



Innovation today,
healthier tomorrows



On the Publication of the Integrated Report 2019

The single most important responsibility that I have been given is to ensure the sustained growth of our company into the future. As such, I will make the most efficient use of all resources available to us, unite our individual strengths, and leverage our wealth of experience so that we can successfully take on this challenge. At the same time, I hope to meet the expectations of all stakeholders in our endeavors to attain this overriding goal.

In the fiscal year ended March 31, 2018, we changed the name of this report from the Annual Report to the Integrated Report and quantitatively and qualitatively enhanced the information on the Environmental, Social, and Governance (ESG) initiatives that form the basis for our value creation process and growth.

Under our Mid-term Business Plan 2022, announced in April 2019, we established a new vision and position we aspire to establish in 2033. In this report, we will explain in detail how we will establish growth engines and build a flexible and efficient organization to grow sustainably and achieve our objective.

Going forward, we will utilize the feedback we receive from our stakeholders with sincerity in our management and use the Integrated Report as a tool for constructive dialogue while striving to enhance corporate value.

Hiroshi Nomura

Representative Director, President and Chief Executive Officer

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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.



Our Mission and Our Strengths

In October 2005, Sumitomo Dainippon Pharma Co., Ltd. was formed 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. Sumitomo Dainippon Pharma, which inherited the spirit of both these companies, will continue to provide innovative and valuable pharmaceutical products to people worldwide with the objective of establishing its position as a “Global Specialized Player” by 2033.



Corporate Mission

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

Management Mission

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

Declaration of Conduct

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

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

Management resources (our strengths)

- **Distinctive R&D capabilities in the three focus areas**
(Psychiatry & Neurology Area, Oncology Area, Regenerative Medicine/Cell Therapy Field)
- **Human resources management that retains excellent talent and maximizes potential of each employee**
- **A platform supporting global business expansion**

Continually creating innovative and

As a research and development-oriented pharmaceutical company with a global presence, Sumitomo Dainippon Pharma aims to create innovative and valuable pharmaceutical products in areas and fields with high unmet medical needs.

Main Products

Japanese Market

Psychiatry & Neurology Area

TRERIEF®

Indications	Parkinson's disease, Parkinsonism in dementia with Lewy bodies
Features	Parkinson's disease drug with levodopa-enhancing effect
Revenue	¥ 15.7 billion



About target disease

- The number of Parkinson's disease patients in Japan is approximately 160,000. 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®

Indications	Schizophrenia
Features	An atypical antipsychotic with antagonistic effects on dopamine D ₂ /D ₃ receptors and serotonin 5-HT _{2A} receptor. Launched a patch formulation in fiscal 2019.
Revenue	¥ 12.2 billion (oral formulation)



About target disease

- Schizophrenia is a chronic, serious and often severely disabling psychiatric disorder. Symptoms such as hallucinations and delusions usually start between ages 16 and 30.
- Approx. 770,000 patients in Japan.
- Ongoing treatment to prevent recurrence is important since the disease tends to be chronic.

Diabetes Area

Trulicity®

Indications	Type 2 diabetes
Features	Once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist
Revenue	¥ 23.1 billion



About target disease

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

Equa®

Indications	Type 2 diabetes	Features	DPP-4 Inhibitor
Revenue	¥ 24.9 billion		

EquMet®

Indications	Type 2 diabetes	Features	A combination agent that combines DPP-4 Inhibitor with metformin
Revenue	¥ 25.1 billion		

Note: Revenue is fiscal 2018 performance results based on Invoice price. However, revenue for Trulicity® is NHI price-based sales, and revenue for Equa® and EquMet® is fiscal 2018 NHI price-based sales of Novartis Pharma K.K.

North American Market

Psychiatry & Neurology Area

LATUDA®

Indications	Schizophrenia, Bipolar I depression
Features	An atypical antipsychotic with antagonistic effects for dopamine D ₂ , serotonin 5-HT _{2A} and serotonin 5-HT ₇ receptors and also acts as a partial agonist on serotonin 5-HT _{1A} receptors
Revenue	¥ 184.5 billion



About target disease

- Schizophrenia affects approximately 2.4 million adults in the U.S.
- Bipolar disorder is a mental health condition that is characterized by mood swings, including periods of depression and mania. It affects approximately 12.6 million adults in the U.S.

APTIOM®

Indications	Partial-onset seizures (Monotherapy / Combination therapy)
Features	APTIOM is the only exclusively once-daily antiepileptic FDA-approved for use as monotherapy or adjunctive therapy for partial-onset seizures in adults.
Revenue	¥ 20.5 billion



About target disease

- In the U.S., epilepsy is the fourth most prevalent neurological condition and approximately 2.9 million people are living with active epilepsy, including approximately 460,000 children aged 0 to 17 years.

Respiratory Area

LONHALA® MAGNAIR®

Indications	Chronic obstructive pulmonary disease (COPD)
Features	A long-acting muscarinic antagonist (LAMA) delivered using the MAGNAIR Nebulizer System, a nebulizer system that applies eFlow® technology
Revenue	¥ 1.4 billion



BROVANA®

Indications	Chronic obstructive pulmonary disease (COPD)
Features	A long-acting beta-agonist (LABA), for use by nebulization.
Revenue	¥ 33.7 billion



About target disease

- COPD is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or lung abnormalities usually caused by significant exposure to toxic particles or gases.
- Approximately 15.7 million adults in the U.S. are diagnosed with COPD. COPD is responsible for over 1.2 million deaths per year, making it the third leading cause of death in the U.S.

Chinese Market

MEROPEN® (brand name in China: MEPEM®)

Indications	General infections, febrile neutropenia
Features	Standard therapy for severe infections, used in many countries
Revenue	¥ 21.2 billion



valuable pharmaceuticals

Research and Development Areas

Research and Development Areas	Opportunities and Risks	Main Development Products	Product Launch Target
Psychiatry & Neurology Area	<p>Opportunities</p> <ul style="list-style-type: none"> Unmet medical needs are high and the impact on healthy life expectancy is significant. In addition to our track record of continually creating products, including the blockbuster LATUDA®, we have unique research and development expertise acquired by Sumitomo Dainippon Pharma. We have strengths in drug discovery platform that utilize cutting-edge technology (in-silico, biomarkers, iPS cells, etc.) <p>Risks</p> <ul style="list-style-type: none"> Due to lack of biomarkers for diagnosis and efficacy evaluation, research and development in this field is challenging with highly uncertainty. There are policy trends aimed at reducing medical and pharmaceutical expenses in Japan and the U.S. 	lurasidone (Schizophrenia / Bipolar depression)	Japan FY2020
		apomorphine (OFF episodes associated with Parkinson's disease)	U.S. FY2020
		dasotraline Binge eating disorder (BED)	U.S. FY2020
		dasotraline Attention-deficit hyperactivity disorder (ADHD)	U.S. Launch target under consideration
		SEP-363856 (Schizophrenia)	U.S. FY2023
Oncology Area	<p>Opportunities</p> <ul style="list-style-type: none"> Unmet medical needs are high, and rapid scientific advances enable success even for a company on the scale of Sumitomo Dainippon Pharma. We have been continuing drug discovery and development, focusing on inter-cellular network in the tumor microenvironment. We have strong collaborative networks within the Group and with academia and biotech companies. <p>Risks</p> <ul style="list-style-type: none"> There is a high degree of difficulty and uncertainty in research and development. The competition and progress in technological innovation are challenging, and the environment surrounding research and development is changing. There are policy trends aimed at reducing medical and pharmaceutical expenses in Japan and the U.S. 	napabucasin (Colorectal cancer)	U.S. Japan FY2021
		alvocidib (AML)	U.S. Launch target under consideration
		TP-0903 (Solid tumors / Hematologic malignancies)	U.S. FY2023
		TP-0184 (Solid tumors)	U.S. FY2023
Regenerative medicine / cell therapy	<p>Opportunities</p> <ul style="list-style-type: none"> Regenerative medicine/cell therapy is promising as an approach to diseases which cannot be resolved with existing therapeutic agents, and the future market is expected to expand. We are able to draw on many years of accumulated research and the comprehensive strengths of Sumitomo Dainippon Pharma and Sumitomo Chemical as well as networks with academia and biotech companies. We are a front runner aiming for the commercialization of iPS cell-derived cell therapy products. <p>Risks</p> <ul style="list-style-type: none"> As Regenerative medicine/cell therapy is a new field, there are no rules in place, including regulatory approval and drug price listing. Each product requires the establishment of different culturing methods and responses on quality control. Technological progress is rapid, requiring constant catch up. 	SB623 (Chronic stroke)	U.S. Launch target under consideration
		Allo iPS cell-derived products (Parkinson's disease)	Japan FY2022*
Infectious Diseases	<p>Opportunities</p> <ul style="list-style-type: none"> International momentum for global health is increasing, particularly for anti-microbial resistance (AMR) countermeasures. Sumitomo Dainippon Pharma has many years of research and development experience, including antibiotics such as MEROPEN® and vaccine adjuvants. The drug discovery research through international networks that include academia, national research institutes, and foundations has been accelerating. <p>Risks</p> <ul style="list-style-type: none"> Medical standards and insurance are undeveloped in emerging countries. 	Allo iPS cell-derived products (Age-related macular degeneration (AMD))	Japan FY2022*

* Launch target is based on our goal pending agreement with partners.

Growing into a global company through a merger of the strengths and cultures of

A long-standing company established in the 19th century by pharmaceutical industry leaders with the aspiration of making good quality pharmaceuticals widely available

Dainippon Pharmaceutical Co., Ltd.

Osaka Pharmaceuticals Co., Ltd. was established by twenty-one prominent leaders in the pharmaceutical industry in Doshomachi, Osaka in 1897. In the following year of 1898, the Pharmaceutical Plant was established in Ebie, Osaka. The company acquired the semi-governmental Dainippon Pharmaceutical Company in Tokyo, and changed the name of the company to Dainippon Pharmaceutical Co., Ltd. Dainippon Pharmaceutical Co., Ltd. operated a wide-ranging business that included the manufacture and sale of animal health products, food additives, and industrial materials in addition to pharmaceuticals.

Strengths (focus research areas)

- Infection
- Cardiovascular
- Psychiatry & Neurology
- Immunology/Inflammation

Main products

- Other (gastrointestinal): Gastrokinetic agent GASMOTIN®
- Cardiovascular (diabetes): Vasodilator PRORENAL®
- Immunology/Inflammation: Long-acting anti-allergic agent EBASTEL®



1897

1984

A pharmaceuticals company that grew out of a chemicals manufacturer and inherited the business spirit and technology of Sumitomo

Sumitomo Pharmaceuticals Co., Ltd.

Sumitomo Pharmaceuticals Co., Ltd. was established in 1984 from the Research, Development and Manufacturing divisions of Sumitomo Chemical Co., Ltd.'s pharmaceuticals business, as well as the Pharmaceutical Sales division of Inabata & Co., Ltd., the sole distributor of Sumitomo Chemical Company's pharmaceuticals. Sumitomo Pharmaceuticals Co., Ltd. grew through the pharmaceuticals business with its focus on the cardiovascular/diabetes area, the psychiatry & neurology area, the immunology (inflammation/allergy) area, and the oncology/infection area.

Strengths (focus research areas)

- Cardiovascular/Diabetes
- Psychiatry & Neurology
- Inflammation/Immunology/Allergy
- Oncology/Infection

Main products

- Cardiovascular: Therapeutic agent for hypertension and angina pectoris AMLODIN®
- Infection: Carbapenem antibiotic MEROPEN®
- Oncology: Natural alpha interferon SUMIFERON®



Aiming for a pioneering pharmaceutical company with a presence

Creation of Sumitomo Dainippon Pharma Co., Ltd.

Background Increasingly challenging business environment in Japan (curbing of healthcare expenses and domestic industry restructuring)

Tougher global competition around new drug development

Objectives Reinforcing the business base in Japan / Strengthening research and development capabilities and enhancing the pipeline of new drugs / Overseas expansion / Cultivating an ambitious corporate culture

October 1, 2005

Formation of Sumitomo Dainippon Pharma through a merger between Dainippon Pharmaceutical and Sumitomo Pharmaceuticals



2009

Acquisition of U.S.-based Sepracor Inc. (now Sunovion Pharmaceuticals Inc.)



2005 2006

Maximizing synergies from the integration

Establishing four mainstay products

- AMLODIN®
- PRORENAL®
- GASMOTIN®
- MEROPEN®

2007 2008 2009

First Mid-term Business Plan (FY2007-2009)

Solid Fundamentals

Establishing an overseas sales organization
Expanding pipeline in the Psychiatry & Neurology area

Our Main New Products

(Japan)

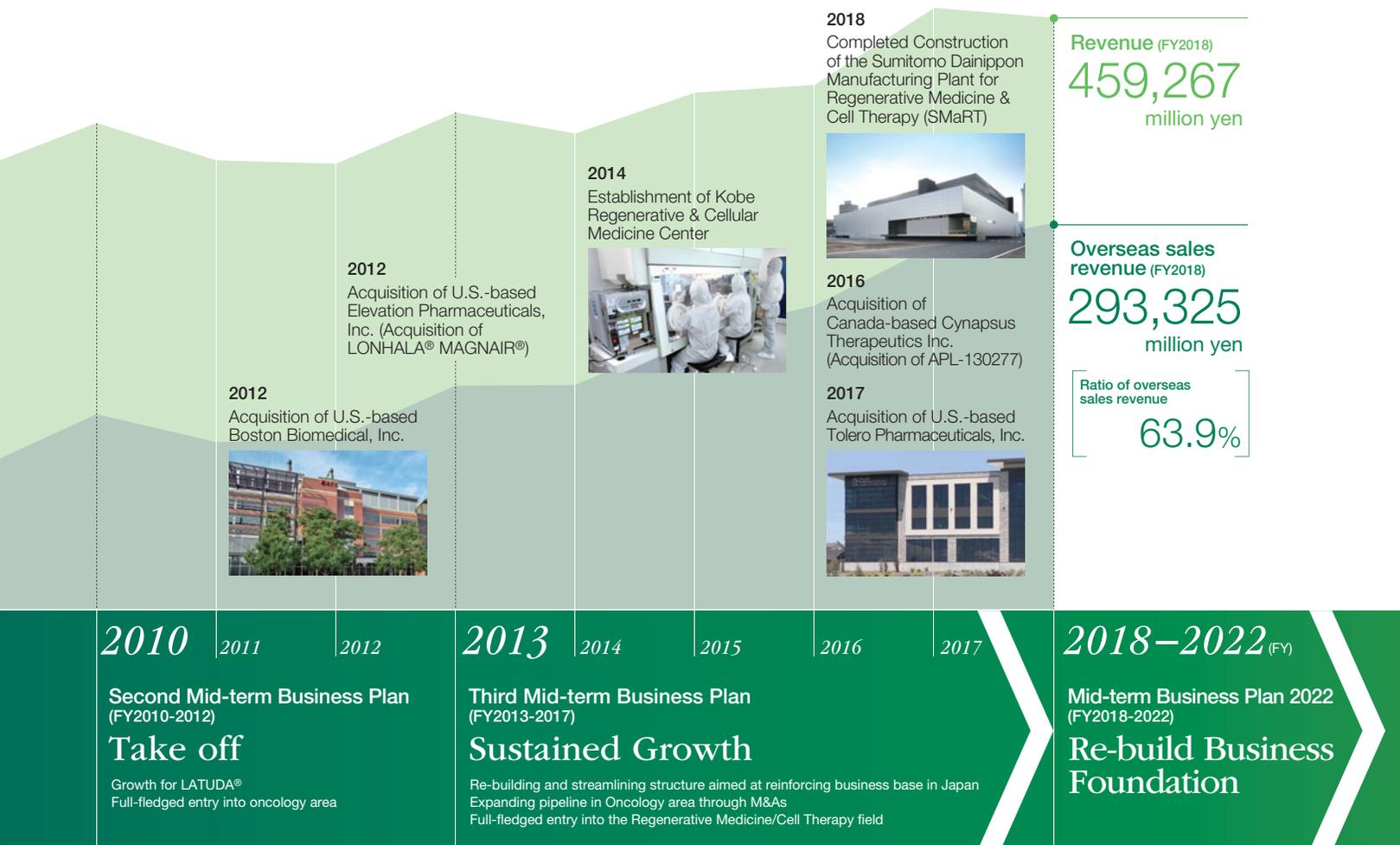
- Therapeutic agent for systemic fungal infection AmBisome®

(Japan)

- Anderson-Fabry disease drug REPLAGAL®
- Atypical antipsychotic LONASEN®
- Therapeutic agent for hypertension AVAPRO®
- Therapeutic agent for Parkinson's disease TRETRIEF®



two companies



(Japan)

- Therapeutic agent for hepatocellular carcinoma MIRIPLA®
- Therapeutic agent for Type 2 Diabetes METGLUCO®
- Therapeutic agent for Type 2 Diabetes SUREPOST®
- Therapeutic agent for hypertension AIMIX®

(North America)

- Atypical antipsychotic LATUDA®



(Japan)

- Therapeutic agent for pruritus REMITCH® (additional indication) Promotion alliance
- Therapeutic agent for Type 2 Diabetes Trulicity® Sales alliance

(North America)

- Antiepileptic APTIOM®
- Therapeutic agent for chronic obstructive pulmonary disease (COPD) Utibron®, etc.

