	(1,647)	
	Decrease by 0.5%	1,772	1,753	

#### 27. Capital Expenditure Commitments

Capital expenditure commitments of acquisition of assets are as follows:

	Millions of yen					
	Transition Date (As of April 1, 2016)	As of March 31, 2017	As of March 31, 2018			
Property, plant and equipment	¥ 1,700	¥ 4,960	¥ 7,073			
Intangible assets	48,407	66,188	74,233			
Total	¥ 50,107	¥ 71,148	¥ 81,306			

### Financial Section Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

Commitments in place to purchase intangible assets are mainly related to purchase of rights on contracts signed with third parties regarding introduction of technology. These contracts have terms related to payment achievement of a development milestone depend upon the progress of development, in addition to the lump-sum payment executed upon signing the contract. The above amount is pre-discounted amount, and includes all potential payments for milestones, assuming that all products in process would be successful, without adjustments made on success probability. Because it is highly uncertain whether a milestone will be achieved, actual payments may be significantly different from these commitment amounts.

# 28. Subsidiaries and Associates

The significant subsidiaries and associates of the Group are as follows: Major Consolidated Subsidiaries

Associates				
Name	Location	Amount of Stated Capital	Principal Businesses (Operating Segment)	Ratio of Voting Rights
Sumitomo Dainippon Pharma America, Inc.	Marlborough, MA, U.S.	USD 1,000	Holding company (North America)	100%
Sunovion Pharmaceuticals Inc.	Marlborough, MA, U.S.	USD 0.01	Manufacturing and sales of pharmaceuticals (North America)	100%
Boston Biomedical, Inc.	Cambridge, MA, U.S.	USD 1	R&D in the oncology area (North America)	100%
Tolero Pharmaceuticals, Inc.	Lehi, UT, U.S.	USD 0.1	R&D in the oncology area (North America)	100%
Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	Suzhou, Jiangsu, China	USD 35 million	Manufacturing and sales of pharmaceuticals (China)	100%
DS Pharma Animal Health Co., Ltd.	Chuo-ku, Osaka	¥100 million	Manufacturing and sales of veterinary medicines, etc. (Other Business)	100%
DSP Gokyo Food & Chemical Co., Ltd.	Kita-ku, Osaka	¥100 million	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc. (Other Business)	100%
DS Pharma Biomedical Co., Ltd.	Suita, Osaka	¥480 million	Manufacturing and sales of pharmaceuticals and diagnostics, etc. (Japan, Other Business)	100%

#### 29. Related Parties

#### (1) Parent company

Sumitomo Chemical Company, Limited is the parent company of the Group.

#### (2) Related party transactions

Transactions and balances with the parent company are as follows:

				Million	s of yen		
Type Company name		Description of	Transition Date (As of April 1, 2016)	Year ended March 31, 2017		Year ended March 31, 2018	
	name	transaction	Outstanding balance	Transaction amount	Outstanding balance	Transaction amount	Outstanding balance
Parent company	Sumitomo Chemical Company, Limited	Lending and collection of funds	¥ 48,427	¥ 29,855	¥ 16,731	¥ 5,467	¥ 21,250

Related party transactions are under general terms and conditions that are the same as those of transactions with a third party. Outstanding balances are not secured by any collateral, and are settled by cash. There is no allowance for doubtful accounts on the outstanding balances.

#### (3) Remuneration of key management personnel

Remuneration of key management personnel is as follows:

	IVIIIIOIIS	s or yerr
	Year ended March 31, 2017	Year ended March 31, 2018
Basic remuneration and bonus	¥ 436	¥ 440

#### 30. Business Combinations

#### (1) Significant business combinations

#### Year ended March 31, 2017

Business combinations by acquisition

(Cynapsus Therapeutics Inc.)

- 1. Overview of business combination
  - (i) Name of acquired company and business description

Name of acquired company: Cynapsus Therapeutics Inc.

- Business description: Developing pharmaceuticals for Parkinson's disease
- (ii) Acquisition date

October 21, 2016 (U.S. Eastern Standard Time)

- (iii) Percentage of voting rights acquired 100%
- (iv) Main reason for business combination

Sunovion Pharmaceuticals Inc. focuses on the Psychiatry & Neurology area as one of the franchises and sells the atypical antipsychotic agent LATUDA<sup>®</sup> and antiepileptic drug APTIOM<sup>®</sup>. The Group concludes that by acquiring Cynapsus Therapeutics Inc. and its treatment of Parkinson disease which is under development, it will be able to further strengthen the development pipelines in Psychiatry & Neurology portfolio, one of the key therapeutic areas.

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> (v) Method for gaining control of acquired company Acquisition of shares by cash consideration

Cynapsus Therapeutics Inc. was reorganized on the acquisition date due to the amalgamation (reorganization under the State of Prentiss-Columbia State of Canada), and Sunovion CNS Development Canada ULC was newly established.

2. The details of fair value of consideration transferred, assets acquired and liabilities assumed on acquisition date are as follows:

Millions of yen
Amount
¥ 69,686
938
175
5,761
3,056
61,982
1,255
63,237
63,237
¥ 63,237

Goodwill comprises mainly excess earning power expected from future business development. Such goodwill is not deductible for tax purpose.

Provisional accounting treatment had been applied to the purchase price allocation in the year ended March 31, 2017, and has been finalized in the year ended March 31, 2018. There have been no adjustments to the provisional amounts.

#### 3. Acquisition-related costs ¥ 681 million

The acquisition-related costs mainly represent advisory fees and others, and recognized in selling, general and administrative expenses.

#### 4. Effect on the Group's performance

(i) Revenue and net profit or loss of acquired company after the acquisition date recognized in the consolidated statement of profit or loss for the year ended March 31, 2017

#### Revenue

Net profit (loss) ¥ (1,624) million

(ii) Revenue and net profit or loss for the year ended March 31, 2017 after the business combination, assuming the business combination had been conducted at the beginning of the

fiscal year ended March 31, 2017 (Unaudited information) Revenue ¥ 408,357 million Net profit (loss) ¥ 28,054 million (Tolero Pharmaceuticals, Inc.)