(China)

- Atypical antipsychotic LONASEN®



(Japan)

- Therapeutic agent for Type 2 Diabetes Equa® / EquMet® Promotion alliance

(North America)

- Therapeutic agent for chronic obstructive pulmonary disease (COPD) LONHALA® MAGNAIR®

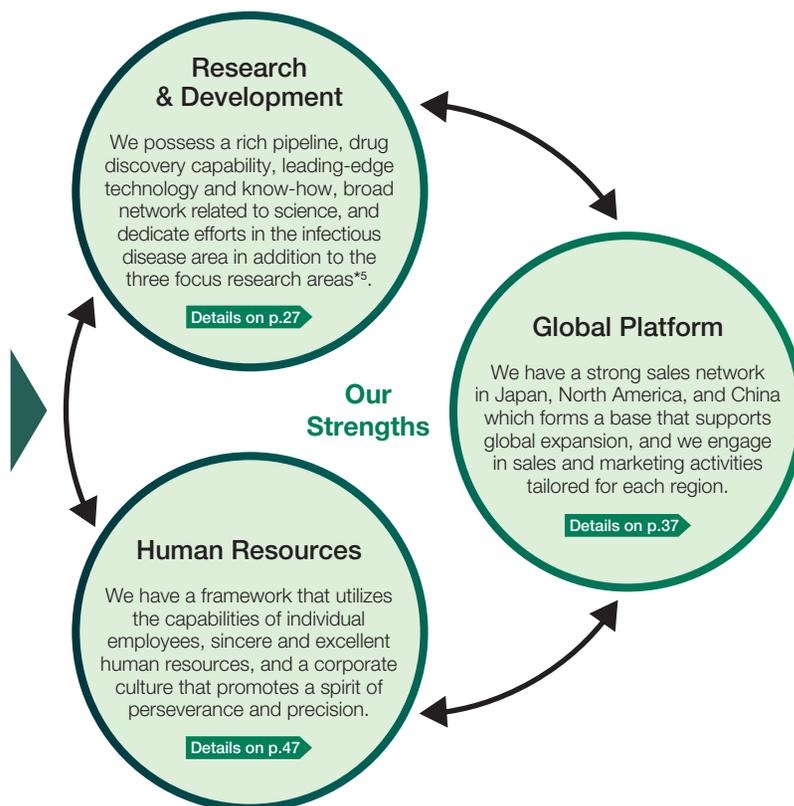


Utilizing our strengths to create the new

By utilizing our Company’s capital (intellectual capital, social and relationship capital, and human capital, etc.) to create and provide 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 sustained corporate value.

Sources of value creation — six types of capital

 Intellectual capital	New drugs under clinical development New drugs launched since the merger*2	24*1 13*1
 Social and relationship capital	Number of medical institutions supplied Number of joint research projects	112,612 113
 Human capital	Number of employees (of which, R&D positions) Number of PC positions*3 Number of participants in the DSP Academy*4 to date Response rate for employee satisfaction survey (fiscal 2018)	3,067 675 41 227 97.9%
 Financial capital	High profitability and robust financial base ROE Ratio of equity attributable to owners of the parent to total assets	10.2% 59.7%
 Manufactured capital	2 plants and 2 research laboratories	
 Natural capital		



As of March 31, 2019 unless otherwise specified
Intellectual capital and financial capital are presented as consolidated figures, and others are presented as non-consolidated figures

*1 As of July 31, 2019

*2 New drugs for which approval obtained since October 2005

*3 Professional Contributor, a job title at Sumitomo Dainippon Pharma

*4 A skill-specific, selective education and training system (details on p.48)

*5 Three focus areas for research: Psychiatry & Neurology, Oncology, Regenerative Medicine/Cell Therapy

drugs patients need

Business Activities

Value provided to society

Value Chain

[Details on p.25](#)

Innovative Drug Discovery

(Number of compounds as of July 31, 2019)

- Psychiatry & Neurology Area**
 New compounds under development: 11
- Oncology Area**
 New compounds under development: 11
- Regenerative Medicine / Cell Therapy Field**
 Projects under development: 6
- Infectious Diseases Area**
 Joint research with academia, etc.

Drug Development, Production, Sale, and Information Provision

- Development (product development and clinical development)
- Sales and Marketing
- Corporate Regulatory Compliance & Quality Assurance / Medical Science
- Production and Quality Control

CSR-based Management / Corporate Governance

- Work Style Innovation, Diversity & Inclusion [Details on p.47-50](#)
- Training and Development of Employees, Health and Safety [Details on p.48, 49](#)
- Strengthening the Corporate Governance, Compliance, and Risk Management Systems [Details on p.59](#)
- Contributing to global health, contributing to local communities [Details on p.51, 53](#)
- Environmental Initiatives [Details on p.54](#)

We have established "Materiality (material issues for CSR-based management)" for our business activities. [Details on p.46](#)

Creating innovative pharmaceutical products and healthcare solutions in areas with high unmet medical needs

Contributing to the development of science

Contributing to improving quality of life (QOL) for patients and their families

Improving sustained corporate value

- Returns to shareholders (stable dividends, increases in dividends linked to improvements in performance)
- Strategic investment aimed at sustained growth (includes research and development investment)

Also contributing to achieving the Sustainable Development Goals (SDGs)

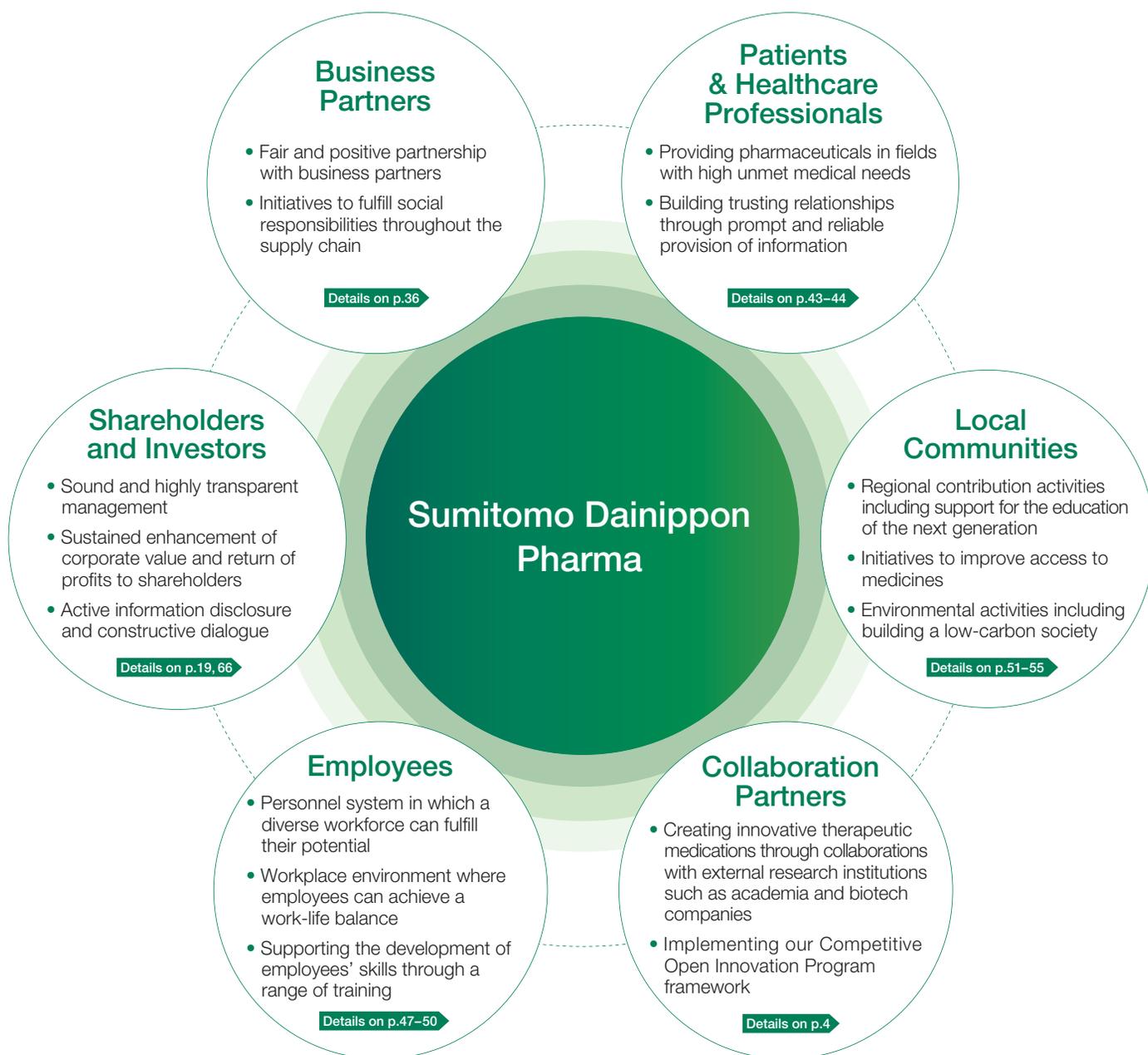


Sustained Growth

Strengthening relationships through

In order to continue providing society with the value of “innovative and valuable pharmaceutical creation,” and to achieve sustained growth ourselves, we believe that it is necessary to deepen dialogue and further strengthen relationships with our stakeholders.

Relationship with Stakeholders



We held an ESG Meeting (discussion meeting) in November 2018.

In November 2018, we held our first ESG Meeting as a forum for explaining our ESG initiatives as well as exchanging opinions with stakeholders.

In this section, we will introduce some of our answers to the questions we received on the day. See our corporate website for details.



Main Questions and Answers

Q In the area of governance, how do you evaluate the balance between risk and return?

A Research and development is the core of our business, and we make firm decisions about whether to proceed to the next stage for individual projects at suitable times in the research and development stage.

Q How do you select the participants for DSP Academy, your selective skill-(career grade-) specific education and training program?

A For example, for the Management Course, which is the highest grade of the DSP Academy, rather than recommendations from departments, the members of the HR Strategy Meeting select 10 people who stand out in a variety of departments as executive candidates for the following fiscal year. The HR Strategy Meeting selects Key talents who have not necessarily worked at Sumitomo Dainippon Pharma for their entire careers, and at least 20% of those selected are women.
(See p.48 for details about the DSP Academy.)

Q What is behind your entry to frontier business in healthcare areas other than pharmaceuticals?

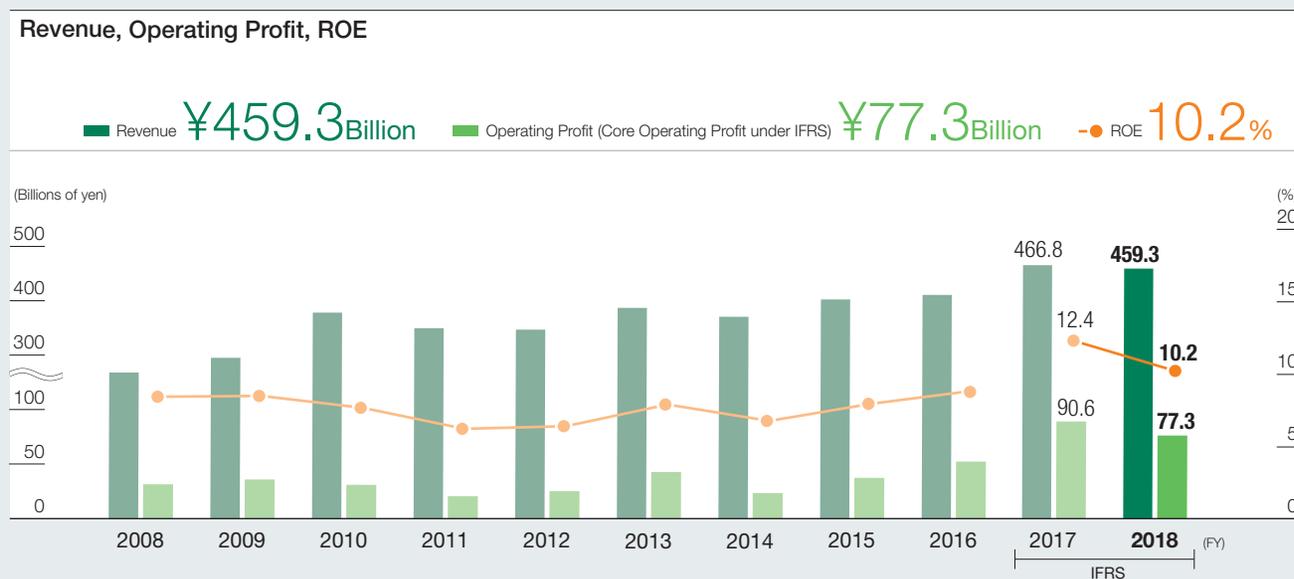
A Rather than being a major departure from the conventional pharmaceutical business, we would like to work on frontier business to provide patients with ways to improve their quality of life (QOL) without being limited to pharmaceuticals.
(See p.34 for details about Frontier business.)

Q Is remuneration for officers determined taking into account the solution of long-term non-financial issues? Are there mechanisms in employee evaluations for increasing the effectiveness of non-financial materiality?

A At the beginning of the fiscal year, the President prepares the management issues and shares them internally. Going forward, by including non-financial materiality in the management issues, we plan to link it with the setting of employee targets. Remuneration for officers is determined on the basis of evaluation through the Company's performance and individual evaluations. In the future, we would like to consider including elements relating to the solution of long-term issues.

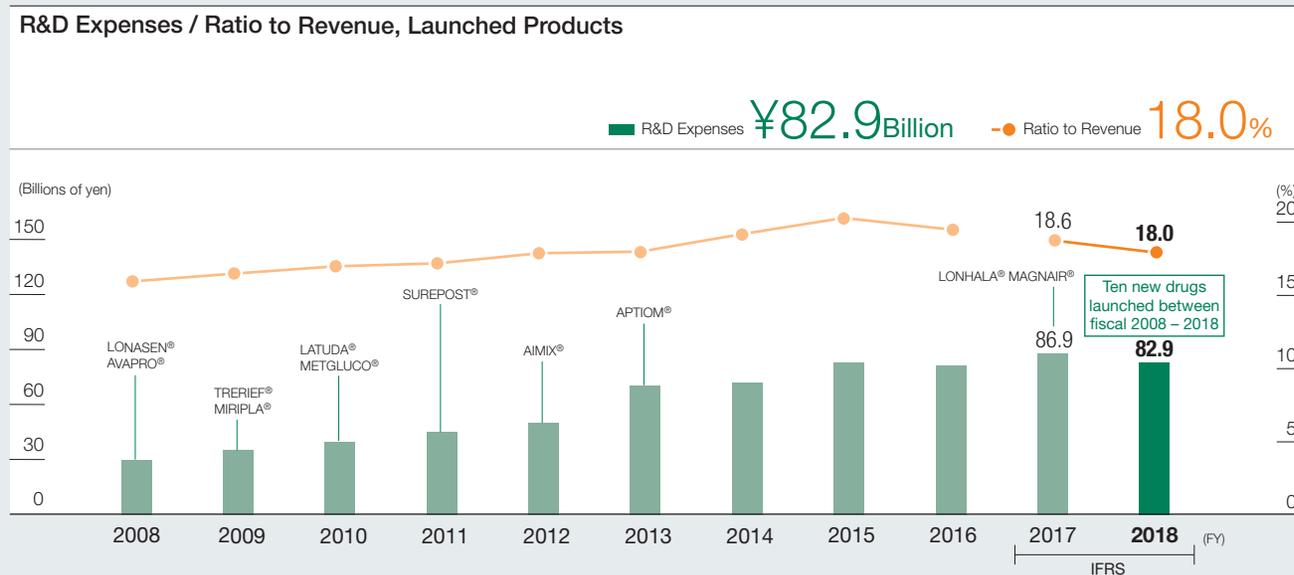
Financial and Non-Financial Highlights

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.



The Group expanded the North America business through the acquisition of Sepracor Inc. (currently, Sunovion Pharmaceuticals Inc.) in the U.S. in 2009 and recorded dramatic growth in revenue in fiscal 2010. Subsequently, LATUDA® in North America grew steadily driving consolidated financial results, and the Group achieved all-time high revenue and core operating profit* in fiscal 2017. ROE was 10.2% in fiscal 2018, with a long-term goal of at least 10%.

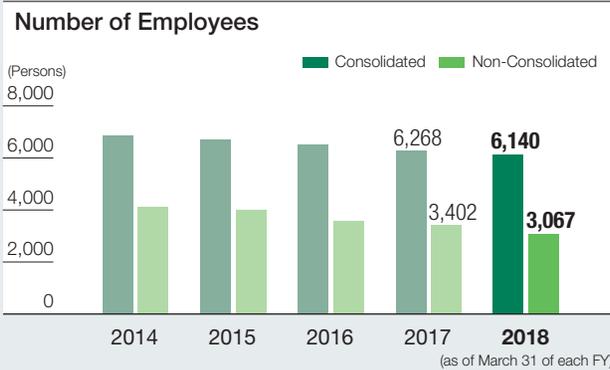
* Core operating profit is calculated by deducting from operating profit any gains and losses resulting from non-recurring factors that the Group designates.



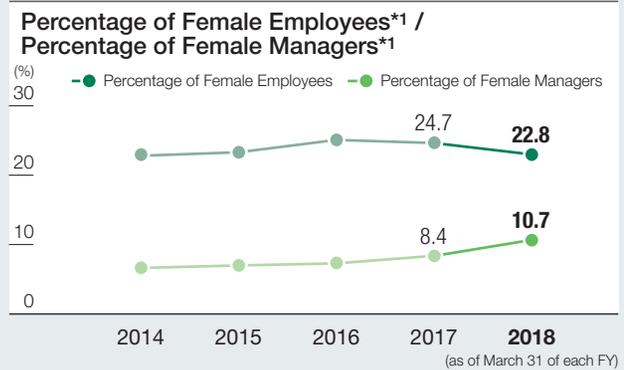
Research and development investment is essential for the Group to delivering innovative new pharmaceuticals to patients. We invest proactively with a target R&D expenses ratio of up to 20%.

As a result, we launched 10 new drugs between fiscal 2008 and fiscal 2018.

Going forward, we will continue to invest proactively in research and development.

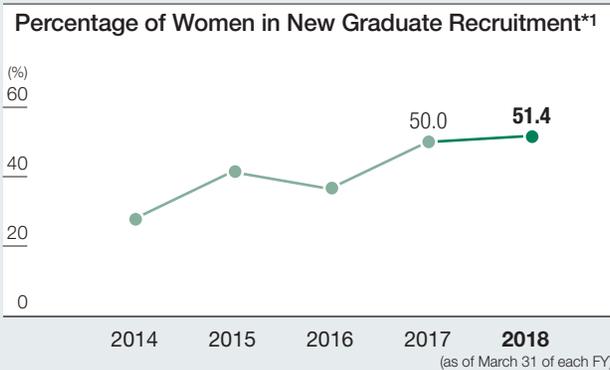


In fiscal 2018, the number of employees (consolidated and non-consolidated) decreased due in part to transfers associated with the establishment of DSP Business Partners Co., Ltd. and relocation and transfers of Genomic Science Laboratories associated with the establishment of the Bioscience Research Laboratory at Sumitomo Chemical Co., Ltd.

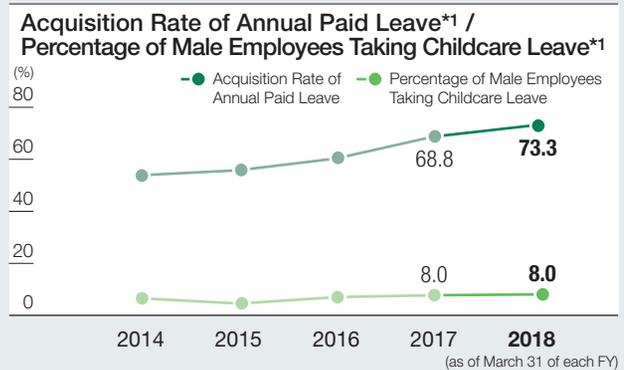


In fiscal 2018, the percentage of female employees decreased due to the secondment of many female employees to DSP Business Partners. On the other hand, there was progress in female employee retention and career development, and the percentage of female managerial staff increased.

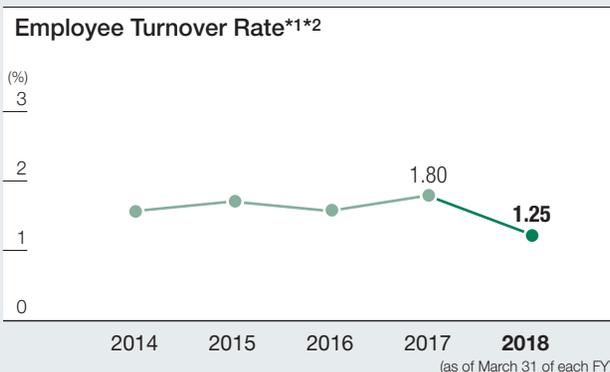
Note: The numbers for the percentage of female managers represent the percentage as of April 1 of the following fiscal year.



Our efforts to promote active participation by women, to create an environment that makes it easy for female employees to combine work with family life, and to support career development have been well received by students, and the percentage of women in new graduate recruitment has been increasing annually.



The acquisition rate of annual paid leave has increased due to the promotion of work style innovation. While there has been no significant change in the percentage of male employees taking childcare leave, at least 90% of employees have taken paternity leave (dubbed "Good Daddy Leave").

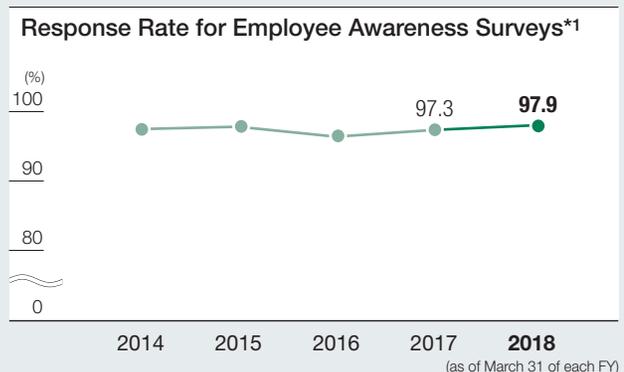


As a result of enhancing our systems and providing an employee-friendly environment, the employee turnover rate due to personal reasons at Sumitomo Dainippon Pharma has been at the 1% level for the past five years.

*1 Non-consolidated

*2 Employee turnover rate due to personal reasons

Note: The CO₂ emissions data provided in this section up until last fiscal year is provided on the "Environment" page (page 55).



Sumitomo Dainippon Pharma conducts fixed-point observations of work satisfaction and company attachment, and has maintained a response rate of at least 95%. This also allows employees to express their opinions frankly to management and is utilized as a tool for two-way communication.

We aspire to be a “Global Specialized Player” with the ability to meet increasingly diversified healthcare needs.

Under our Mid-term Business Plan 2022 (fiscal 2018–2022), Sumitomo Dainippon Pharma is working to reshape our business foundation through the “establishment of growth engines,” and the “building of a flexible and efficient organization.” We will reduce the impact that the approaching expiry of the exclusive marketing period for LATUDA® in North America is expected to have on our business performance, and recover as soon as possible through such measures as aggressive research and development, pipeline expansion, and the launch of a frontier business to achieve sustained growth. We will continue striving to create innovative drugs and provide diverse solutions, as we aspire to establish ourselves as a “Global Specialized Player” by 2033 with the ability to meet increasingly diversified healthcare needs.

Hiroshi Nomura

Representative Director, President
and Chief Executive Officer



Q₁ Looking back over fiscal 2018 (the year ended March 31, 2019), how would you rate the Group's business performance?

A₁ We experienced declines in revenue and profit due to lower sales in Japan and impairment losses in North America.

The fiscal 2018 consolidated performance saw a year-on-year decline in sales and profit, attributed to a decrease in sales in Japan and the recording of impairment loss on intangible assets in North America, among other factors. While the North America segment recorded revenue growth due to an increase in sales of LATUDA® and APTIOM®, the Japan segment recorded a decline in sales due to the impact of NHI drug price revisions implemented in April 2018, as well as lower sales of long-listed products. As a result, revenue was ¥459.3 billion, down ¥7.6 billion year-on-year, and core operating profit was ¥77.3 billion, down ¥13.3 billion. In addition to the decline in core operating profit, we recorded impairment losses on R&D and marketing rights in North America, and incurred structural reform expenses associated with the consolidation of our production sites. Consequently, the operating profit was ¥57.9 billion, down ¥30.3 billion.

In terms of R&D, we received approval in July 2018 for our partial change application for an additional

indication of Parkinsonism in dementia with Lewy bodies for TRERIEF® in Japan. We also obtained approval in March 2019 for RETHIO® in pediatric malignant solid tumors. With regards to LATUDA®, we obtained approval of the drug for the treatment of schizophrenia in China in January 2019, while we also applied for approval of the drug for schizophrenia and bipolar depression in Japan in July 2019. In July 2018, we submitted an application for approval of the LONASEN® transdermal patch for schizophrenia in Japan and obtained approval in June 2019. We received Complete Response Letters (CRLs) from the U.S. Food and Drug Administration (FDA) indicating that approval is not possible at present for dasotraline for ADHD and apomorphine hydrochloride for OFF episodes associated with Parkinson's disease, for which we have pending applications for approval in the U.S. However, we are preparing to resubmit the application for apomorphine hydrochloride. At present, we are reviewing the development plans for dasotraline for ADHD, and SB623 for chronic stroke, which failed to achieve the primary endpoints in the Phase 2b study.

Thus, while we recorded declines in revenue and profit on the business performance front in fiscal 2018, core operating profit, which is our focus, was in line with the initial forecast due to appropriate cost controls and the results of structural reform. On the other hand, we consider delays in R&D and market launch plans to be

Financial Results for Fiscal 2018 (Billions of yen)

	FY2017	FY2018	YOY change (%)
Revenue	466.8	459.3	-7.6 (-1.6%)
Core operating profit	90.6	77.3	-13.3 (-14.7%)
Operating profit	88.2	57.9	-30.3 (-34.4%)
Net profit attributable to owners of the parent	53.4	48.6	-4.8 (-9.0%)

Major topics of Fiscal 2018

Japan

- Improved efficiency in manufacturing (consolidated 4 production sites into 2 sites)
- Declines in revenue and profit due to NHI price revisions and decreases in revenue for long-listed products

North America

- LATUDA® ANDA lawsuits concluded through settlement, except for one lawsuit pending, with condition of settlement that generic versions of LATUDA® may enter the market commencing February 20, 2023
- Launched LONHALA® MAGNAIR®
- Revenue shortfall in respiratory portfolio

China/Others

- Achieved steady growth

R&D

- Success in 3 approvals, 1 NDA submission
- Received Complete Response Letters for dasotraline (ADHD) and apomorphine from FDA
- Success in pivotal study: Schizophrenia for lurasidone (Japan)
- Success in POC*1 study: Schizophrenia for SEP-363856 (US) / Not successful in POC study: Chronic stroke for SB623 (US)
- Initiated clinical studies for 4 assets / Initiated Phase 2 study for 1 asset

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

important issues that need to be addressed.

Moreover, one of the main topics of fiscal 2018 was the resolution of the LATUDA® Abbreviated New Drug Application (ANDA) lawsuits in North America through settlement, except for one lawsuit. The settlement has made it possible for generic drug manufacturers to market generic versions of LATUDA® from February 2023. Until this time, Sumitomo Dainippon Pharma plans to invest the cash flow generated by LATUDA® in future growth opportunities.

Q₂ How do you regard the future environment for pharmaceutical companies?

A₂ We believe that it will be an era of diversified healthcare needs requiring not only new drug development, but also contributions to disease prevention and global health.

Sumitomo Dainippon Pharma in April 2019 announced the Mid-term Business Plan (MTBP) 2022, which runs from fiscal 2018 to fiscal 2022. Its release was delayed due to the timing of the LATUDA® ANDA lawsuits. In the formulation of the plan, we considered the changes in the environment for pharmaceutical companies that are expected over the next 15 years.

Although it is difficult to forecast the future accurately, the acceleration of the 4th Industrial Revolution on a global

scale, together with the aging society and the decline in the working population mainly in developed countries, particularly Japan, can be considered to be macro-trends. It is also expected that the status of Japan and Europe in the global economy will fall due to the rise of China and other emerging countries. Moreover, we expect that society's demand for contributions to global health issues, such as infectious disease control, will increase even more due to rising populations in Asia and Africa. In addition to advancing healthcare, the need for disease prevention is expected to rise further in the future.

In the world of medicine, we expect to see progress with respect to understanding disease mechanisms, early diagnosis, and prevention and intervention methods, making more diseases treatable. In addition, we also expect commercialization of new treatment methods, particularly the use of new modalities*², such as regenerative medicine and precision medicine*³. Furthermore, the use of digital technology, such as big data, artificial intelligence (AI), and the Internet of Things (IoT), will facilitate more advanced and efficient services in the medical and healthcare sector.

In this environment, the role of pharmaceuticals will remain important, and pharmaceuticals will continue to be the major part of the solution we will provide for unmet medical needs. We anticipate that the pharmaceutical companies of the future will increasingly be expected to play a societal role, which will include enhancing preventative healthcare services and contributing to global health, in addition to creating new drugs as innovative treatments. The message of our MTBP is that the next 15

Changes in environment surrounding pharma (Anticipated changes over the next 15 years)

<p>Society</p> <ul style="list-style-type: none"> • Acceleration of the 4th Industrial Revolution • Aging society with fewer working population • Rise of China and other emerging countries, relatively lower positioning of Japan and Europe • Increasing corporate social responsibilities for contribution to global health 	<p>Healthcare/ Healthcare System</p> <ul style="list-style-type: none"> • Further aging society • Higher pressure on healthcare costs • More disease-prevention measures available and more diseases treatable • Realization of new modalities such as regenerative medicine • Greater use of big data and AI technologies 	<p>Healthcare Industry</p> <p>Solution to unmet medical needs</p> <ul style="list-style-type: none"> • Pharmaceutical products remain at the core of solutions • Digital technologies become available • Preventive medical care becomes available
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years will be a “Time for Change.” It is our aim to establish a new business model that can achieve sustained growth over the medium-to-long term by embracing these changes in social needs and advances in medical technology and information technology to proactively transform our business.

*2 Modality traditionally referred to the use of medicines, such as low molecular compounds, biopharmaceuticals, and nucleic acid medicine, but here we include therapies using digital technology.

*3 Precision medicine refers to a new approach involving a shift from conventional genome research to clinical medicine that includes stratification of individual patients in an effort to deliver more effective treatment.

Q₃ Please explain your medium-to-long term corporate vision.

A₃ We aspire to establish ourselves as a “Global Specialized Player” by 2033 with the ability to meet increasingly diversified healthcare needs.

Under our MTBP, we have formulated our new vision, “For Longer and Healthier Lives: We unlock the future with cutting-edge technology and ideas,” in view of the changes in the external environment. We have also set a position we aspire to establish in 2033 as a “Global Specialized Player” with the ability to meet increasingly diversified healthcare needs. While 15 years may appear to be a long period of time, it encompasses three 5-year plans that will pass quickly considering the time required for pharmaceutical R&D. We recognize that during this period,

setting priorities and demonstrating strengths in our specialty fields is important.

As the “Global Specialized Player” that we aspire to become, we will be a company that provides diverse healthcare solutions demanded by society through our new frontier business, in addition to being a global leader in psychiatry and neurology, oncology, and regenerative medicine/cell therapy, which are our three focus areas.

In the psychiatry and neurology area, where we already have a high profile in the global market, we aim to continue to be an innovator with the ability to make high quality contributions to patients through development of new drugs and provision of treatment options for diseases that continue to be difficult to treat. We will position the oncology area as a new engine to drive sustained growth for Sumitomo Dainippon Pharma with the anticipated introduction of several global products and the establishment of a global “DSP oncology” brand. In the regenerative medicine/cell therapy area, our cell culturing and differentiation technology is extremely advanced, and we are confident that exhibiting our uniqueness through the pursuit of sophisticated production technology and state-of-the-art science based on open innovation will allow us to establish an unrivaled position. We aim to turn a profit in this area during the period of the next MTBP (2023-2027), and to expand it into a business worth around ¥200 billion on the global scale by 2033. We plan to launch initially in Japanese markets products that are currently under development in the neurology and ophthalmology areas, and in overseas markets during the

Goal and Vision 2033





next MTBP period. Furthermore, we aim to expand into next-generation medical treatments, such as genome editing, peripheral organ regeneration, and autologous cell therapy, by 2033. We already have employees around the world who are actively engaged in our three focus areas, and we expect that the reinforced focus on these areas will boost their motivation.

In addition to our three focus areas, we will promote R&D in the infectious disease area through collaboration with academia. At present, we are promoting research projects that include drugs to treat antimicrobial resistant bacterial infections, and a universal influenza vaccine and malaria vaccine using our vaccine adjuvant, with a target launch in the 2020s. In addition to fulfilling our aspiration to contribute to global health, the planned drugs to treat antimicrobial resistant bacterial infections and the universal influenza vaccine are projected to become blockbuster products.

The frontier business is rooted in our desire to not just treat already sick people, but also help people stay healthy amid an expansion of future healthcare needs that will extend from prevention through convalescence. We laid the groundwork in the current MTBP period by setting up the Frontier Business Office in April 2019. We will strive to commercialize healthcare solutions that provide new value to society, focusing on areas where we can anticipate synergies with our existing pharmaceutical operations with the objective of creating a business worth ¥100 billion on the global scale by 2030. During the current MTBP period, we will evaluate internal and external projects under development and new opportunities at an early stage, and commercialize those that are promising. During the next MTBP period, we plan to establish the frontier business as a new growth engine worth tens of billions in yen.

Q₄ Please explain the specific growth strategies in the Mid-term Business Plan 2022.

A₄ We will focus on the establishment of new growth engines and the reinforcement of the organizational foundation to support them, as part of efforts to prepare for post-LATUDA® revenue replacement*⁴.

*⁴ After the expiry of the exclusive marketing period for LATUDA® in the U.S.

Under this MTBP, we will significantly reshape our business foundation through the “establishment of growth engines” and the “building of a flexible and efficient organization.” As for the reason why we believe it is necessary to reshape our business foundation, it would be a major challenge to forecast our growth in the next MTBP, assuming that there was no LATUDA®. We are aware that our sense of urgency should not be diminished because we currently have revenue from LATUDA®, and we want to demonstrate the changes needed to “reshape our business foundation”, using revenue and cash flow during the exclusive marketing period for LATUDA® for our future growth. Going forward, we plan to reinforce this awareness through dialogue with our employees to ensure continued alignment and unity.

In terms of the “establishment of growth engines,” we will not only continue to focus on R&D and business growth in our three focus areas, but also promote drug discovery utilizing external networks, primarily at our sites in Japan and the U.S. In addition, we will also work to strengthen our innovation base through new approaches to drug discovery, such as the realization of precision medicine by leveraging cutting edge research results and biomarkers. Moreover, in order to obtain results even in highly uncertain areas, we will focus on improving the probability of success and efficiency in research and development through targets that anticipate changes in the scientific and medical environment; evidence-based and objective evaluation and decision-making; thorough risk management; biomarkers; and big data.

In the psychiatry and neurology area, we are prioritizing the global development of SEP-363856, a new generation anti-psychotic agent which does not bind to dopamine 2 (D₂) receptor. With a target launch in fiscal 2023, we hope to grow SEP-363856 into a product with growth potential beyond LATUDA®. In the oncology area, we are prioritizing the speedy development of napabucasin and early stage assets for the early establishment of an

oncology franchise.

In terms of our regional strategy, we will reinforce business infrastructure, with China as the third pillar after the leading markets of Japan and North America. We will also position Asia as a future growth market and reinforce the functions of our Southeast Asian subsidiaries. In Japan, we will work on a turnaround to a growth trajectory during the current MTBP period by launching new products, including LATUDA® and LONASEN® tape promoting the development of SEP-363856 and napabucasin, which are global development compounds; and expanding in-licensed products in the diabetes area by leveraging our solid Japan marketing base. These and other measures will lay the groundwork to achieve ¥200 billion in revenue during the next MTBP period. The environment for medical representatives (MRs) in Japan has changed, but we will focus on education of MRs more than in the past, and expect to be able to return to a growth trajectory by introducing new products.