- 1. Overview of business combination
  - (i) Name of acquired company and business description

Name of acquired company: Tolero Pharmaceuticals, Inc. ("Tolero")

Business description: Research and development of pharmaceutical in the areas of oncology and hematological disorders

(ii) Acquisition date

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

- (iii) Percentage of voting rights acquired 100%
- (iv) Main reason for business combination

Tolero is a biotechnology venture 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 Tolero is 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 Group to reinforce own 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.

(v) Method for gaining control of acquired company Acquisition of shares by cash consideration

	Millions of yen						
	Provisional fair value in the initial accounting	Fair value adjustment	Provisional fair value (as adjusted)				
Fair values of the assets acquired and the liabilities assumed							
Intangible assets	¥ 59,843	¥ (14,335)	¥ 45,508				
Cash and cash equivalents	115	—	115				
Other assets	54	—	54				
Deferred tax liabilities	20,365	(5,304)	15,061				
Other liabilities	799	—	799				
Fair values of the assets acquired and the liabilities assumed (net amount)	38,848	(9,031)	29,817				
Goodwill	18,586	3,911	22,497				
Total	¥ 57,434	¥ (5,120)	¥ 52,314				
Fair value of consideration transferred							
Cash	22,165	_	22,165				
Contingent consideration	35,269	(5,120)	30,149				
Total	¥ 57,434	¥ (5,120)	¥ 52,314				
<u> </u>	,	( ) /	,				

2. The details of fair value of consideration transferred, assets acquired and liabilities assumed on acquisition date are as follows:

Goodwill comprises mainly excess earning power expected from future business development. Such goodwill is not deductible for tax purpose.

Provisional accounting treatment had been applied to the purchase price allocation in the year ended March 31, 2017, and has been finalized in the year ended March 31, 2018 and the consolidated statement of financial position as of March 31, 2017 has been adjusted retrospectively.

As a result, provisional fair value of certain assets acquired, liabilities assumed and consideration transferred have been adjusted as described above.

3. Contingent consideration

The contingent consideration of the acquisition of Tolero is possibly to be paid at a maximum amount of USD 430 million (¥45,688 million) before considering the time value of money in the future as a development milestone for chemical compounds currently being developed by Tolero. In addition, there is a possibility to pay a maximum amount of USD 150 million (¥15,938 million) before considering the time value of money for commercial milestones based on the revenue earned after the commencement of sales.

The Group recognized the contingent consideration as Other financial liabilities in the consolidated statement of financial position in consideration of the time value of money.

The fair value hierarchy of the contingent consideration is classified as Level 3. The change in the fair value of contingent consideration is accounted for in the Selling, general and administrative expenses in the consolidated statement of profit or loss.

#### 4. Acquisition-related costs ¥ 1,066 million

The acquisition-related costs mainly related to advisory fees and others, and recognized in selling, general and administrative expenses.

- 5. Effect on the Group's performance
  - (i) Revenue and net profit or loss of acquired company after the acquisition date recognized in the consolidated statement of profit or loss for the year ended March 31, 2017
    - Revenue
    - Net profit (loss) ¥ (208) million
  - (ii) Revenue and net profit or loss for the year ended March 31, 2017 after the business
  - combination, assuming the business combination had been conducted at the beginning of the fiscal year ended March 31, 2017. (Unaudited information)
    - Revenue ¥ 408,357 million

Net profit (loss) ¥ 30,558 million

#### Year ended March 31, 2018

There are no significant business combinations

31. Subsequent Events There are r

There are no significant subsequent events.

#### 32. First-time Adoption of IFRS

The Group presents consolidated financial statements that comply with IFRS from the year ended March 31, 2018. The most recent consolidated financial statements prepared in accordance with generally accepted accounting principles in Japan (hereinafter "Japanese GAAP") are for the year ended March 31, 2017, and the date of transition from Japanese GAAP to IFRS is April 1, 2016.

Accounting policies as stated in Note 3 Significant Accounting Policies in the Notes to consolidated financial statements are applied to the consolidated financial statements for the years ended March 31, 2018 and 2017 and the consolidated statement of financial position as of April 1, 2016 (Transition Date).

#### (1) Exemption rules of IFRS 1

In principle, IFRS 1 provides a company that presents its first IFRS financial statements ("First-time Adopter") shall comply with each IFRS retrospectively. However, IFRS 1 provides voluntary exemptions from the application of certain standards required by IFRS.

The exemptions that the Group applies in connection with the transition from Japanese GAAP to IFRS are as follows:

#### 1. Business combinations

IFRS 1 provides that a First-time Adopter may elect not to apply retrospectively IFRS 3 to past business combinations that occurred before the date of transition to IFRS. However, if a First-time Adopter restates any business combination to comply with IFRS 3, it shall restate all later business combinations to comply with IFRS 3.

The Group elects to use this exemption and not to apply retrospectively IFRS 3 for the business combinations that occurred before the date of transition to IFRS.

As a result, the amount of goodwill arising from the business combinations that occurred before the date of transition to IFRS is stated at the carrying amount of the goodwill in accordance with Japanese GAAP as of the date of transition to IFRS. However, impairment test on goodwill was performed as of the date of transition of IFRS regardless of whether there was an indication of impairment.

#### 2. Deemed cost

IFRS 1 provides that a First-time Adopter may elect to use the fair value of an intangible asset, etc. at the date of transition to IFRS as deemed cost at the date of transition to IFRS. The Company elects to use this exemption for certain intangible assets and uses the fair value at the date of transition to IFRS as deemed cost.