In North America, we will pursue profit maximization for LATUDA®, while continuing our focus on growing LONHALA® MAGNAIR®, promoting development of SEP-363856, which is a priority, and obtaining approval for napabucasin. We will also focus on obtaining approval for and launching dasotraline and apomorphine, in preparation for LATUDA® revenue replacement. In addition, we also plan to secure compounds in the psychiatry and neurology area that will drive growth in the first half of the next MTBP period through M&As.

In China, we will continue to expand MEROPEN®, in

addition to focusing on the early establishment of new products in the psychiatry and neurology area such as LONASEN® and LATUDA®, and working on the simultaneous development of SEP-363856 in Japan and China. We will further implement compliance education in China to promote a culture that prioritizes compliance over everything else. In Southeast Asia, we will reinforce the functions of our subsidiaries in Singapore and Thailand, and strengthen the business infrastructure as growth markets after China.

Another strategy pillar of the MTBP is strengthening the organizational foundation to support these growth engines. We will use digital innovation to enable our organization and talent to identify changes in the external environment and adapt proactively and flexibly, while maintaining the ability to do things diligently, which is called “CHANTO” in Japanese.

It is not uncommon for pharmaceutical projects to extend over a long period of five to ten years. However, we expect to create better products by keeping a watchful eye on changes in the external environment and incorporating advances in social systems and technology.

Our concept of “CHANTO” refers to the capability to continuously foster and deliver innovation to patients and other customers, while transforming our organization in flexible ways to adapt to changes in the world. Pharmaceutical R&D may not always proceed as expected. However, obtaining approval for and launching our pipeline of products in a timely manner is essential for future growth. Even in difficult circumstances, we have to complete our

Mid-term business plan 2022 basic strategies: Rebuild business foundation



R&D and deliver innovative treatments to patients. As expected, our employees have always performed their jobs professionally in the past. Just as in the world of professional athletes there are various levels ranging from novices to top players, there are also various levels for delivering complete performance as professionals in the workplace. Going forward, we would like all employees to ask themselves what “CHANTO” means for their job and to further develop their skills to produce the highest quality results as true professionals. It is also important to constantly discuss “CHANTO” and instill the concept across the organization.

Q₅ Please explain your business goals and financial strategy.

A₅ We will aim for ¥600 billion in revenue and ¥120 billion in core operating profit in fiscal 2022 through proactive R&D investment and strategic M&As.

In terms of the business goals for fiscal 2022, the final year of the current MTBP, we are targeting ¥600 billion in revenue and ¥120 billion in core operating profit. In achieving these goals, we are also aiming for ROIC of 10% and ROE of 12% as the KPIs of capital efficiency. With regards to streamlining expenses, we recognize that we implemented adequate retrenchment in fiscal 2016 through fiscal 2017. Going forward, we will aim to enhance capital

efficiency primarily through the expansion of core operating profit.

We will continue utilizing profit earned for strategic investment, including M&As and aggressive investment in R&D. We expect the cumulative profit of core segments to be more than ¥850 billion between fiscal 2018 and fiscal 2022, of which we plan to allocate ¥450 billion for R&D investment. We have also set an M&A range of ¥300 billion to ¥600 billion using cash generated and financial leverage. In terms of our M&A and in-licensing strategy, we will prioritize product pipeline enhancement, rather than corporate expansion. We believe that a certain level of large-scale investment is necessary as we will target late-stage assets for pipeline acquisitions in the psychiatry and neurology area, which will contribute to profit from fiscal 2023 onward. We also plan to prioritize investment aimed at the acquisition of pipeline products and technologies in the three focus areas, which will contribute to profit from fiscal 2028 onward.

Financial goals and dividend policy

FY2022 Business goals

Revenue	¥600billion
Core operating profit	¥120billion
ROIC	10%
ROE	12%

Dividend policy

Maintain a consistent payment policy but also consider reflecting any improvement in the Company's performance in the dividend payment 5-year average payout ratio: 20% or higher
ROE (Return on Equity) Aim to achieve ROE of 10% or more over the long term

FX rates: 1US\$ = ¥110, 1RMB = ¥16.5 ROIC: (core operating profit –income taxes) / (capital + interest-bearing liabilities)

Note: Business goals 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 goals and involve both known and unknown risks and uncertainties. Accordingly, goals may not be realized as described.

Q₆ Do you have a fiscal 2019 message for stakeholders?

A₆ We will aim to instill an awareness of “CHANTO” and achieve our goals.

In fiscal 2019 (the year ending March 31, 2020), we are forecasting revenue of ¥475 billion, up ¥15 billion year-on-year, and core operating profit of ¥77 billion, as North America will offset the decline in revenue and profit in Japan.

Regarding dividends, we place emphasis on the appropriate distribution of results backed by performance, and our policy is to provide stable dividends, in addition to offering increases in the dividend linked to any improvement in performance. Further, we aim for a five-year average payout ratio of at least 20% under the MTBP. Based on these policies, we plan to pay an annual dividend of ¥28 per share in fiscal 2019, which is unchanged from the previous fiscal year.

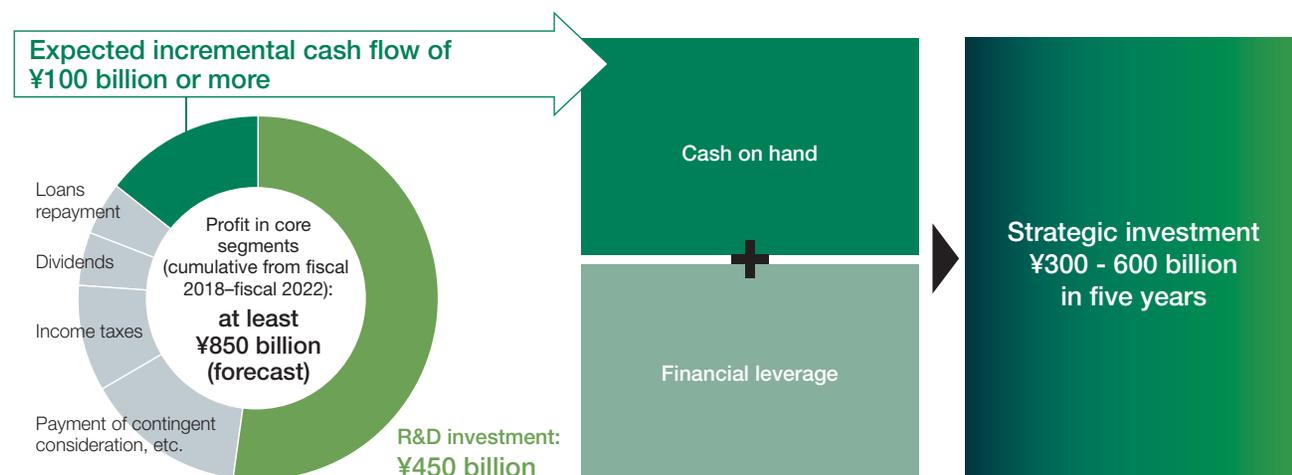
Based on the Mid-term Business Plan 2022, we will reshape our business foundation through the “establishment of growth engines” and the “building of a flexible and efficient organization.” Fiscal 2019, which is the second year of the plan, will be an important year for creating the foundation, which is aimed at achieving ¥200 billion in future revenue in Japan, establishing a path for growth in North America in preparation for post-LATUDA® revenue replacement, and laying the groundwork for growth



markets in China and the rest of Asia. As a professional organization, we are committed to instilling company-wide awareness of “CHANTO,” and steadily achieving our financial and non-financial goals. We aspire to establish ourselves as a “Global Specialized Player” in order to realize sustained growth and enhance corporate value over the medium- to long-term. We look forward to the ongoing support of all our stakeholders.

Representative Director, President and Chief Executive Officer

Financial Policy: Ensure Strategic Investment with Financial Leverage





I look forward to seeing Sumitomo Dainippon Pharma demonstrate its unique competitive strengths in the global pharmaceutical industry.

Shinichiro Hyogo

Chief Analyst & Chief Fund Manager ESG Department
Asset Management Division
Mitsubishi UFJ Trust and Banking Corporation

Dialogue with the Chairman

We will nurture our corporate culture and develop our human resources to accelerate innovation.

We are evolving into a professional group that can consistently produce reliable results.

Masayo Tada

Representative Director, Chairman



Sumitomo Dainippon Pharma is currently working on the “building of a flexible and efficient organization” to support medium- to long-term business growth under our Mid-term Business Plan 2022.

This year, we invited Shinichiro Hyogo, Chief Analyst and Chief Fund Manager in the Asset Management Division at Mitsubishi UFJ Trust and Banking Corporation, to discuss our corporate culture and human resource development programs with Masayo Tada, Chairman of Sumitomo Dainippon Pharma. Shinichiro Hyogo has been responsible for Sumitomo Dainippon Pharma as a buy-side analyst since before the merger between Dainippon Pharmaceutical and Sumitomo Pharmaceuticals as well as playing an

active role in ESG investment, including service as a government committee member and giving lectures.

—We will nurture a culture that identifies changes in the business environment and continually rises to new challenges in a proactive manner.

Hyogo: It has been over ten years since the merger. How do you think the corporate culture has evolved over this period at Sumitomo Dainippon Pharma?

Tada: The 2005 merger between Daiinippon Pharmaceutical and Sumitomo Pharmaceuticals was a major decision to ensure our ability to continue thriving in the pharmaceutical industry, and it was necessary to achieve synergies as quickly as possible. The issue that received the maximum attention from the management team at the time was a fusion and harmony of minds.

Hyogo: It would not be a good start if every employee was heading in a different direction. I also experienced a large-scale merger at the bank I used to belong to, and was acutely aware of the difficulties involved in combining corporate organizations with disparate histories.

Tada: We researched examples of post-merger organizational management successes and failures with the help of an external consulting company. We were prepared for it to take two or three years to achieve harmony, but things went more smoothly than expected. As a result, we are proud to have nurtured an amazing corporate culture, in which the positive elements that both companies possessed before the merger are even more pronounced, namely diligence, integrity, respect for others, and trust. However, there has not been as much progress in terms of “nurturing a corporate culture that rises to challenges,” which was part of our basic strategy at the time of the merger and implied a culture that is capable of rapidly identifying changes in the business environment and proactively addressing those new opportunities. Ever since my time as President, we have been taking a variety of measures to help such a culture take root, but we are aware that further steps are still necessary.

Hyogo: Generally, the bigger a company grows, the stronger the orientation of its employees toward stability becomes. However, for sustained growth, a pharmaceutical company must innovate to continue providing highly novel, differentiated pharmaceuticals. Doing this requires the ability to constantly rise to challenges and take risks. If we are talking about whether there is enough power to drive such innovation in the organization, your view is that it is still inadequate.

Tada: Yes. When I served as President, I considered it my biggest challenge. We had previously established the slogan “Change for Challenge!”, “Seek Something New!” Now, in the Mid-term Business Plan 2022, we are prioritizing the emphasis on “CHANTO (capability to continuously foster and deliver innovation to patients and other customers, while transforming our organization in flexible ways to adapt to changes in the world),” and the “nurturing of our corporate culture and development of human resources to accelerate transformation.”

Hyogo: What kind of measures do you think are required

to establish this “culture of challenge”?

Tada: The first requirement is the dedication of managers or leaders. I have dedicated myself to overseas expansion and entry into new fields in the past, and will reiterate my dedication internally and externally in the future together with other members of the management team. The second requirement is awareness in the workplace. Our managers need to fully understand the meaning and importance of a challenge, and provide support for the challenges taken on by every employee. The third requirement is the establishment of a personnel system that encourages people to take on challenges. I believe that it is difficult to properly identify the attitude of employees toward challenges in terms of numbers, and it is important how we evaluate their efforts and provide incentives. The fourth element is the diversity of human resources, which means we will have to recruit talented employees with unique ideas and special skills. For example, if we want to bring about digital innovation within our organization, we should recruit individuals with the required skills, rather than having our employees with other skillsets take on this specific capability. I think we should establish and foster a culture of challenge by combining these four elements.

Hyogo: Did the acquisition of Sunovion Pharmaceuticals Inc. (formerly Sepracor) in the U.S. and overseas biotech companies, have any significant impact on corporate culture?

Tada: As you say, the first U.S. acquisition in 2009 was a major step toward globalization for us. As it was a major acquisition worth around ¥250 billion, which was comparable to our net sales at the time, the decision to make the acquisition in the first place was a statement of intent about challenge, and employees must have been keenly aware that the company was embarking on significant change. I experienced first-hand how diversity of human resources creates dynamism in various aspects ranging from values and approaches to work styles at overseas companies. In addition, we subsequently acquired biotech companies, including Boston Biomedical Inc. in 2012 and Tolero Pharmaceuticals Inc. in 2017, whose employees have been competing in a world where they are used to taking on challenges. There is no need to make our corporate culture identical to theirs, but we will learn what we can from their entrepreneurial spirit and work to incorporate it in transforming our own corporate culture.

— We will create a professional organization that can maximize results through active job rotations and selective training.

Hyogo: Moving on, I will ask about the personnel system. I have the impression that Sumitomo Dainippon Pharma implements more active personnel rotations than other companies. For example, director-level personnel serve successively in various departments. Is this also aimed at increasing the diversity of human resources in your organization?

Tada: Yes. We implement active job rotations for various grades of employees, not just directors, as a measure aimed at “nurturing a corporate culture that rises to challenges.” Based partly on my own experience, I am convinced that people grow most in a new environment. When transferred to a new department, employees make great use of their brains to adapt to that environment. This means that they study various aspects and build new relationships in order to achieve their new mission. Such new experiences serve as a stimulus for growth. In addition, that division also benefits from the addition of employees with experience accumulated in a different department. While there may be a slight decline in work-readiness at the departments that transferred individuals, after a while new personnel who gained opportunities through the transfer of their predecessors should grow and fill the gaps.

Hyogo: This means that appropriate job rotations can be expected to have a significant vitalizing effect both for the individual and the organization. However, I think many occupations at a pharmaceuticals company require a high

level of expertise, so do employees gain sufficient specialist skills and experience when transferred after two to four years?

Tada: It is as you say. In order to solve that problem, we have revised the personnel system at Sumitomo Dainippon Pharma, and we have been providing two career paths for executive employees since fiscal 2016. One path is the Professional Contributor (PC) role, which maximizes results through outstanding individual skills. The other path is the Professional Manager (PM) role, which maximizes results through expert organization management skills.

Hyogo: The work styles of employees and what they demand from a company are also changing with the times, so the personnel system and the human resource development process will also have to change in a flexible manner.

Tada: We have made various enhancements to our training system. In the past, the system was based on grade-specific training for all employees. However, in addition to this traditional system, we launched the DSP Academy in fiscal 2016 as a training system to encourage “challenge.” This is a selective training program that targets ambitious employees in each level from newer employees and supervisors to middle management who have the potential to be executive leaders in the future.

Hyogo: Approximately, how many employees have been selected for the DSP Academy?

Tada: Including the Management Course, which aims to train our future corporate managers, there are four levels for early identification of future division manager candidates, next-generation leader candidates, and employees with outstanding performance. We expect approximately 400 employees in total to participate in the five years, which began in fiscal 2016. Going forward, we will further improve our individual training programs to transform our employees into professionals who can consistently contribute to Sumitomo Dainippon Pharma Group’s achievements.

— We will discover next-generation leader candidates through the HR Strategy Meeting.

Hyogo: The topic of diversity in human resources came up a bit earlier than planned. How do you plan to promote diversity and inclusion, including active participation by women, in the future?

Tada: I think we are making steady progress with regards to active participation by women. At present, many women are playing important roles at Sumitomo Dainippon



Pharma, and two women appointed as Executive Officers are serving as positive role models for women seeking to advance their careers.

Hyogo: Through what mechanisms are you developing the next generation of leaders?

Tada: The head of Global Corporate Strategy, who led her team in developing the Mid-term Business Plan 2022, was a graduate of the Management Course, for which I served as a mentor. The HR Strategy Meeting also serves a major role in developing and selecting the next generation of leaders in general, including women. This type of meeting is convened periodically with all of the Directors, some of the Executive Officers, and the heads of divisions as necessary. Such meetings have been held at least 100 times over the past ten years. At each meeting, we deliberate on personnel issues, including work style reform and diversity, and also discuss promising talent in the manager class by name. We also introduced a talent management system in fiscal 2018 to boost employee development.

Hyogo: You have a mechanism for creating a list of next-generation leader candidates through a series of such meetings and developing these candidates through grade-specific selective training. What is the percentage of female managers at present?

Tada: It is about 10%. We had set a target of at least 10% by 2020, but we achieved the goal more than a year and a half earlier. In the future, our aim is that the percentage of female managers will be about the same as the percentage of female career track employees (approximately 20%). We are also conscious of continuing to identify women for 20% of the opportunities for selective training.

Hyogo: Finally, please explain your approach to compliance.

Tada: Compliance is the area where Sumitomo Dainippon Pharma is making the greatest efforts. By taking the time to provide thorough training, we have reinforced a strong focus on conducting business with the highest standards to always achieve our sales objectives in a compliant manner. This makes me feel that awareness of compliance has definitely been instilled well into the workplace. In fact, also in the China market, we have provided thorough training and education that prioritizes compliance over everything else, including sales.

Hyogo: It is because Sumitomo Dainippon Pharma has always had a corporate culture that values diligence, integrity, and trust in the first place that the understanding of laws and regulations has deepened and awareness of compliance has naturally increased. I think that it will be possible to further develop your organization and promote diversity of human resources to nurture a culture of



challenge in the future precisely because Sumitomo Dainippon Pharma has such an amazing corporate culture, including a high level of compliance awareness, and robust professional development.

Tada: I agree. In order to transform our corporate organization into one that takes on challenges and produces steady results, I think we obviously need to reinforce these elements in our culture.

Hyogo: You are right. From the perspective of long-term investment, we are reassured when companies can create organizations with a high level of reproducibility. Although there may be difficulties in the short term, a company will always benefit in the long-term if its organization is generating reproducible positive business results.

Tada: Human resources are the key to that.

Hyogo: Yes. I heard some very interesting things in today's discussion. I look forward to seeing Sumitomo Dainippon Pharma demonstrate its unique competitive strengths in the global pharmaceutical industry through human resource development.