#### 3. Exchange differences on translation of foreign operations

IFRS 1 provides that a First-time Adopter need not comply with certain requirements in IAS 21 The Effects of Changes in Foreign Exchange Rates for cumulative translation differences that existed at the date of transition to IFRS. If the exemption is used, the cumulative translation differences of all foreign operations are deemed to be zero at the date of transition to IFRS.

The Group elects to use this exemption, deems the cumulative translation differences of foreign operations as zero and reclassifies all to retained earnings at the date of transition to IFRS.

#### (2) Reconciliations from Japanese GAAP to IFRS

The reconciliations that are required for disclosures on the first-time adoption of IFRS are shown below.

The column of "Reclassification" in the reconciliation tables represents those items that do not affect retained earnings and comprehensive income. The column of "Recognition and measurement differences" in the reconciliation tables represent those items that affect retained earnings and comprehensive income.

The reconciliation tables presented in Japanese yen is rounded to the nearest million yen. Accordingly, there exist differences from the amounts presented in prior years' annual securities reports of which are rounded down when they are less than one million yen.

#### 1. Reconciliation of net profit and comprehensive income (i) Year ended March 31, 2017

	(.)		01,2011	Millions of yen			
- Accounts under Japanese GAAP	Japanese GAAP	Reclassification	Retrospective adjustment on purchase price allocation in business combination (l)	Recognition and measurement differences	IFRS	Note	Accounts under IFRS
Net sales	¥ 411,645	¥ —	¥ —	¥ (3,288)	¥ 408,357	(a)	Revenue
Cost of sales	100,078	114	_	(5,567)	94,625	(b)	Cost of sales
Gross profit	311,567	(114)	_	2,279	313,732		Gross profit
Selling, general and administrative expenses	258,807	(80,618)	259	3,220	181,668	(C)	Selling, general and administrative expenses
	_	80,820	_	553	81,373	(d)	Research and development expenses
	_	305	_	3,249	3,554	(e)	Other income
	_	13,973	_	(14)	13,959	(f)	Other expenses
Operating profit	52,760	(13,984)	(259)	1,769	40,286		Operating profit
Non-operating income	3,521	(3,521)	_	_	_		
Non-operating expense	1,939	(1,939)	_	_	_		
Extraordinary income	5,754	(5,754)	_	_	_		
Extraordinary loss	12,878	(12,878)	_	_	_		
	_	8,989	_	(5,807)	3,182	(g)	Finance income
	_	667	_	20	687	(h)	Finance costs
Profit before income taxes	47,218	(120)	(259)	(4,058)	42,781		Profit before taxes
Income tax expenses	18,225	(120)	_	(6,640)	11,465	(i)	Income tax expenses
Net profit	28,993	—	(259)	2,582	31,316		Net profit
Consolidated statement of comprehensive income							Other comprehensive income
Other comprehensive income							Items that will not be reclassified to profit or loss
Change in unrealized gain (loss) on securities	(6,661)	_	_	3,775	(2,886)	(j)	Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income
Remeasurements of defined benefit plans	1,119	_	_	2,158	3,277	(k)	Remeasurements of defined benefit liability (asset)
							Items that are or may be reclassified subsequently t profit or loss:
Foreign currency translation adjustment	(2,296)	_	(9)	434	(1,871)		Exchange differences on translation of foreign operations
Deferred losses on hedges	(7)	_	_	_	(7)		Cash flow hedges
Total other comprehensive income	(7,845)	_	(9)	6,367	(1,487)		Total other comprehensive income
Comprehensive income	¥ 21,148	¥ —	¥ (268)	¥ 8,949	¥ 29,829		Total comprehensive incom

(Note) Increases and reversal of provisions for sales returns are included in Revenue.

#### (a) Revenue

#### (Recognition and measurement difference)

Under Japanese GAAP, lump sum receipts on out-licensing of technologies, etc. based on license agreements and royalty income, were included in Net sales. However, under IFRS such revenues from contracts are included in Other operating income because such license transactions which transfer all the rights and obligations to the customers are determined as sales of intangible assets at the inception of the contract.

#### (b) Cost of sales

(Recognition and measurement difference)

Under Japanese GAAP, certain subsidiaries used the First-in, first-out cost formula to measure cost of inventories. Under IFRS, Cost of sales decreased because the cost formula of all consolidated subsidiaries has been unified to the average method.

#### (c) Selling, general and administrative expenses

#### (Reclassification)

Under Japanese GAAP, research and development expenses are included in Selling, general and administrative expenses. However, under IFRS, research and development expenses are separately presented.

(Differences in recognition and measurement)

Under Japanese GAAP, goodwill was amortized on a straight-line basis over the period during which the effect of such goodwill last for but not exceed 20 years after recognition. However, under IFRS, goodwill is not amortized. As a result, Selling, general and administrative expenses decreased.

Under Japanese GAAP, contingent consideration arising from a transaction, which is accounted for as a business combination under Japanese GAAP at the acquisition date, was not recognized as a liability until the timing of delivery or transfer is reliable after the business combination. However, under IFRS, contingent consideration in a business combination is measured at fair value and recognized as a financial liability. The change of fair value of such financial liabilities is recognized in Selling, general and administrative expenses. As a result, the increase of fair value is recognized in Selling, general and administrative expenses.

Under Japanese GAAP, if any indication of impairment exists, the carrying amount of the asset and asset group and the total undiscounted estimated future cash flows were compared, and only if the total undiscounted estimated future cash flows fell below the carrying amount, impairment losses were recognized to the extent of the recoverable amount based on the total discounted estimated future cash flows. Under IFRS, if any indication of impairment exists, the carrying amount of the asset and asset group and the recoverable amount based on the total discounted estimated future cash flows are compared, and if the recoverable amount based on the total discounted estimated future cash flows are compared, and if the recoverable amount falls below the carrying amount, impairment losses are recognized to the extent of the recoverable amount. As a result, under IFRS, impairment losses on marketing rights in Japan are recognized, as the relevant profitability is expected to be declining and the recoverable amount of discounted future cash flow falls below the carrying amount of such assets.

As a result of the above, Selling, general and administrative expenses increased.

#### (d) Research and development expense

#### (Reclassification)

Under Japanese GAAP, research and development expenses were included in Selling, general and administrative expenses. Under IFRS, research and development expenses are separately presented.

### Financial Section Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

(e) Other income

(Recognition and measurement difference)

Under Japanese GAAP, lump sum receipts on out-licensing of technologies, etc. based on license agreements and royalty income, were included in Net sales. However, under IFRS such revenues from contracts are included in Other income because such license transactions which transfer all the rights and obligations to the customers are determined as sales of intangible assets at the inception of the contract.

(f) Other expenses

#### (Reclassification)

Under Japanese GAAP, business structure improvement expenses and losses associated with termination of research and development projects were presented in Extraordinary loss. Under IFRS, such expenses are included in Other expenses.

Donations presented in non-operating expense and certain expenses presented in other of non-operating expense under Japanese GAAP, are presented in Other expenses under IFRS.

(g) Finance income

(Reclassification)

Under Japanese GAAP, interest income, dividend income, and foreign exchange gains were presented in non-operating expense. Under IFRS, interest income, they are presented in Finance income.

(Recognition and measurement difference)

Under Japanese GAAP, gains on sale of investment securities were recognized in extraordinary income. Under IFRS, they are recognized as Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income.

- (h) Finance costs
  - (Reclassification)

Under Japanese GAAP, interest expense was presented in non-operating expense. Under IFRS, it is presented in Finance costs.

(i) Income tax expenses

(Recognition and measurement difference)

Under Japanese GAAP, deferred tax assets related to elimination of unrealized gains and losses of inventories were calculated using the seller's statutory effective income tax rate. Under IFRS, the buyer's statutory effective income tax rate is used for calculation deferred tax assets. In addition, income tax expenses decreased due to the origination of temporary differences arising from other IFRS adjustments.

(j) Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income

(Recognition and measurement difference)

Under Japanese GAAP, the gains on sales of investment securities recognized in extraordinary income and the related income tax expenses were adjusted to other comprehensive income (reclassification adjustment). Under IFRS, as such reclassification adjustments are not permitted, they are reversed.

Under Japanese GAAP, unlisted securities were measured at acquisition cost. Under IFRS, they are measured at fair value.

(k) Remeasurements of defined benefit liability (asset)

(Recognition and measurement difference)

Under Japanese GAAP, actuarial gains and losses arising from defined benefit plans and past service cost are recognized in other comprehensive income when incurred and amortized over a certain period of years within the average remaining service period of employees which was calculated when such gains and losses and past service cost occurred. Under IFRS, actuarial gains and losses are recognized in other comprehensive income, and past service cost is recognized in profit and loss when incurred. The actuarial gains and losses recognized in other comprehensive income are reclassified to retained earnings immediately.

As for the Company and domestic consolidated subsidiaries which have defined benefit plans, there exist differences on the actuarial assumptions, such as discount rates, between Japanese GAAP and IFRS.

(I) Retrospective adjustment on purchase price allocation in business combination Provisional accounting treatment had been applied to the purchase price allocation in the business combination with Tolero Pharmaceuticals, Inc. in the year ended March 31, 2017, and was finalized in the year ended March 31, 2018 and therefore retrospective adjustment was made.

As a result, Selling, general and administrative expenses increased by ¥259 million, and Other comprehensive income decreased by ¥9 million.

### Financial Section Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

#### 2. Reconciliations of equity

(i) IFRS Transition Date (April 1, 2016)

	Millions of yen								
			Recognition and measurement						
Accounts under Japanese GAAP	Japanese GAAP	Reclassification	differences	IFRS	Note	Accounts under IFRS			
Assets						Assets			
Non-current assets						Non-current assets			
Property, plant and equipment	¥ 61,824	¥ —	¥ 1,841	¥ 63,665	(a)	Property, plant and equipment			
Goodwill	76,950	_	_	76,950		Goodwill			
In-process research and development	60,145	19,486	(810)	78,821	(C)	Intangible assets			
Intangible assets (others)	19,486	(19,486)	_	_					
Investment securities	60,433	1,052	3,747	65,232	(d)	Other financial assets			
Retirement benefit assets	67	_	(67)	_	(n)				
Other	4,954	(1,092)	_	3,862		Other non-current assets			
Deferred tax assets	2,313	63,991	7,276	73,580	(e)	Deferred tax assets			
Allowance for doubtful debts	(41)	41	_	_					
Total non-current assets	286,131	63,992	11,987	362,110		Total non-current assets			
Current assets						Current assets			
Merchandise and finished goods	48,101	11,487	(15,077)	44,511	(f)	Inventories			
Work-in-process	3,206	(3,206)	_	_					
Raw materials and supplies	8,281	(8,281)	_	_					
Notes and accounts receivable	107,166	1,697	(207)	108,656	(g)	Trade and other receivables			
Investment securities	81,039	(31,662)	_	49,377	(h)	Other financial assets			
Loans receivables	48,427	(48,427)	_	_					
Deferred tax assets	63,991	(63,991)	_	_	(e)				
	_	_	_	_		Income taxes receivable			
Other	6,455	(2,263)	1,069	5,261	(j)	Other current assets			
Cash and time deposits	54,922	80,650	_	135,572	(k)	Cash and cash equivalents			
Allowance for doubtful debts	(4)	4	_	_					
Total current assets	421,584	(63,992)	(14,215)	343,377		Total current assets			
Total assets	¥ 707,715	¥ —	¥ (2,228)	¥ 705,487		Total assets			