Tada: Thank you. We will do our best to meet your expectations.

We fulfill our mission as a pharmaceutical

Research

In addition to our three focus areas (Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy), we dedicate our efforts to Infectious Diseases.



- Basic research (2–3 years)
We discover and create new compounds that will form the base for medicines.
- Non-clinical studies (3–5 years)
We examine the efficacy and safety of candidate compounds for medicines using animals and cultured cells.

Details on p.27

Development

Based on our global development framework, we aim for early approval by formulating strategic development plans and promoting efficient clinical development.



- Clinical studies (3–7 years) Clinical studies for obtaining approval are divided into three stages*1 and are conducted in medical institutions such as hospitals with the enrollment of healthy people and patients after obtaining their consent. Details on p.27
- In addition to clinical development, we also carry out product development (development of active pharmaceutical ingredients and formulations).
- After verifying efficacy, safety, and quality in various studies, we apply to the Ministry of Health, Labour and Welfare for approval.

Obtaining Approval

Production and Quality Control

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



- After obtaining approval as a pharmaceutical product, we consistently produce high quality drugs under our global supply chain system that covers procurement of raw materials through to distribution based on rigorous quality control.
- We provide medical institutions and dispensing pharmacies all over Japan with pharmaceuticals.

Details on p.36



Corporate Regulatory Compliance & Quality Assurance / Medical Science

From the development stage to the post-marketing stage, we assure the quality of products and information globally. We create, provide, and disseminate high-level information based on robust scientific evidence that meets medical needs.

- We have established a quality assurance system that delivers global "A-N-SHI-N"².
- We conduct integrated management of safety information, including adverse reactions, from the development stage (clinical studies) to the post-marketing stage and engage in proactive safety measures and provision of information.

CSR-based Management

We identify Material Issues to deepen CSR-based Management. Details on p.45

Special Feature

Dialogue with the Chairman

We will nurture our corporate culture and develop our human resources to accelerate innovation. Details on p.21

Corporate Governance

We aim to build a more effective system. Details on p.59

Outside Director Roundtable Discussion

Details on p.57

*1 Phase 1 study: testing to confirm safety, including adverse reactions, among a small number of healthy people; Phase 2 study: testing to confirm effective and safe dose and method of administration, etc. among a small number of patients; Phase 3 study: testing to compare and review efficacy and safety with existing drugs among a large number of patients.
 *2 A-N-SHI-N: Trustworthiness, reliability, peace of mind, making people feel reassured and safe.

company and deliver value to society.

Sales and Marketing

We engage in activities tailored to the region centered on Japan, North America, and China.



- We provide information on the proper use of pharmaceutical products to healthcare professionals through our daily medical information provision activities.

[Details on p.37](#)

- We respond to inquiries on the quality, efficacy, and safety of our products from patients, their families, and healthcare professionals.
- We produce appropriate information materials, support the provision of information by MRs, and review externally-directed information and materials.

[Details on p.43](#)

Value Delivered to Society

1. By continually creating solutions, primarily innovative pharmaceutical products, we not only treat patients, but also contribute to improving the quality of life (QOL) for patients and their families.
2. In addition to a stable supply of high quality pharmaceutical products, we provide information for the proper use of pharmaceutical products and the correct understanding of diseases to medical professionals, patients and their families in an appropriate manner.
3. We contribute to scientific advancement by elucidating disease mechanisms and developing new modalities such as regenerative medicine/cell therapy based on our research and development activities, and open up new possibilities for prevention and treatment.

Innovation today, healthier tomorrows

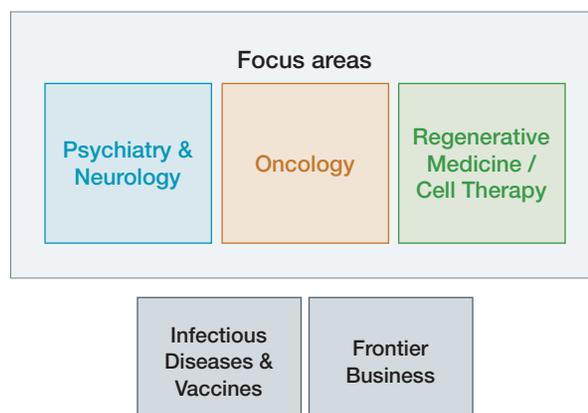


Research & Development

Note: The risks and opportunities in each region are described on page 4.

In addition to advancing drug discovery in our three focus areas (Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy), we aim to contribute to global health through the Infectious Diseases area and the provision of new health solutions through the launch of Frontier Business.

We will enhance our innovation base with new approaches to drug discovery and strive to strengthen our development capabilities to produce concrete achievements.



Psychiatry & Neurology area

We are promoting competitive drug discovery research based on unique platforms for drug discovery, developed through the incorporation of cutting-edge technology. Moreover, we are aiming to improve the success rate of research and development by selecting suitable drug discovery targets and biomarkers from big data. This includes genome information and imaging, and leveraging the knowledge obtained from clinical trials for our own products in translational research. We aim to optimize treatments for psychiatric disorders through drug discovery research based on neural circuit pathology. For neurological disorders, we aim to develop innovative disease-modifying treatments through drug discovery based on molecular pathophysiology.

We design a strategic development plan based on a globally integrated development organization, across Japan and U.S. businesses, with the aim of implementing efficient clinical development and obtaining approval as early as possible.

Direction of drug discovery

Psychiatric disorders (Schizophrenia, depression, psychiatric symptoms related to neurological disorders)

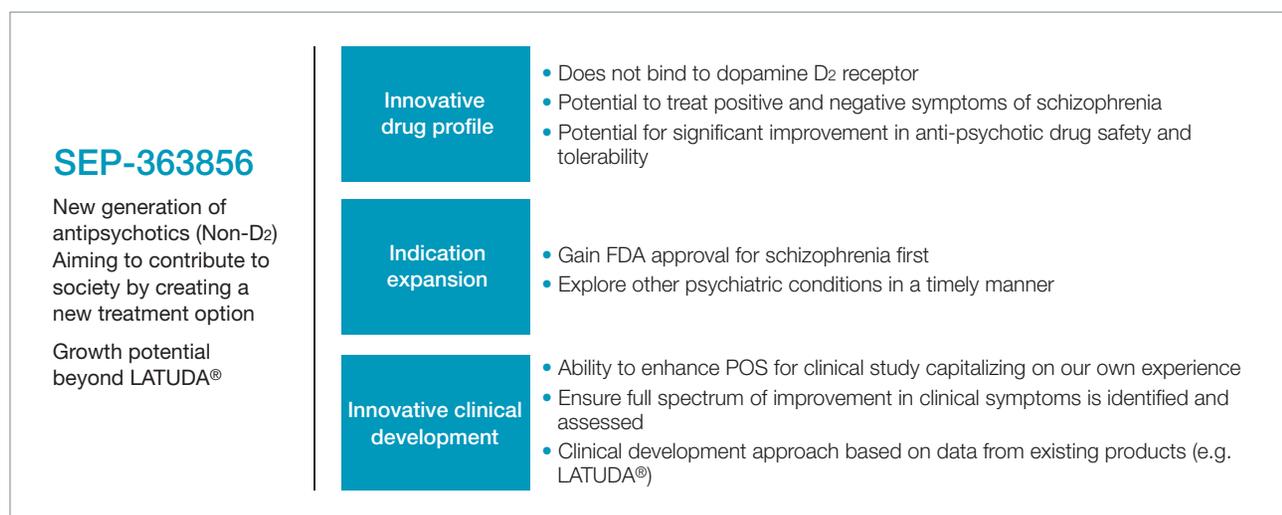
We aim to increase the probability of success and optimize treatments through drug discovery based on neural circuit pathology. We also strive to increase the probability of success in clinical development through patient stratification using new evaluation indicators.

Neurological disorders (Dementia, Parkinson's disease, rare diseases)

We seek to develop innovative disease-modifying drugs through drug discovery based on molecular pathophysiology. We aim to increase the probability of success in research and development by investigating the causes of disease using analysis of big data to select drug discovery targets. We also are conducting drug discovery programs to support the research and development of preventive medicines.

Priorities in Psychiatry & Neurology area

We will promote the late-stage clinical development of SEP-363856, leveraging expertise accumulated through the research and development of our own pharmaceuticals.



Main late stage assets

New generation of antipsychotics aimed at creating new treatment paradigm: SEP-363856

SEP-363856, which has potential as a post-LATUDA® revenue replacement, is a non-D₂ drug, which unlike the existing medications, does not show affinity to dopamine D₂ receptors. Although the molecular targets involved in its efficacy profile are unclear, it is thought to work as an agonist for the serotonin 5-HT_{1A} receptor and TAAR1 (trace amine-associated receptor 1).

It demonstrated positive results in a registration study for schizophrenia. In May 2019, it received Breakthrough Therapy designation* from the U.S. Food and Drug Administration (FDA), and the Phase 3 study is scheduled to commence in the U.S. in fiscal 2019 with the aim of market launch during fiscal 2023. We also aim for the fastest possible launch in Japan and China, and plan to start the Phase 2 study during fiscal 2019 in these regions. Our goal is to develop SEP-363856 into a new generation of antipsychotic to create a new treatment option.

* Breakthrough Therapy designation: The drugs targeted by the system need to show that significant improvements on existing treatments can be expected at key clinical endpoints through the results of preliminary clinical trials.

SEP-363856 has the potential to have a broad effect on the negative symptoms of schizophrenia, and we will begin to expand its indications with the intent to develop it into a blockbuster drug that goes beyond LATUDA®.

Dasotraline (SEP-225289)

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.

We have submitted a New Drug Application to the FDA for binge eating disorder (BED) and are aiming for a U.S. launch during fiscal 2020.

The essential feature of BED is recurrent episodes of binge eating that occur at least once per week for three months (binge eating is defined as eating an abnormally large amount of food in a discrete period of time accompanied by a sense of lack of control). It is estimated that 4.1 million people are affected by BED in the U.S.

We received a Complete Response Letter (CRL) from the FDA for dasotraline in attention deficit hyperactivity disorder (ADHD), and we are currently considering our development plan for this indication.

Research & Development

Apomorphine hydrochloride (APL-130277)

APL-130277 is a sublingual film formulation of apomorphine, a dopamine agonist approved for acute intermittent treatment of OFF episodes associated with Parkinson's disease.

We received a CRL from the FDA for the New Drug Application to treat OFF episodes in Parkinson's disease. However, we plan to reapply for APL-130277 during 2019 with the aim of a U.S. launch during fiscal 2020.

One million people in the U.S. and an estimated four to six million people worldwide live with Parkinson's disease. Parkinson's disease is a chronic, progressive neurodegenerative disease characterized by motor symptoms such as tremors at rest and rigidity (muscle stiffness) and significant non-motor symptoms, including cognitive impairment and mood disorders.

OFF episodes are the re-emergence or worsening of symptoms (motor and non-motor) despite appropriate treatment, and can occur multiple times a day. OFF episodes are experienced by 40 to 60% of Parkinson's disease patients and may worsen in frequency and severity over the course of the illness.

Latuda (lurasidone hydrochloride)

We submitted a New Drug Application in Japan in July 2019 for schizophrenia and bipolar depression. We are aiming for a Japan launch during fiscal 2020.

Fiscal 2019 Events/Objectives

Events/objectives completed as of July 2019 ✓

- ✓ LONASEN® tape: obtained approval for schizophrenia in Japan
- ✓ Dasotroline: applied for binge-eating disorder in the U.S.
- ✓ Lurasidone hydrochloride: applied for schizophrenia and bipolar depression in Japan
- SEP-363856: commenced next-phase studies for schizophrenia
 - ✓ Phase 3 study in the U.S.
 - Phase 2 study in Japan

Vision 2033

We aim to be an innovator that makes a high quality contribution in specific diseases and categories.

Oncology Area

We will work on unique seeds and themes through research focused on cell-cell interaction in the tumor microenvironment* with the aim of discovering innovative new drugs. Moreover, we will strive for innovative technologies utilizing external collaboration and promote drug discovery and development leveraging big data and digital technologies. We will also promote network-based drug discovery between Sumitomo Dainippon Pharma, its U.S. subsidiaries, and external institutions with the aim of

integrating research and development to move to clinical trials as early as possible.

At the development stage, we steadily promote the development of late stage assets in addition to actively striving for early-stage clinical development.

*Tumor microenvironment: the microenvironment formed around a tumor and surrounding host-derived cells is related to tumor pathology, and significantly influences prognosis, sensitivity and resistance to treatment.

Priorities in Oncology area

We will ensure development of napabucasin, a late stage asset, with the aim of application, approval, and launch as soon as possible. For early stage assets, we will accelerate POC approval through cutting-edge technologies, and establish an oncology franchise.

Main late stage assets

Napabucasin (BBI608)

Napabucasin is a small molecule oral medication with a novel mechanism. It is activated in vivo by the enzyme NQO1, which is expressed in cancer cells, and inhibits the pathways involved in cancer cell stemness, including STAT3, and cancer progression by producing reactive oxygen species. It is expected to ultimately lead to cancer cell death.

We are promoting a joint international Phase 3 study in a combination for colorectal cancer with the aim of launch in Japan and the U.S. during fiscal 2021.

Main early stage assets

Alvocidib (DSP-2033)

Alvocidib is a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), a member of cyclin-dependent kinase family, which activates transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anticancer activity observed with alvocidib.

We are conducting a joint international Phase 2 study (combination / Zella 201 study) for patients with relapsed/refractory acute myeloid leukemia (AML). We have commenced a Phase 1 study for first-time AML patients and are conducting a clinical study for myelodysplastic syndrome (MDS) as well. We are also in the process of conducting a clinical study for AML in Japan.

TP-0903

TP-0903 is an AXL receptor tyrosine kinase inhibitor, which is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. TP-0903 may have anti-cancer activities on various cancer types through blocking transition from epithelial to mesenchymal phenotype by inhibiting AXL.

We are conducting a Phase 1/2 study for chronic lymphocytic leukemia in the U.S. and a Phase 1 study for solid tumors in the U.S. and Japan.

TP-0184

TP-0184 inhibits activin A receptor type 1 (ACVR1, also known as ALK2) kinase, part of the transforming growth factor beta (TGFβ) receptor superfamily. Mutations in the ACVR1 gene have been identified in various tumors, including diffuse intrinsic pontine glioma (DIPG; one of common pediatric brain tumors).

We are conducting a Phase 1 study in the U.S. for solid tumors

Fiscal 2019 Events/Objectives

Events/objectives completed as of July 2019 ✓

- Napabucasin: promote joint international Phase 3 study for colorectal cancer and pancreatic cancer
 - ✓ Completed interim analysis in H1 FY2019
 - ✓ Colorectal cancer: received recommendation to continue study from independent Data and Safety Monitoring Board (DSMB) as a result of interim analysis in June 2019
 - ✓ Pancreatic cancer: received recommendation to terminate study from DSMB as a result of interim analysis in July 2019

Vision 2033

We will possess several global products and aim to establish a worldwide "DSP oncology" brand.

Research & Development

Regenerative Medicine / Cell Therapy field

We are working to achieve early commercialization through our open innovation-based unique growth model, which pursues advanced industrialization and manufacturing expertise, and cutting-edge science, and are implementing six research and development projects. We are steadily promoting research projects mainly in Neurology and Ophthalmology seeking early commercialization. We are also setting our sights on next-generation regenerative medicine (gene therapy, organ regeneration, genome editing, autologous cell therapy, and peripheral services including diagnosis and rehabilitation), including the regeneration of organs, and aim for global expansion (Japan, the U.S., and Asia). First, we will aim to realize financial contributions mainly in Japan and the U.S. during the next MTBP period (fiscal 2023–2027).

Main Projects

Chronic stroke (SB623)

SB623 is an allogeneic cell product, derived from bone marrow stromal cells. SB623 has been studied 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. A Phase 2b study was conducted in the U.S. with SanBio, Inc. to evaluate the effects of SB623 on chronic stroke, and detailed analysis is currently ongoing. We plan to determine the future development policy based on the results of the detailed analysis.

AMD (Age-related macular degeneration)

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. In June 2019, we modified the joint development system, with Sumitomo Dainippon Pharma becoming the

development entity and both companies now able to apply for manufacturing and marketing approval based on the results of clinical trials. In collaboration with Healios K.K., Sumitomo Dainippon Pharma is preparing to commence sponsor-initiated clinical trials of retinal pigment epithelial cells using iPS cells for age-related macular degeneration in Japan.

Parkinson's disease

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.

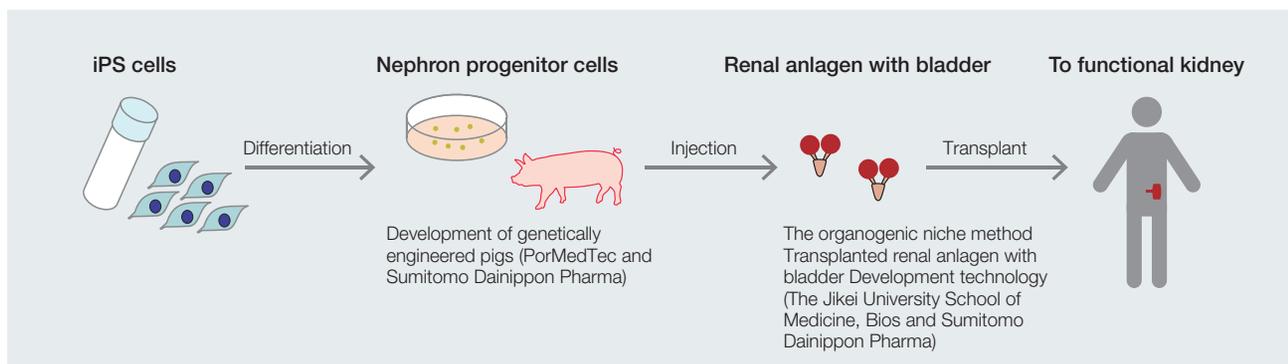
Kyoto University Hospital started, in fiscal 2018, an investigator-initiated clinical study in regenerative medicine for Parkinson's disease using dopaminergic neural progenitor cells derived from iPS cells of healthy (allogeneic) donors. Based on the results of the investigator-initiated clinical study, we are aiming to acquire approval for the cells as a regenerative medicine product.

Renal failure

Sumitomo Dainippon Pharma has commenced efforts for joint research and development with The Jikei University School of Medicine and others on renal regeneration with the fetal organ niche method using iPS cells as a new business in the Regenerative Medicine/Cell Therapy business.

Sumitomo Dainippon Pharma aims to realize renal regeneration by fiscal 2027. We expect to provide renal regeneration for patients who are waiting for kidney transplants for a long time due to problems such as organ shortages and medical expenses, contributing to medical treatment.

Renal Regeneration Project Using iPS Cells



Regenerative Medicine/Cell Therapy Business Plan (as of July 29, 2019)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Chronic stroke (SB623)	SanBio	North America	Allo mesenchymal stem cell	Completed Phase 2b study Development strategy and launch target under consideration
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	In progress: clinical research Preparing to start clinical study (Japan)
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	Preparing to start clinical research
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	In progress: clinical research
Kidney failure	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cellbased induced nephron progenitor cells (organ)	In progress: pre-clinical study

} Aim to launch in FY2022*

* Launch target is based on our goal pending agreement with partners.

Fiscal 2019 Events/Objectives

- SB623: Determine development plan for chronic stroke in the U.S.
- Allogeneic iPS cell-derived pharmaceuticals (age-related macular degeneration): start sponsor-initiated clinical trials

Vision 2033

We will aim for sales revenue in the Regenerative Medicine/Cell Therapy business of around ¥200 billion on a global scale in 2033.

Research & Development

Other areas

Imeglimin (PXL008)

Imeglimin was in-licensed from Poxel SA in October 2017 and 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 pancreas, muscles, and the liver, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis.

We have conducted three Phase 3 studies for Type 2 Diabetes in Japan and obtained positive test results for the Phase 3 studies of monotherapy and combination therapy with an insulin formulation. We plan to confirm the results of the remaining Phase 3 study during 2019 and aim to apply for approval in Japan in fiscal 2020 based on these results.

Fiscal 2019 Events/Objectives

Events/objectives completed as of July 2019

Obtain two Phase 3 study results in Japan

TIMES 2: long term monotherapy or combination therapy with existing hypoglycemic agents

TIMES 3: insulin combination therapy

Product Launch Target (as of July 29, 2019)

Area	FY2019	FY2020	FY2021	FY2022	FY2023
Japan	LONASEN® (Schizophrenia/Transdermal patch) Approved in June 2019	lurasidone (Schizophrenia/ Bipolar depression)	napabucasin (Colorectal cancer)	Allo iPS cell-derived*2 products (AMD)	
	RETHIO® (Conditioning treatment prior to autologous HSCT for malignant lymphoma)		imeglimin (Type 2 diabetes)	Allo iPS cell-derived products*2 (Parkinson's disease)	
U.S.	dasotraline (ADHD) Launch target under consideration	Apomorphine (OFF episodes associated with Parkinson's disease)	napabucasin (Colorectal cancer)	SB623*2 (Chronic stroke) Launch target under consideration	SEP-363856 (Schizophrenia)
		dasotraline (BED)			TP-0903*1 (Solid tumors/ Hematologic malignancies)
		alvocidib*1 (AML) Launch target under consideration			TP-0184*1 (Solid tumors)

 : Psychiatry & Neurology : Oncology : Regenerative medicine / cell therapy : Others

 Expect peak annual sales to be 50 billion yen or more (described in the first launch)

*1 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

*2 Launch target is based on our goal pending agreement with partners.

Infectious diseases & vaccines (AMR and adjuvanted vaccines)

Collaborating with Academia to Contribute to Global Health

In addition to contributing to global health through joint research with academia and others, we will aim for commercialization during the next MTBP period (fiscal 2023—2027). We also expect that it will contribute to earning profit.

Main Projects

Drug discovery to treat antimicrobial resistance (AMR)

We are promoting joint drug discovery research with Kitasato Institute to treat antimicrobial resistance (AMR) covered by the Japan Agency for Medical Research and Development (AMED)'s CiCLE (Cyclic Innovation for Clinical Empowerment).

Drug discovery of adjuvanted vaccines

We are implementing drug discovery of adjuvanted vaccines by combining TLR7 agonist adjuvant, our foundation technology, with promising antigens from outside. We are working on a malaria vaccine with Ehime University, etc. and a universal influenza vaccination with the National Institute of Infectious Diseases, etc.

Fiscal 2019 Events/Objectives

- Promote joint research with academia and others

Frontier business

Sumitomo Dainippon Pharma has launched frontier business with the objective of providing new solutions to solve issues in healthcare fields other than pharmaceuticals. We will work for commercialization during the current MTBP period and aspire to establish frontier business as a growth engine during the next MTBP period (fiscal 2023—2027).

Vision of frontier business: Contribute to “wide-ranging well-being” together with pharmaceutical products

We will build a business platform consisting of key technologies (including ICT and engineering) and networks (including partnership with startups and venture capitals) in areas where we can create synergies with our

pharmaceutical business to respond to future needs for healthcare. We will initiate multiple pilot trials for business seeds and explore commercialization mainly in Japan, the U.S. and China.

Main Projects

Investment in MELTIN MMI and conclusion of joint research and development agreement

In October 2018, Sumitomo Dainippon Pharma concluded an agreement for a joint research and development utilizing bio-signal processing and robotics.

As part of our pioneering of frontier business, we will engage in joint research and development that includes medical equipment utilizing the technologies of MELTIN MMI.

Research & Development

Commencement of joint research into medical equipment to alleviate behavioral and psychological symptoms of dementia

In February 2019, Sumitomo Dainippon Pharma concluded a joint research agreement with Aikomi Co., Ltd. to develop and examine the business potential of medical equipment to alleviate behavioral and psychological symptoms of dementia, an area in which there are significant unmet medical needs.

■ Fiscal 2019 Events/Objectives

- Promote current projects and pioneer new themes

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

Sumitomo Dainippon Pharma has established the Research Ethical Review Committee which 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.

Production and Quality Control

Product supply to support global expansion

At Sumitomo Dainippon Pharma, our greatest mission as a pharmaceutical company is to provide a stable supply of high-quality pharmaceuticals based on fundamentally secured safe operation.

For our production sites in Japan, we have closed the Ibaraki Plant and the Ehime Plant, making a transition to be a two-plant operation: Suzuka and Oita. We have developed a global supply chain which is based on manufacturing at these two plants and includes contract manufacturers in Japan and other countries and overseas procurement of raw materials and pharmaceutical intermediates. By doing this, we have achieved a structure for the stable supply of products.

In terms of logistics sites, we also relocated the aging distribution center in Kazo (Saitama Prefecture) to Saitama (Saitama Prefecture) in fiscal 2018, realizing a structure that can deliver products promptly to our pharmaceuticals wholesalers all over Japan from our two sites in Saitama and Kobe (Hyogo Prefecture).

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. The manufacturing, shipping, and global distribution of Sumitomo Dainippon Pharma's products have been rigorously reviewed and obtained the approval of overseas health authorities, including the FDA, the EMA (the European Medicines Agency) and the TGA (Australia's Therapeutic Goods Administration), in addition to Japan's Ministry of Health, Labour and Welfare. 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.

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

CSR procurement

We consistently conduct "transactions that are balanced, fair and transparent" based on Sumitomo Dainippon Pharma's Ethics in Procurement. We evaluate and select business partners according to the standards outlined in our Criteria for Selecting New Business Partners. These criteria provide the standard 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 environment protection and consideration. We also encourage our business partners to cooperate with us in promoting their CSR procurement.

Prevention of medical malpractice

Since packaging and label designs for pharmaceuticals are highly regulated, including the provision of information, which 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 prevent mix-ups of drugs by medical institutions and patients, such as printing the product name onto tablets and the lids (top side) of bottles and changing to highly distinctive packaging and label designs.

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 conduct ecofriendly production activities through the automation of facilities and other laborsaving measures, appropriate inventory control and the introduction of co-generation systems in addition to the development of green products, the design of green facilities, and the operation of green logistics guidelines.

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.

Sales and Marketing

Basic Policy of Regional Strategy



Main Points of Regional Strategy in MTBP 2022

Japanese Market

Transform to steady growth

- Maximize product value in Diabetes area (Trulicity®, imeglimin)
- Maximize product value in Psychiatry & Neurology area (TRERIEF®, LONASEN® Tape, lurasidone)
- Execute strategic in-licensing/partnership opportunities
- Establish business foundation in Regenerative Medicine / Cell Therapy

Establish oncology business foundation

- Establish sales & marketing organization for napabucasin

- Promote proper use of new product RETHIO®

- Optimize structure to collect and communicate drug safety information

Optimize business operation

- Provide appropriate scientific information to healthcare providers
- Achieve safe, secure and stable production as well as optimal CoGs
- Leverage digital technology to maximize efficiency and effectiveness of business operations

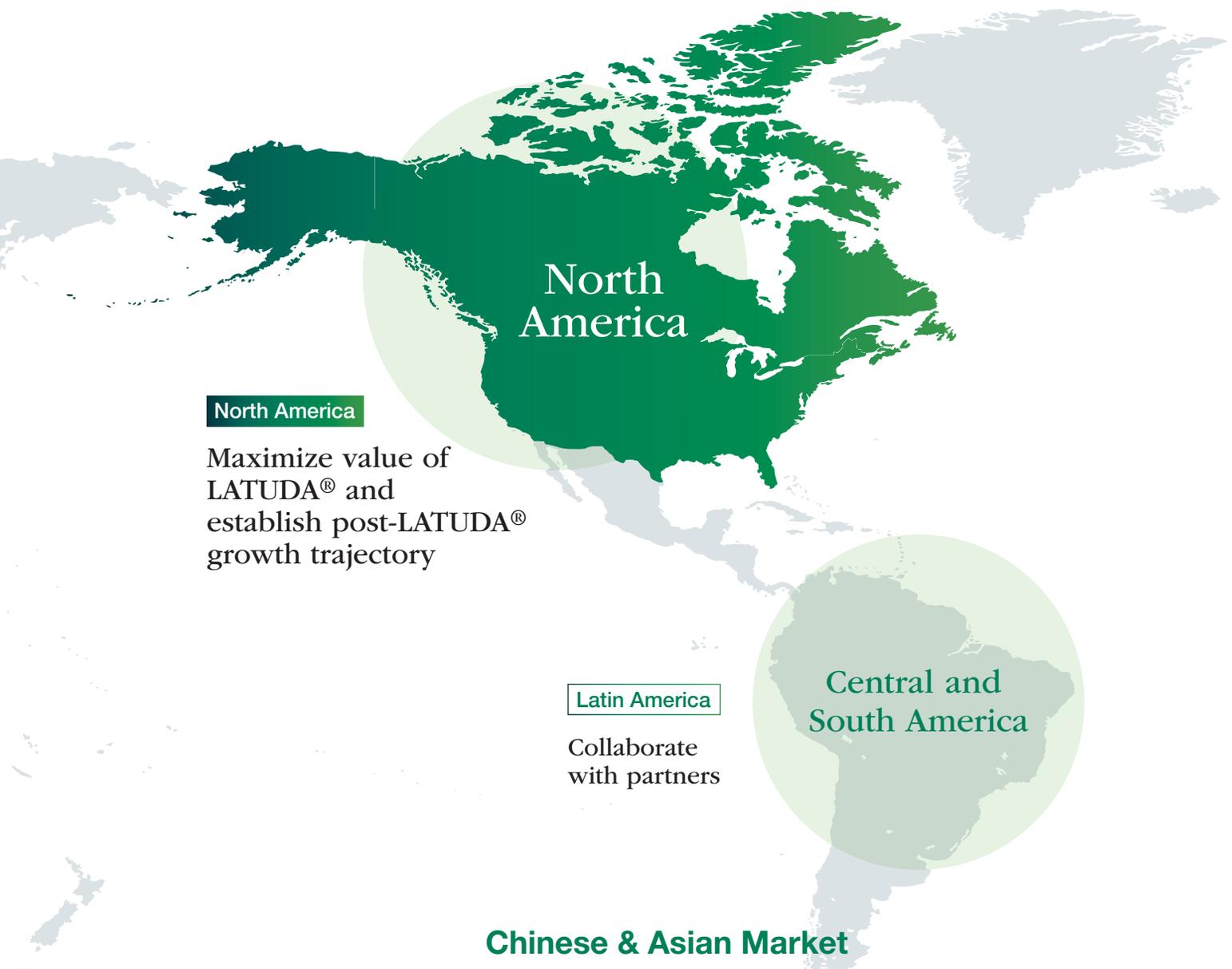
North American Market

Maximize value of Psychiatry & Neurology and Respiratory products

- Maximize value of LATUDA®
- Accelerate development of SEP-363856
- Gain approval of and launch dasotraline and apomorphine
- Accelerate to achieve early contribution of LONHALA® MAGNAIR® in profit

Establish Oncology business foundations

- Gain approval of napabucasin
- Establish sales and marketing organization for launch



North America

Maximize value of LATUDA® and establish post-LATUDA® growth trajectory

Latin America

Collaborate with partners



Chinese & Asian Market

Pursue opportunity for strategic investment & partnership

- Expand pipeline
- Explore co-promotion partnership, leveraging our commercial footprint

Optimize business operation

- Leverage highly talented human resources with expertise in focus areas
- Leverage digital technology to maximize efficiency and effectiveness of business operations

Develop and implement regional strategy for Asian market

- Develop and implement business strategy for the Asian market as well as expand R&D pipeline
- Pursue business opportunity in Regenerative Medicine/Cell Therapy and Frontier areas

Further expand China business

- Reinforce business infrastructure as the third pillar after Japan and North America
- Maximize revenue from MEROPEN®

- Ensure successful launch of new products (LONASEN® and LATUDA®)
- Participate in global development

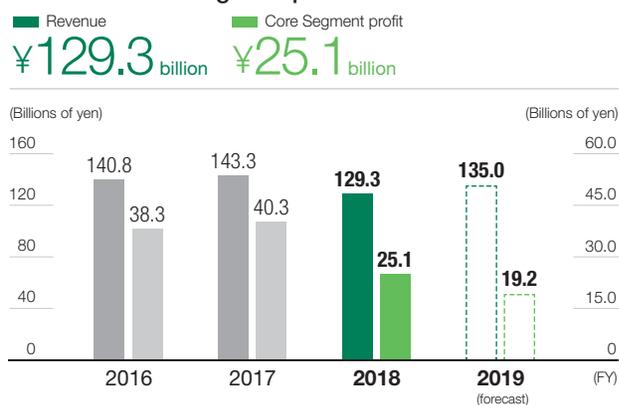
Reinforce business in Southeast Asia

- Reinforce business functions in subsidiaries in Singapore and Thailand
- Maximize revenue from MEROPEN® and LATUDA® through strategic alliance with local partners

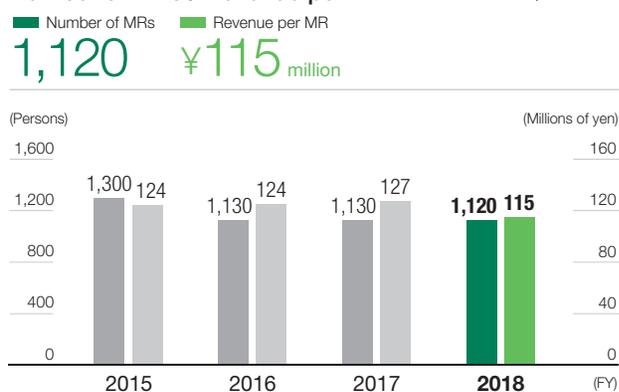
Pharmaceutical Business Japanese Market



Revenue / Core Segment profit



Number of MRs / Revenue per MR * MR: Medical Representative



Notes: 1. Net sales and segment profit follow Japanese accounting standards up to fiscal 2016.
2. The numbers MR represent the numbers as of March 31 of the fiscal year.

Fiscal 2018 Main Initiatives and Business Results

Revenue decreased by 9.8% year-on-year to 129.3 billion yen. Sales of Trulicity®, SUREPOST®, REPLAGAL®, and other products increased, but revenue decreased due to difficulties in offsetting the impacts of NHI drug price revisions and declines in sales of long-listed products, including AIMIX® for which new generics have been released.

Core segment profit decreased by 37.6% year-on-year to 25.1 billion yen. This major decrease is chiefly attributable to the decrease in gross profit due to NHI drug price revisions and declines in sales of long-listed products.

Revenue of Major Products

(Before reduction of rebates; Billions of yen)

Brand Name	Therapeutic Indication	FY 2017	FY 2018	Rate of change (%)	FY 2019 forecast
Trulicity®*	Therapeutic agent for type 2 diabetes	15.9	23.1	72	28.2
TRERIEF®	Therapeutic agent for Parkinson's disease	16.1	15.7	(4)	17.1
REPLAGAL®	Therapeutic agent for Anderson-Fabry disease	11.7	12.5	8	11.8
LONASEN® tablet/powder	Atypical antipsychotic	12.6	12.2	(4)	5.2
METGLUCO®	Therapeutic agent for type 2 diabetes	10.9	10.1	(8)	9.3
SUREPOST®	Therapeutic agent for type 2 diabetes	5.0	6.1	10	6.2
AmBisome®	Therapeutic agent for systemic fungal infection	4.3	4.0	(3)	3.9
AMLODIN®	Therapeutic agent for hypertension and angina pectoris	11.4	9.1	(23)	7.5
AIMIX®	Therapeutic agent for hypertension	18.8	8.2	(106)	3.7
LONASEN® Tape	Atypical antipsychotic	—	—	—	1.8
Euqa® /EquMet®	Therapeutic agent for type 2 diabetes				16.0

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

Fiscal 2019 Business Plan and Outlook

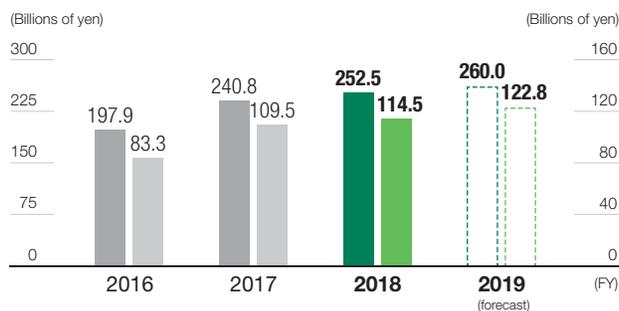
In fiscal 2019, although the entry of generics for LONASEN® tablet and powder and a decline in sales of existing long-listed products are anticipated, we expect revenue growth due to such factors as the commencement of a marketing alliance for Equa®/EquMet® and the launch of LONASEN® Tape in addition to an expansion in sales of TRERIEF® and Trulicity®.