-	Millions of yen								
Accounts under Japanese GAAP	Japanese GAAP	Reclassification	Recognition and measurement differences	IFRS	Note	Accounts under IFRS			
iabilities and net assets						Liabilities and equity			
iabilities						Liabilities			
_ong-term liabilities						Non-current liabilities			
Bonds	¥ 20,000	¥ 8,000	¥ —	¥ 28,000		Bonds and borrowings			
Long-term debt	8,000	(8,000)	_	_					
	_	156	_	156	(I)	Trade and other payables			
	_	11,500	58,374	69,874	(m)	Other financial liabilities			
Retirement benefit liabilities	16,159	_	5,750	21,909	(n)	Retirement benefit liabilities			
Fair value of contingent consideration	8,968	(8,968)	_	_					
Other	12,184	(6,514)	504	6,174	(O)	Other non-current liabilities			
Deferred tax liabilities	16,209	_	(12,148)	4,061	(e)	Deferred tax liabilities			
Total long-term liabilities	81,520	(3,826)	52,480	130,174		Non-current liabilities			
Current liabilities						Current liabilities			
Short-term debt	1,010	22,000	_	23,010		Bonds and borrowings			
Corporate bonds due within one year	10,000	(10,000)	_	_					
Long-term debts due within one year	12,000	(12,000)	_	_					
Trade notes and accounts payable	12,153	31,709	(334)	43,528	(q)	Trade and other payables			
	.2,.00	5,944	704	6,648	(q)	Other financial liabilities			
Income taxes payable	26,358	2,098	-	28,456	(r)	Income taxes payable			
Reserve for bonuses	10,809	46,980	(32)	57,757	(r) (s)	Provisions			
Reserve for sales return	9,086	(9,086)	(32)	51,151	(3)	FTOVISIONS			
Reserve for sales rebates	49,224	(49,224)							
Other payables	34,213	(34,213)							
Other	14,869	9,618	1,833	26,320	(t)	Other current liabilities			
Total current liabilities	179,722	3,826	2,171	185,719	(1)	Current liabilities			
Total liabilities	261,242		54,651	315,893		Total liabilities			
Vet assets	201,242		04,001	010,030		Equity			
Common stock	22,400			22,400		Share capital			
Capital surplus	15,860			15,860		Capital surplus			
Retained earnings	341,402		(15,044)	326,358	(u)	Retained earnings			
Treasury share	(663)		(10,0++)	(663)	(4)	Treasury shares			
Total accumulated other comprehensive income	67,474		(41,835)	25,639	(v)	Other components of equity			
Total net assets	446,473		(56,879)	389,594	(-)	Total equity			
101011151 000510	440,473	—	(00,019)	009,094		i otal equity			

### Financial Section Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

(ii) As of March 31, 2017

	( )	,					
_				Millions of yen			
Accounts under Japanese GAAP	Japanese GAAP	Reclassification	Retrospective adjustment on purchase price allocation in business combination (w)	Recognition and measurement differences	IFRS	Note	Accounts under IFRS
Assets							Assets
Non-current assets							Non-current assets
Property, plant and equipment	¥ 59,253	¥ —	¥ —	¥ 1,868	¥ 61,121	(a)	Property, plant and equipment
Goodwill	90,565	_	3,825	5,804	100,194	(b)	Goodwill
In-process research and development	193,970	19,775	(14,135)	(2,496)	197,114	(C)	Intangible assets
Intangible assets (others)	19,775	(19,775)	_	_	_		
Investment securities	48,034	1,228	_	3,419	52,681	(d)	Other financial assets
Retirement benefit assets	647	_	_	(647)	_	(n)	
Other	4,568	(1,255)	_	_	3,313		Other non-current assets
Deferred tax assets	711	60,956	_	(4,578)	57,089	(e)	Deferred tax assets
Allowance for doubtful debts	(29)	29	_	_	_		
Total non-current assets	417,494	60,958	(10,310)	3,370	471,512		Total non-current assets
Current assets							Current assets
Merchandise and finished goods	54,973	13,833	_	(8,520)	60,286	(f)	Inventories
Work-in-process	3,356	(3,356)	_	_	_		
Raw materials and supplies	10,477	(10,477)	_	_	_		
Notes and accounts receivable	110,932	2,026	_	(226)	112,732	(g)	Trade and other receivables
Investment securities	34,195	(16,701)	_	_	17,494	(h)	Other financial assets
Loan receivables	16,731	(16,731)	_	_	_		
Deferred tax assets	60,956	(60,956)	_	_		(e)	
	-	5,750	-	484	6,234	(i)	Income taxes receivable
Other	13,431	(8,545)		325	5,211	(j)	Other current assets
Cash and time deposits	71,408	34,195	_	_	105,603	(k)	Cash and cash equivalents
Allowance for doubtful debts	(4)	4	_	_	_		
Total current assets	376,455	(60,958)	_	(7,937)	307,560		Total current assets
Total assets	¥ 793,949	¥ —	¥ (10,310)	¥ (4,567)	¥ 779,072		Total assets