Pharmaceutical Business North American Market



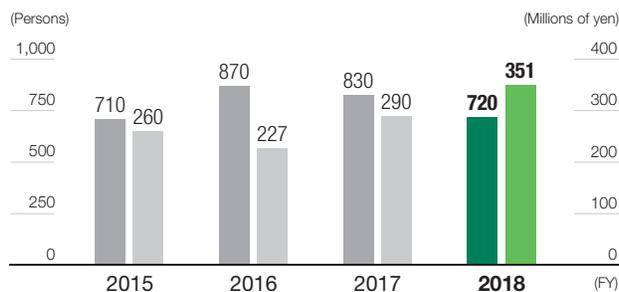
Revenue / Core Segment profit

Revenue: **¥252.5 billion**
Core Segment profit: **¥114.5 billion**



Number of MRs / Revenue per MR * MR: Medical Representative

Number of MRs: **720**
Revenue per MR: **¥351 million**



Notes: 1. Net sales and segment profit follow Japanese accounting standards up to fiscal 2016.
2. The numbers MR represent the numbers as of March 31 of the fiscal year.

Fiscal 2018 main initiatives and business results

Revenue increased by 4.9% year-on-year to reach 252.5 billion yen. This increase is primarily attributable to the growth in sales of APTIOM® and the launch of LONHALA® MAGNAIR®, on top of strong sales of LATUDA®.

Core segment profit increased by 4.6% year-on-year to reach 114.5 billion yen. This increase is attributable to the increase in gross profit due to an increase in sales.

Revenue of major products (Billions of yen)

Brand Name	Therapeutic Indication	FY 2017	FY 2018	Rate of change (%)	FY 2019 forecast
LATUDA®	Atypical antipsychotic	178.6	184.5	3.3	189.3
BROVANA®	Therapeutic agent for COPD	33.1	33.7	1.7	33.0
APTIOM®	Antiepileptic	15.7	20.5	30.9	22.5
LONHALA® MAGNAIR®	Therapeutic agent for COPD	-	1.4	-	4.2
XOPENEX®	Therapeutic agent for asthma	4.0	4.6	15.8	4.1

Fiscal 2019 business plan and outlook

Revenue is expected to grow due to sales expansion of LATUDA®, APTIOM®, and LONHALA® MAGNAIR®.

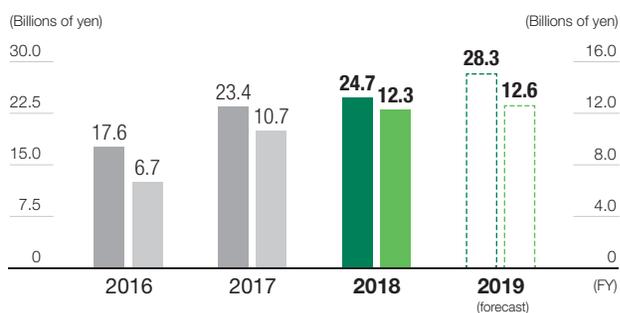
Revenue is thus expected to increase slightly year-on-year to 260.0 billion yen.

Pharmaceutical Business Chinese and Asian Market



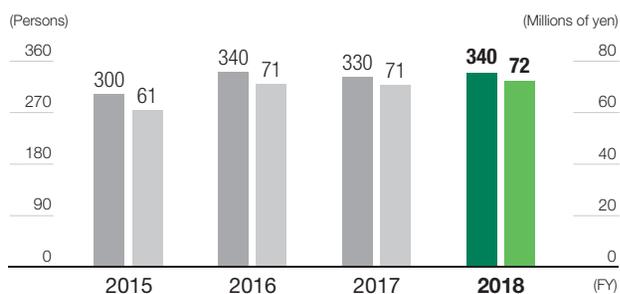
Revenue / Core Segment profit

Revenue: ¥24.7 billion
Core Segment profit: ¥12.3 billion



Number of MRs / Revenue per MR * MR: Medical Representative

Number of MRs: 340
Revenue per MR: ¥72 million



Notes: 1. Net sales and segment profit follow Japanese accounting standards up to fiscal 2016.
2. The numbers MR represent the numbers as of March 31 of the fiscal year.

China Business

Fiscal 2018 Main Initiatives and Business Results

Sumitomo Dainippon Pharma sells five products in the Chinese market, which are MEROPEN®, ALMARL®, SEDIEL®, GASMOTIN®, and LONASEN®. The 330 MRs of Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. cover 30 provinces and cities (areas: main cities, provinces, and autonomous regions).

Revenue increased by 5.6% year-on-year to reach 24.7 billion yen. This increase is attributable to an increase in sales of mainstay MEROPEN® and other products. Core segment profit increased by 14.8% year-on-year to reach 12.3 billion yen.

Revenue of Major Products (Billions of yen)

Brand Name	Therapeutic Indication	FY 2017	FY 2018	Rate of change (%)	FY 2019 forecast
MEROPEN®	Carbapenem antibiotic	20.4	21.2	4.4	22.6

Fiscal 2019 Business Expansion and Outlook

The challenging environment due to such factors as changes in the bidding system will persist. However, in addition to working to expand the Chinese business led by MEROPEN®, we will focus efforts on sales of LONASEN® launched in 2018, and LATUDA®, which we plan to launch in fiscal 2019. Thus, we forecast revenue and profit growth year-on-year in Chinese segment.

Southeast Asia Business

We will commence activities to provide pharmaceutical information based on our Singapore subsidiary, the functions of which we strengthened to form our Southeast Asia regional headquarters in April 2019, and our Thai subsidiary established in January 2019, and aim for sustained growth in the Southeast Asia region by maximizing the value of current products (LATUDA® and MEROPEN®) and strengthening our business base in each country. Furthermore, we will continue to promote the early launch of products under development.

Related Business

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

In the food ingredients and food additives business, the company develops and sells food ingredients and additives for use in manufacturing safe, high-quality foods. Products include polysaccharides, primarily GLYLOID® (tamarind seed gum), the first product of its kind successfully produced by 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.

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.

In the animal health products business, the company manufactures and sells 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. We also operate a clinical testing business, which is vital for definitive diagnosis.

Furthermore, we have been expanding our business areas with the aim of transformation into a company that can provide comprehensive solutions to respond to various needs of veterinarians, pet owners, and livestock farmers at each stage of healthcare cycle of examination, testing, diagnosis, medication, and follow up care. Twice a year, we also run the New Business Search Program to Support Animal Health, which is aimed at combining the seeds of research organizations and start-ups with the management resources of the company for their commercialization.

In terms of new business, to realize practical use of regenerative medicine in veterinary medical treatment, in

June 2019, we applied for manufacturing and marketing approval of injection of the world's first* canine (allogenic) adipose tissue-derived mesenchymal stem cell for improvement of clinical signs associated with intervertebral disc herniation in dogs. In a collaboration with Nestle Japan, we also began handling Nestle's Purina Pro Plan Veterinary Diets, veterinary diets and supplements for pets in December 2018.

We help people live fulfilling, happy lives by supporting animal health.

*As of June, 2019, internal survey by DS Pharma Animal Health

Prescription Drugs Business DS Pharma Promo Co., Ltd.

DS Pharma Promo Co., Ltd., which merged with DS Pharma Biomedical Co., Ltd., a wholly-owned subsidiary of Sumitomo Dainippon Pharma, as the surviving company on April 1, 2019, manufactures and sells authorized generic (AG) products*. DS Pharma Promo is principally responsible for the Sumitomo Dainippon Pharma Group's AG business, creating high value-added products and engaging in activities to provide accurate information in collaboration with Sumitomo Dainippon Pharma. The in-vitro diagnostic drug business of DS Pharma Biomedical was transferred to a company that is a joint venture (SB Bioscience Co., Ltd.) between Sumitomo Dainippon Pharma and Sumitomo Bakelite Co., Ltd. in April 2019.

* Generic drugs that are authorized by brand-name pharmaceutical companies and manufactured using active pharmaceutical ingredients, additives, and manufacturing methods, etc. that are identical to those of brand-name drugs, and that are marketed prior to other generics drugs with a patent license from brand-name pharmaceutical companies

Corporate Regulatory Compliance & Quality Assurance / Medical Science

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., China, and other countries, and, after receiving approval from each country’s regulatory authority, delivering products. In order to provide products that patients and healthcare professionals around the world can use with “A-N-SHI-N,” the Group has established global policies^{*2} for quality and safety management. Under a Global Regulatory Compliance System, we are striving to provide high quality products.

Furthermore, we supervise all manufacturing and packaging contractors for our pharmaceutical products in their various countries to assure the quality of pharmaceuticals 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.

^{*2} <https://www.ds-pharma.com/csr/customer/safety.html>

Efficient inquiry-response system with our quality information system

In Japan, Sumitomo Dainippon Pharma’s Quality Information System is designed to ensure efficient responses to inquiries about product quality from healthcare professionals. We use this system in conformity to Good Quality Practices (GQP)^{*3}. When an inquiry is raised in this system, 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 plans and implements actions to prevent recurrence.

Departments such as Safety Management, Sales & Marketing, Manufacturing, and Quality Assurance can access the system so that they can promptly evaluate safety and respond to complaints. Our Quality Information System also has a search function which enables us to analyze inquiry and 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.

^{*3} Good Quality Practice: A standard for managing the quality of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (manufacturing and marketing quality assurance standard).

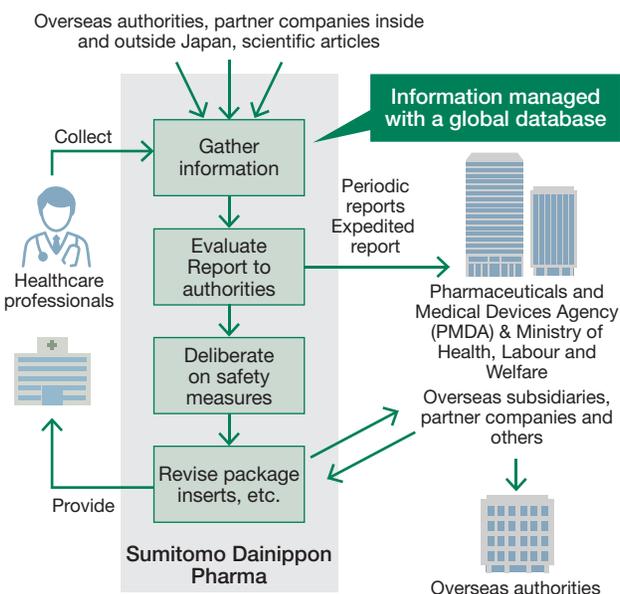
Centralized management of safety information from development to post-marketing

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 a wide range of post-marketing information from medical institutions, partner companies, and regulatory authorities etc. in each country, in addition to safety information generated at the early development stages.

A centralized global database manages and evaluates safety information collected in Japan and overseas, leading to the planning of the necessary measures to ensure the safety and proper use of pharmaceuticals and the implementation of safety measures in a timely manner. We implement safety management activities of this nature as part of product pharmacovigilance in compliance with the Pharmaceuticals, Medical devices and Other Therapeutic Products Act and Good Vigilance Practice (GVP).^{*4}

^{*4} Good Vigilance Practice: A standard for managing the post-marketing safety of pharmaceuticals, quasi-pharmaceuticals, cosmetics and medical devices (post-marketing safety management standard).

■ Collecting and providing safety information



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 occur undesired effects.

Sumitomo Dainippon Pharma promptly and accurately provides healthcare professionals with information on the proper use of pharmaceuticals in order to ensure that the effects of each pharmaceutical can be produced more safely. 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 for healthcare professionals.

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.

Medical Science

Medical needs are learned on site Offering true value with our pharmaceutical products

Sumitomo Dainippon Pharma’s Medical Information Department and Medical Affairs Department 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 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 products 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. 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 information on our products, support MRs’ provision of information, review information and materials directed to external parties, and check slides for lecture meetings.

We also provide documents such as “Kusuri-no-shiori”, drug information sheet, and “Instructional Leaflets” which are used by healthcare professionals in explaining to patients. In order to be able to offer 24-hour support for regional healthcare, we will

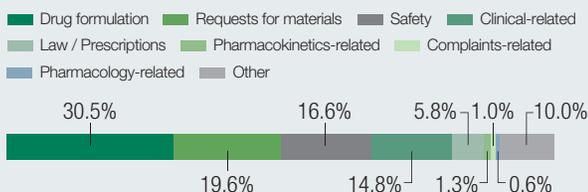


utilize our website and other methods, and continue to deliver and communicate easy-to-understand information to patients and families, while addressing the on-site needs of healthcare institutions.

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.

Inquiries during FY2018: Approximately 38,900



Setting material issues to deepen

Our Approach to CSR-based Management



Atsuko Higuchi

Executive Officer
Corporate Communications; Human Resources

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. In addition to developing innovative products and healthcare solutions, we hope to promote CSR-based management by maintaining and reinforcing our corporation governance system, pursuing fair and transparent corporate activities, ensuring compliance, strengthening our environmental initiatives, promoting work style innovation and diversity & inclusion, and strengthening training and development for our employees.

In promoting CSR-based management, we are also conscious of contributing toward the achievement of the United Nations Sustainable Development Goals (SDGs). While concentrating most efforts on Goal 3: Good health and well-being, Sumitomo Dainippon Pharma is also actively addressing Goal 17: Partnerships for the goals, Goal 12: Responsible consumption and production, and Goal 8: Decent work and economic growth.

Moreover, Sumitomo Dainippon Pharma values dialogue with diverse stakeholders, and, going forward, we will continue to review the material issues (materiality) for CSR-based management in light of the feedback obtained through this dialogue.

Our Top Priority Sustainable Development Goals and Targets

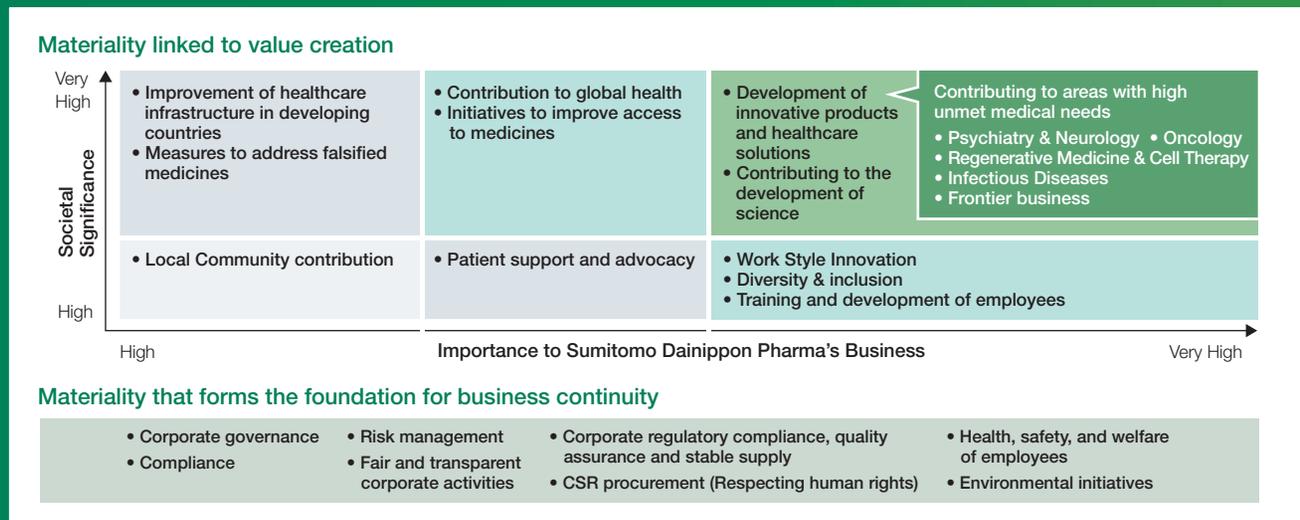
Goals	Targets	Goals	Targets
 <p>3 GOOD HEALTH AND WELL-BEING</p>	<p>3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.</p> <p>3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.</p>	 <p>12 RESPONSIBLE CONSUMPTION AND PRODUCTION</p>	<p>12.4 By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.</p>
 <p>8 DECENT WORK AND ECONOMIC GROWTH</p>	<p>8.5 By 2030, achieve full and productive employment and decent work for all women and men, including for young people and persons with disabilities, and equal pay for work of equal value.</p>	 <p>17 PARTNERSHIPS FOR THE GOALS</p>	<p>17.17 Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships.</p>

CSR-based management

Materiality (Material Issues for CSR-based Management)

Sumitomo Dainippon Pharma identified the materiality (material issues for CSR-based management) to be addressed through our business activities in July 2018. However, we have now updated our materiality in light of subsequent social changes, the progress of our initiatives, and the feedback obtained through dialogue with stakeholders. The updates were determined following deliberation by the Management Committee and shared with all of the Directors at the Executive Committee.

Materiality (Material Issues for CSR-based Management)



Updates

As a result of the updates, materiality has been divided into the two categories below.