				Millions of yen			
- Accounts under Japanese GAAP	Japanese GAAP	Reclassification	Retrospective adjustment on purchase price allocation in business combination (w)	Recognition and measurement differences	IFRS	Note	Accounts under IFRS
Liabilities and net assets							Liabilities and equity
Liabilities							Liabilities
Long-term liabilities							Non-current liabilities
Bonds	¥ 10,000	¥ —	¥ —	¥ —	¥ 10,000		Bonds and borrowings
Long-term debt	_	_	_	_	_		
	—	—	—	—	—		Trade and other payables
	—	39,989	(4,813)	65,697	100,873	(m)	Other financial liabilities
Retirement benefit liabilities	13,498	_	_	2,876	16,374	(n)	Retirement benefit liabilities
Fair value of contingent consideration	39,909	(39,909)	_	_	_		
Other	8,855	(1,977)	_	474	7,352	(O)	Other non-current liabilities
Deferred tax liabilities	32,583		(5,229)	(27,282)	72	(e)	Deferred tax liabilities
Total long-term liabilities	104,845	(1,897)	(10,042)	41,765	134,671		Non-current liabilities
Current liabilities							Current liabilities
Short-term debt	40,000	18,000	_	_	58,000		Bonds and borrowings
Corporate bonds due within one year	10,000	(10,000)	_	_	_		
Long-term debts due within one year	8,000	(8,000)	_	_	_		
Notes and accounts payable	14,514	33,440	_	(560)	47,394	(p)	Trade and other payables
	_	13,193	_	724	13,917	(q)	Other financial liabilities
Income taxes payable	8,818	1,183	_	_	10,001	(r)	Income taxes payable
Reserve for bonuses	10,986	65,942	_	(23)	76,905	(s)	Provisions
Reserve for sales return	11,315	(11,315)			_		
Reserve for sales rebates	65,653	(65,653)	_	_	_		
Other payables	36,988	(36,988)	-	-	_		
Other	22,173	2,095	_	1,648	25,916	(t)	Other current liabilities
Total current liabilities	228,447	1,897	_	1,789	232,133		Current liabilities
Total liabilities	333,292	_	(10,042)	43,554	366,804		Total liabilities
Net assets							Equity
Common stock	22,400	_	_	_	22,400		Share capital
Capital surplus	15,860	—	_	_	15,860		Capital surplus
Retained earnings	363,629	_	(259)	(5,601)	357,769	(u)	Retained earnings
Treasury share	(667)				(667)		Treasury shares
Total accumulated other comprehensive income	59,435		(9)	(42,520)	16,906	(v)	Other components of equity
Total net assets	460,657		(268)	(48,121)	412,268		Total equity
Total liabilities and net assets	¥ 793,949	¥ —	¥ (10,310)	¥ (4,567)	¥ 779,072		Total liabilities and equity

(a) Property, plant and equipment

(Recognition and measurement difference)

Under Japanese GAAP, the usage fees based on certain power supply contracts that are not in the form of lease agreements, were recognized as expenses upon payment. However, under IFRS, regardless of whether such contacts are lease agreements in a legal form or not, the transactions based on the contracts, from which the right of use of the specific underlying assets have been substantially transferred can be judged, are treated as lease transaction. As a result, Property, plant and equipment increased due to the recognition of the leased assets arising from certain contracts.

#### (b) Goodwill

(Recognition and measurement difference)

Under Japanese GAAP, goodwill was amortized on a straight-line basis over the period during which the effect of such goodwill last for but not exceed 20 years after recognition. However, under IFRS, goodwill is no longer amortized, which causes Goodwill increased.

#### (c) Intangible assets

(Recognition and measurement difference)

Under Japanese GAAP, all of the research and development expenditures were recognized as expense when incurred. Under IFRS, such expenditures which meet certain requirements are recognized as intangible assets. The fair value at the date of transition to IFRS of part of the intangible assets are used as deemed cost. At the date of transition to IFRS, the carrying amounts under Japanese GAAP of the intangible assets to which deemed cost was applied, are ¥10,248 million, and their fair value are ¥1,802 million.

Under Japanese GAAP, if any indication of impairment exists, the carrying amount of the asset and asset group, and the total undiscounted estimated future cash flows were compared, and only if the total undiscounted estimated future cash flows fell below the carrying amount, impairment losses were recognized to the extent of the recoverable amount based on the total discounted estimated future cash flows. Under IFRS, if any indication of impairment exists, the carrying amount of the asset and asset group, and the recoverable amount based on the total discounted estimated flows are compared, and if the recoverable amount based on the total discounted estimated future cash flows are compared, and if the recoverable amount falls below the carrying amount, impairment losses are recognized to the extent of the recoverable amount. Impairment losses on marketing rights in Japan were recognized for the year ended March 31, 2017, as the relevant profitability is expected to be declining and the recoverable amount falls below the carrying amount of such assets. As a result, intangible assets decreased under IFRS.

(d) Other financial assets (non-current)

#### (Reclassification)

Under Japanese GAAP, the deposits arising from property rental contacts were presented in other under investments and other assets. Under IFRS, they are presented in Other financial assets under Non-current assets.

(Recognition and measurement difference)

Under Japanese GAAP, unlisted securities were measured at the acquisition costs. Under IFRS, such instruments are measured at fair value, which causes Other financial assets increased.

- (e) Deferred tax assets and deferred tax liabilities
- (Reclassification)

Under Japanese GAAP, deferred tax assets and liabilities are presented separately in current assets, non-current assets, and non-current liabilities. Under IFRS, they are presented separately in non-current assets and non-current liabilities.

(Recognition and measurement difference)

Under Japanese GAAP, deferred tax assets related to elimination of unrealized gains and losses of

inventories were calculated using the seller's statutory effective income tax rate. Under IFRS, the buyer's statutory effective income tax rate is used for calculation deferred tax assets. In addition, income taxes are recognized as a result of the origination of temporary differences arising from other IFRS adjustments and the review on the recoverability of deferred tax assets due to the transition to IFRS

Under Japanese GAAP, the Group offset the deferred tax assets and liabilities in current portion and non-current portion, respectively. Under IFRS, as all deferred tax assets and liabilities are classified as non-current items, which increased the offset amount, Deferred tax assets and Deferred tax liabilities decreased accordingly.

#### (f) Inventories

#### (Reclassification)

Under Japanese GAAP, inventories are presented in the separate accounts of merchandise and finished goods, work-in-process, and raw materials and supplies. Under IFRS, all the inventory accounts are presented aggregately in Inventories.

#### (Recognition and measurement difference)

Under Japanese GAAP, certain subsidiaries used the First-in, first-out cost formula to measure cost of inventories. Under IFRS, Inventories decreased because the cost formula of all consolidated subsidiaries has been unified to the average method.

#### (g) Trade and other receivables

#### (Reclassification)

Under Japanese GAAP, other receivables were presented in other under current assets. Under IFRS, they are presented in Trade and other receivables,

(Recognition and measurement difference)

Under Japanese GAAP, certain subsidiaries recognized revenue upon delivery. Under IFRS, revenue is recognized at the time when the significant risks and rewards of ownership of the goods are transferred to customers (i.e. upon arrival), which causes Trade and other receivables decreased.

#### (h) Other financial assets (current)

#### (Reclassification)

Under Japanese GAAP, the investment securities with the maturity of three months or less from the acquisition date are recognized in Current assets. Under IFRS, they are presented in Cash and cash equivalents.

In addition, under Japanese GAAP, loan receivables were separately presented. Under IFRS, they are included in Other financial assets under Current assets.

#### (i) Income taxes receivable

#### (Reclassification)

Under Japanese GAAP, income taxes receivable were included in other under Current assets. Under IFRS, they are separately presented as Income taxes receivable.

#### (j) Other current assets

#### (Reclassification)

Under Japanese GAAP, other receivables are included in other under Current assets. Under IFRS, they are included in Trade and other receivables.

#### (k) Cash and cash equivalents

#### (Reclassification)

Under Japanese GAAP, the investment securities with the maturity of three months or less the acquisition date were presented under Current assets. Under IFRS, they are included in Cash and cash equivalents.

### Financial Section Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2018 and 2017

(I) Trade and other payables (non-current)

(Reclassification)

Under Japanese GAAP, the long-term liabilities were presented in other under Long-term liabilities. Under IFRS, they are included in Trade and other payables under Non-current liabilities.

#### (m) Other financial liabilities (non-current)

(Reclassification)

Under Japanese GAAP, the fair value of the contingent consideration arising from the acquisition of a subsidiary located in the U.S.A. that complies with Generally Accepted Accounting Principles in United States of America (hereinafter referred to as "US GAAP"), is presented separately in fair value of contingent consideration under Non-current liabilities. Under IFRS, it is presented Other financial liabilities under Non-current liabilities.

(Recognition and measurement differences)

Under Japanese GAAP, contingent consideration arising from a transaction, which is accounted for as a business combination under Japanese GAAP at the acquisition date, was not recognized as a liability until the timing of delivery or transfer is reliable after the business combination. However, under IFRS, contingent consideration in a business combination is measured at fair value and recognized as in Other financial liability under non-current liabilities. As a result, Other financial liabilities under Non-current liabilities increased.

Under Japanese GAAP, the usage fees based on certain power supply contracts that are not in the form of lease agreements, were recognized as expenses upon payment. However, under IFRS, regardless of whether such contacts are lease agreements in a legal form or not, the transactions based on the contracts, from which the right of use of the specific underlying assets have been substantially transferred can be judged, are treated as lease transaction. As a result, Other financial liabilities under Non-current liabilities increased due to the recognition of the lease obligations arising from such contracts.

#### (n) Retirement benefit assets and liabilities

(Recognition and measurement difference)

Under Japanese GAAP, actuarial gains and losses arising from defined benefit plans and past service cost are recognized in other comprehensive income when incurred, and amortized over a certain period of years within the average remaining service period of employees which was calculated when such gains and losses and past service cost occurred. Under IFRS, actuarial gains and losses are recognized in other comprehensive income, and past service cost is recognized in profit and loss when incurred. The actuarial gains and losses recognized in other comprehensive income are reclassified to retained earnings immediately.

As for the Company and domestic consolidated subsidiaries which have defined benefit plans, there exist differences on the actuarial assumptions, such as discount rates, between Japanese GAAP and IFRS. As a result, retirement benefit liabilities increased.

#### (o) Other non-current liabilities

#### (Reclassification)

Under Japanese GAAP, the consolidated subsidiaries that comply with US GAAP recognized a liability according to U.S. Financial Accounting Standards Board Interpretation No. 48 Accounting for Uncertainty in Income Taxes. Under Japanese GAAP, such liability was presented in other under Long-term liabilities. Under IFRS, it is presented in "Income taxes payable" under Current liabilities. (Recognition and measurement difference)

Under Japanese GAAP, unused paid absences and other long-term employee benefits are not recognized as liabilities. However, under IFRS, such obligations shall be recognized as liabilities. As a result, Other non-current liabilities increased accordingly.

(p) Trade and other payables (current)

#### (Reclassification)

Under Japanese GAAP, other payables are separately presented under Current liabilities. Under IFRS, they are presented in "Trade and other payables" under Current liabilities.

#### (q) Other financial liabilities (current)

#### (Reclassification)

Under Japanese GAAP, the fair value of the contingent consideration arising from the acquisition of a subsidiary located in the U.S.A. that complies with US GAAP, which is expected to be paid within one year, was presented other under Current liabilities. Under IFRS, it is presented in Other financial liabilities under Current liabilities.

#### (Recognition and measurement difference)

Under Japanese GAAP, the usage fees based on certain power supply contracts that are not in the form of lease agreements, were recognized as expenses upon payment. However, under IFRS, regardless of whether such contacts are lease agreements in a legal form or not, the transactions based on the contracts, from which the right of use of the specific underlying assets have been substantially transferred can be judged, are treated as lease transaction. As a result, Other financial liabilities under Current liabilities increased due to the recognition of the lease obligations arising from such contracts.

#### (r) Income taxes payable

#### (Reclassification)

Under Japanese GAAP, the consolidated subsidiaries that comply with US GAAP recognized a liability according to U.S. Financial Accounting Standards Board Interpretation No. 48 Accounting for Uncertainty in Income Taxes. Under Japanese GAAP, such liability was presented in other under Long-term liabilities. Under IFRS, it is presented in "Income taxes payable" under Current liabilities.

#### (s) Provisions (current)

#### (Reclassification)

Under Japanese GAAP, reserve for sales return and reserve for sales rebates were separately presented under Current liabilities. Under IFRS, they are presented in Provisions under Current liabilities.

#### (t) Other current liabilities

#### (Reclassification)

Under Japanese GAAP, reserve for bonus was separately presented under Current liabilities. Under IFRS, it is presented in Other current liabilities under Current liabilities.

#### (Recognition and measurement difference)

Under Japanese GAAP, unused paid absences are not recognized as liabilities. However, under IFRS, such obligations shall be recognized as liabilities. As a result, Other current liabilities increase accordingly.

(u) Retained earnings

	Millions of yen	
	Transition Date (As of April 1, 2016)	As of March 31, 2017
Reclassification of cumulative exchange difference on translation for foreign operations at the date of transition to IFRS	¥ 47,548	¥ 47,548
Adjustment to goodwill	_	5,804
Adjustment to other financial liabilities (non-current)	(59,078)	(66,421)
Adjustment to inventories	(15,077)	(8,520)
Adjustment to retirement benefit liabilities	(5,817)	(3,523)
Others	(2,044)	(3,193)
Sub-total	(34,468)	(28,305)
Adjustments for tax effects	19,424	22,704
Total	(15,044)	(5,601)

(v) Other components of equity

(Recognition and measurement difference)

Under Japanese GAAP, unlisted securities were measured at acquisition cost. Under IFRS, they are measured at fair value. The resulting difference is recognized in Other components of equity.

Under Japanese GAAP, actuarial gains and losses arising from defined benefit plans and past service cost are recognized in other comprehensive income when incurred and amortized over a certain period of years within the average remaining service period of employees which was calculated when such gains and losses and past service cost occurred. Under IFRS, actuarial gains and losses are recognized in other comprehensive income, and past service cost is recognized in profit and loss when incurred. The actuarial gains and losses recognized in other comprehensive income are reclassified to retained earnings immediately.

The Group uses the exemption provided by IFRS 1, deems the cumulative translation differences of foreign operations as zero and reclassifies all to retained earnings at the date of transition to IFRS.

### (w) Retrospective adjustment on purchase price allocation in business combination

Provisional accounting treatment had been applied to the purchase price allocation in the business combination with Tolero Pharmaceuticals, Inc. in the year ended March 31, 2017, and was finalized in the year ended March 31, 2018 and therefore retrospective adjustment was made.

As a result, the following account balances as of March 31, 2017 changed accordingly: Goodwill increased by ¥3,825 million, and In-progress research and development, Fair value of contingent consideration, Deferred tax liabilities, Retained earnings and Accumulated other comprehensive income decreased by ¥14,135 million, ¥4,813 million, ¥5,229 million, ¥259 million and ¥9 million, respectively.

3. Reconciliations to cash flows

For the year ended March 31, 2017

There is no material difference on the consolidated statement of cash flows prepared under Japanese GAAP and under IFRS.

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 financial statement of financial position as at March 31, 2018, and the consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information expressed in Japanese yen.

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

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in 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 judgment, 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, 2018, and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

KPMG AZSALLC

June 19, 2018 Osaka, Japan

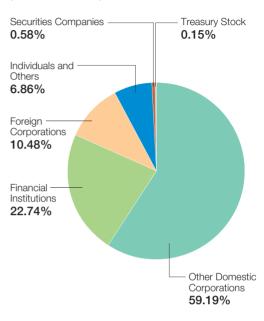
#### Principal Shareholders

(As of March 31, 2018)

Name	No. of Shares Held (Thousands of Shares)	Percentage of Shareholding
Sumitomo Chemical Co., Ltd.	204,834	51.56
Inabata & Co., Ltd.	21,882	5.51
The Master Trust Bank of Japan, Ltd. (Trust account)	21,478	5.41
Japan Trustee Services Bank, Ltd. (Trust account)	12,976	3.27
Nippon Life Insurance Company	7,581	1.91
SMBC Trust 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
Trust & Custody Services Bank, Ltd. (Security investment trust account)	3,597	0.91
Sumitomo Dainippon Pharma Employee shareholders' association	3,486	0.88

#### **Composition of Shareholders**

(As of March 31, 2018)



Note: Percentage of shareholding is calculated excluding treasury stock (601,983 shares).



### Share Price Range and Trading Volume

## External Evaluations of Sumitomo Dainippon Pharma Group on Sustainability

## Dow Jones Sustainability Indices

In Collaboration with RobecoSAM 🍋

#### **Dow Jones Sustainability Indices (DJSI)**

The DJSI are SRI indices developed through collaboration between S&P Dow Jones Indices (U.S.) and RobecoSAM (Switzerland). Sustainability of corporate activity is evaluated on the basis of three dimensions — economic, environmental, and social— with recognition given to outstanding companies. Sumitomo Dainippon Pharma was selected to the Dow Jones Sustainability Asia/Pacific Index (DJSI Asia/Pacific), the Asia Pacific subset of the 2017 Dow Jones Sustainability Indices (DJSI) as of September 2017.

#### MSCI (1) 2018 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<sup>®</sup>) 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 continuously satisfied the requirements to become a constituent of this index since 2017.



FTSE Blossom 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 continuously satisfied the requirements to become a constituent of this index since 2017.



#### **MSCI ESG Leaders Indexes**

The MSCI ESG Leaders Indexes is a globally renowned ESG investment index created by MSCI Inc. of the U.S. Sumitomo Dainippon Pharma has been independently assessed according to the MSCI ESG Leaders Indexes criteria, and has continuously satisfied the requirements to become a constituent of this index since 2010.



#### **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 since 2003.



#### **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 has been independently assessed according to the SNAM Sustainability Index criteria, and has continuously satisfied the requirements to become a constituent of this index since 2017.



#### Corporate Data As of April 1, 2018

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 MUFG Bank, 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)





FTSE Blossom Japan



Member of SNAM Sustainability Index 2018



MSCI 💮

2018 Constituent MSCI Japan ESG Select Leaders Index

2018 Constituent MSCI ESG

MSCI ESG Leaders Indexes

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



CSR Site https://www.ds-pharma.com/csr/