1. Materiality linked to value creation, which is highly unique and vital for the sustained growth of Sumitomo Dainippon Pharma
2. Materiality that forms the foundation for business continuity, which is essential for the continuation of our business activities

Although we have listed materiality that forms the foundation for business continuity separately from the map for materiality linked to value creation, we treat corporate governance and compliance as particularly key issues.

Moreover, we sorted the following issues and improved the terminology used.

- Quality assurance, Product safety, Responsibility for drug induced suffering
→ Sorted into Corporate regulatory compliance, quality assurance
- Climate change initiatives, Preventing environmental accidents, Biodiversity, Effective use of water resources, Prevention of air pollution, Reduction of waste
→ Sorted into Environmental initiatives
- See the table comparing the changes posted on our website for other updates.

Reasons for Selection of Main Materiality and Connection with Value Creation

Development of innovative products and healthcare solutions, Contributing to the development of science

The development of innovative products and healthcare solutions to address unmet medical needs is our business and the source of value creation. We can also contribute to the development of science through drug discovery and research, product development, and clinical development.

Training and development of employees, Work Style Innovation, Diversity & inclusion

A business is composed of its employees. Upgrading the capabilities of employees, improving labor productivity, and effectively utilizing human resources is essential for our sustained growth.

Contribution to global health, Initiatives to improve access to medicines

Sumitomo Dainippon Pharma engages in drug discovery and research in the areas of malaria and antimicrobial resistant (AMR) infectious diseases. We also strive to improve access to our products for patients who need them, including responding to requests for development of unapproved and off-label drugs in Japan and public education aimed at improving medicine-related literacy. Such efforts contribute to global health in addition to expanding our business.

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.

Therefore, with our basic concept of work style innovation, which is to build a win-win relationship between employees and the company to enable employees to work with a firm sense of fulfillment and produce results, it is our aim that each and

every person will fulfill their own roles and produce results in the limited time.

We designated fiscal 2018 as a year for deepening the work style innovation we launched in 2017, and we stepped up our initiatives for work style innovation. This included continuing to hold our Work Style Innovation Meetings at each work site for employees to discuss revisions to work style, holding training as an opportunity for all officers and employees to consider work style innovation, and establishing the Work Style Innovations site on our intranet to share each department's goals and case studies of initiatives, including messages from officers.

Furthermore, as part of our office environment reforms, we introduced

open, unassigned desk space at both our Osaka and Tokyo head offices and we are promoting initiatives that lead to employee productivity improvements.

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

Related SDGs



Main Initiatives in FY2018

Established a staggered work hours system

Office environment reforms (introduction of unassigned desk space at some business sites, including Osaka Head Office and Tokyo Head Office)

Implementation of training for officers and employees

Participation in telework days

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 70% utilization rate for paid leave in fiscal 2018
- Encouraged employees to consistently take their paid leave

Promoted smoking cessation advice

- Made all Sumitomo Dainippon Pharma work sites in Japan completely no-smoking (closed smoking areas) as of March 31, 2019



Promoting creation of employee-friendly workplaces



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

Number of participants in the DSP Academy*

* Number of participants from fiscal 2016 to fiscal 2018

227

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. Training participants develop a comprehensive view of business overall from a broad perspective and the imagination to create new value.

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 the three-year period of the program up until April 2019, eight talented young employees had been dispatched overseas. We hope that the program will not only have an effect on the growth of the participants themselves, but also on fostering an organizational culture of challenge.

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.

Related SDGs



Health, Safety, and Welfare of Employees

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

In February 2019, Sumitomo Dainippon Pharma was recognized for the third year in a row under the “Certified Health & Productivity Management Outstanding Organizations 2019 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.

Sumitomo Dainippon Pharma treats health management for employees as one of the key issues of corporate management. In October 2017, we formulated our Declaration of Health Innovation, and we have taken concrete measures aimed at maintaining and promoting the health of our employees and their families. In

particular, we have been implementing company-wide efforts on smoking cessation advice for some time as an activity aimed at achieving zero smokers among our employees, which we set as a specific initiative in our Declaration of Health Innovation. We have been promoting even more effective efforts by clearly stating our goals in the Declaration of Health Innovation, and we made all of our work sites in Japan completely no-smoking (closed smoking areas) as of March 31, 2019.

Related SDGs



employees to pursue transformation and to generate innovative ideas in order to continue achieving our Corporate Mission. To this end, 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 have been implementing full-scale work style innovation initiatives since 2017. As part of this, we believe that the presence of “Ikuboss” supervisors, who encourage rank and file employees in both their careers and their broader lives, is extremely important in order to balance improving corporate competitiveness with achieving work-life balance.

We received the “Platinum Kurumin” in July 2017 while working to create a rewarding environment which is easy to work in for employees who are raising children. In each workplace, we promote a mindset of understanding and assistance for employees facing diverse life events who require flexible work styles.

Diversity & Inclusion

Achieving Work-Life Balance

At Sumitomo Dainippon Pharma, we consider that it is essential for all





Expanding areas in which women actively participate

Supporting Women's Active Participation

At Sumitomo Dainippon Pharma, we consider that it is essential for each and every employee to take on appropriate duties in accordance with their capabilities, irrespective of their gender, in order to realize our Corporate Mission. We have vigorously strived for active participation by women as one focus of our efforts on diversity and inclusion.

We believe that an equal ratio of men and women among our employees and among our managerial staff is one yardstick of our vision for women's active participation. In our General Business Owner Action Plan required under the Act on Promotion of Women's Participation and Advancement in the Workplace, which came into force in 2016, we have set a goal of at least 10% female managerial staff in 2020, and we have been actively promoting initiatives. In 2017, we received the highest "Eruboshi" certification (three stars) as

a company making excellent progress implementing initiatives for the active involvement of female employees. As of April 2019, women accounted for 10.7% of managerial staff at Sumitomo Dainippon Pharma, achieving the goal set in 2016 at least 18 months ahead of schedule.

The achievement of this goal is merely one checkpoint among our long-term initiatives. Going forward, Sumitomo Dainippon Pharma will continue to encourage growth through education in accordance with capabilities for each and every employee, irrespective of their gender, and create an environment that allows all employees to reach their full potential.

Supporting Active Participation by People with Disabilities through Appropriate Placement

Sumitomo Dainippon Pharma recognizes that it is the common responsibility of society to enhance social welfare through the employment

Main Initiatives in FY2018

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

of persons with mental disabilities.

In July 2018, Cocowork Co., Ltd., was established to support independence of persons with mental disabilities by cultivating leafy vegetables, etc. in solar-powered hydroponic.

As part of our efforts to create a comfortable work environment, we introduced a communication support application and provide sign language interaction at internal sessions for hearing-impaired employees.

Related SDGs



Contributing to Global Health and Improving Access to Medicines

In recent years, expectations of pharmaceutical companies related to contributing to improving access to medicines have increased further. Sumitomo Dainippon Pharma has identified “Improvement of healthcare infrastructure in developing countries” and “Initiatives to improve access to medicines” as material issues, and we believe that working on establishment of healthcare systems in developing countries, training and developing human resources, and educating the public will not only contribute to achieving the SDGs, but also lead to an increase in our presence as a global pharmaceutical company. Since we recognize that access to medicines is an issue on a global scale, we value the importance of Goal 17: Partnerships for the Goals. While emphasizing the establishment of a sustainable framework, we are working toward solving issues by collaborating with government agencies, international institutions, research institutions, and civil society.

Related SDGs



Main Initiatives in FY2018

Participation in Access Accelerated

Since January 2017, we have taken part in Access Accelerated, which is a partnership initiative with organizations that include 24 global pharmaceutical companies and the World Bank. Through this involvement, we are striving to improve access to medicines for non-communicable diseases in developing countries.

In fiscal 2018, there were efforts to improve access to medicines through such means as pharmaceutical regulatory easing targeting 20 low- to middle-income countries in Africa and Asia and 90 Accelerated Access programs were promoted at individual companies targeting 99 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.

- Trained 15 Community Care volunteers for Mothers and New-borns (CCMN)
- Visited the homes of 91 antenatal women and 63 postnatal women
- Held practical cooking workshop for preparing highly nutritious baby food three times with participation by 93 local women

Initiatives Aimed at Appropriate Use of Antibiotics and Countermeasures to Antimicrobial Resistance (AMR)

In June 2019, we commenced a drug susceptibility study targeting Vietnam aimed at the appropriate use of antibiotics and countermeasures to antimicrobial resistance (AMR). Through the joint implementation of the study and sharing of its results, we aim to further spread awareness about the importance of using drug susceptibility data in routine testing as information for making decisions when medical institutions are selecting the best antibiotics for treatment.

Initiatives for Unapproved and Off-label Drugs

In areas with high unmet medical needs, providing new treatment options is very important. Sumitomo Dainippon Pharma puts an emphasis on responding to requests for development of unapproved and off-label drugs as an initiative to improve access to medicines. We developed an intravenous drip infusion indicated for conditioning treatment prior to autologous hematopoietic stem cell transplantation for pediatric malignant solid tumors for which we obtained approval in March 2019 and launched in May 2019.

Initiatives to Improve Medicine-related Literacy

Using pharmaceuticals with a proper appreciation and understanding of treatment methods and adverse reactions is very important in improving access to medicines. Sumitomo Dainippon Pharma aims to improve the medicine-related literacy of patients. In addition to providing “Kusuri-no-shiori,” “Instructional Leaflets,” and guidance for patients using our pharmaceuticals and their families to promote appropriate use, we also strive to educate the public through our health information site and by holding public lectures (27 lectures in fiscal 2018).

Home visit by a maternal and child health volunteer



© Toshihiro Kubo



Sunovion employees who participated in the NAMI Walk in Boston



Website of the Japan Epilepsy Research Foundation
<https://www.epi-fj.jp/>

Patient Support and Advocacy

Sumitomo Dainippon Pharma strives to provide support for areas with high unmet medical needs as part of our social contribution activities. In fiscal 2018, we endorsed and contributed to activities for Rare Disease Day (RRD) 2019, an event for worldwide Rare Disease Day held on the last day of February and organized by RRD Japan. Officers and employees also wore RRD2019 badges and helped with awareness raising activities.

Implementing Support through Donations

In the spirit of our global slogan 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 2018, Sumitomo Dainippon Pharma provided donations to The Support Network for NANBYO Children of Japan, Future Code, Nobel, and NPO Florence.

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 2018, 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.

Advancing patient advocacy in the U.S.

Our U.S. subsidiary Sunovion Pharmaceuticals Inc. partners with patient advocacy organizations across the U.S., while also developing premier advocacy programs to advance education and awareness of serious psychiatric, neurological and respiratory conditions. For example, during fiscal 2018, Sunovion continued to support the National Alliance on Mental Illness (NAMI) walks across the U.S., while also expanding Be Vocal, partnership between five leading mental health advocacy organizations and Sunovion, which aims to bring mental health to the forefront by spotlighting real people living with mental health conditions and showcasing their unique stories. Sunovion was also involved with Moving Day, a walk to support The Parkinson's Foundation mission in the U.S., and implemented initiatives to support Epilepsy Awareness and COPD Awareness Months.

Related SDGs



Local Community Contribution, Including Supporting 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 2018, participating students numbered approximately 1,800 at 20 schools, with 51 of our employees serving as instructors.

Publishing the SUKOYAKA Compass Website

Since fiscal 2012, Sumitomo Dainippon Pharma has published SUKOYAKA Compass as a part of our website aimed at the children who will be forging the future. Through SUKOYAKA Compass, children learn about the importance of understanding and using medicines correctly, and we also hope that they develop an interest in medicine and that it helps with education about medicines.

Through SUKOYAKA Compass, we publish diverse content, including

“Kusuri-no-i-ro-ha,” which introduces information about medicine that we think we know but actually don't, such as what medicine is, how medicine works, and the process for producing medicines, “O-kusuri Q&A,” which explains things like how to use medicines in a Q&A format, “Kusuri no Jiyu Kenkyu Guide,” which provides a guide to methods of independent research on medicines and ways of organizing research, “Kusuri no Shigoto Zukan,” which introduces work at a pharmaceutical company and the work of a pharmacist, and “Kusuri no Chosen,” which introduces the cutting-edge research at Sumitomo Dainippon Pharma. In addition, a navigator called Scoppi explains medicines and answers questions to make the site child-friendly.

Related SDGs



SUKOYAKA Compass
<https://www.ds-pharma.co.jp/sukoyaka/>



Scoppi, the navigator on SUKOYAKA Compass

No. of employees teaching courses in visiting lectures

51

Schools using DSP visiting lectures / No. of attendees

20 schools

1,800 attendees



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 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 both of its two plants (Suzuka Plant and Oita Plant).

Contributing to Building a Low-carbon Society

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 CO₂ emissions by 23% by fiscal 2020, compared to fiscal 2005. As of fiscal 2018, we had reduced emissions by 28%. In particular, in recent years, we have systematically promoted the installation of LED lighting, and we have also been working to calculate greenhouse gas emissions across the supply chain. In addition, by fiscal 2030 we will reduce CO₂ emissions by at least 30% compared to fiscal 2017, and we are reviewing specific reduction rates with the aim of acquiring SBT (Science Based Targets) certification by fiscal 2020.

Promoting Environmental Communication

In fiscal 2018 following on initiatives from fiscal 2017, we participated in verification for the “Environmental Reporting Platform Development Pilot Project - ESG Dialogue Platform” of

Japanese Ministry of the Environment, and engaged in active dialogue with institutional investors. Through this dialogue, we aim to identify and put into practice even better environmental activities which contribute to the preservation of the global environment at the same time as enhancing our value.

Third-Party Assurance

Fiscal 2018 environmental information indicated with a  in the Integrated Report 2019 has received third-party assurance from KPMG AZSA Sustainability Co., Ltd. in order to enhance the reliability of the information. The Independent Assurance Report is on page 56.

Related SDGs



Sumitomo Dainippon Pharma's Environmental Management

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

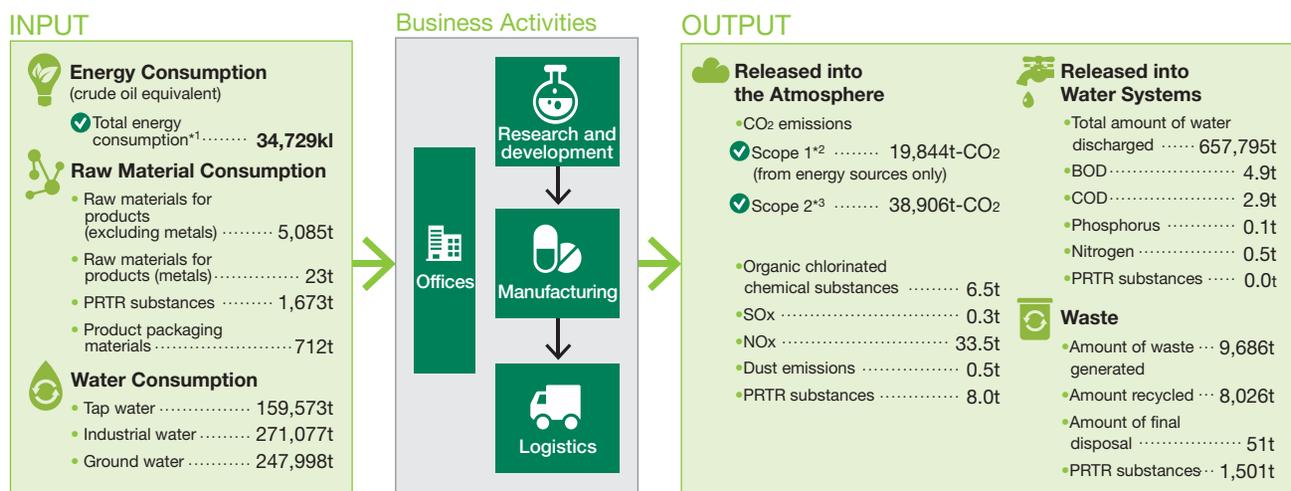
Mid-term Environmental Plan

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

Annual Implementation Plan

To formulate an Annual Implementation Plan of action for achieving the goals of the Mid-term Environmental Plan

■ Overview of Environmental Impact (FY2018)



Boundary of calculation : Facilities in Japan only (plants, research laboratories, distribution centers, Osaka Head Office, Tokyo Head Office, Tokyo Kyobashi Office, branches and business offices)
 Methods of Calculation and Emissions Intensity, etc.

*1 (Purchased electricity × unit calorific value + purchased heat × unit calorific value + fuel consumption × unit calorific value) × 0.0258 kl/GJ
 The unit calorific values and the types of fuel to be calculated are based on “Act on the Rational Use of Energy.” However, starting in fiscal 2018, when the unit calorific values of electricity and heat for sites located on the premises of Sumitomo Chemical Co., Ltd. are provided by Sumitomo Chemical Co., Ltd., those values are used.

*2 Fuel consumption × fuel unit calorific value × fuel CO₂ emissions factor
 The unit calorific values and CO₂ emissions factors are based on “Greenhouse Gas Emissions Accounting, Reporting, and Disclosure System” which is provided in “Act on Promotion of Global Warming Countermeasures.”

*3 Purchased electricity × electricity CO₂ emissions factor^{#1} + purchased heat × heat CO₂ emissions factor^{#2}
 Notes:#1 The value (0.33 t-CO₂ / thousand kWh) which The Federation of Pharmaceutical Manufacturers’ Associations of JAPAN has adopted to manage the progress of its CO₂ reduction target

#2 The values based on “Greenhouse Gas Emissions Accounting, Reporting, and Disclosure System” which is provided in “Act on Promotion of Global Warming Countermeasures.” However, we use values provided by Sumitomo Chemical Co, Ltd. for sites located on the premises of Sumitomo Chemical Co., Ltd. (Ehime Plant only until fiscal 2017 and all sites from fiscal 2018)

■ Scope 3 CO₂ Emissions by Category: Total 289,841 t-CO₂

Category	Methods of Calculation and Emissions Intensity, etc.	FY2018 Emissions (t-CO ₂)	Boundary
1 ✓ Purchased goods and services	Calculated by multiplying the purchase price of raw materials and purchased products by the emissions intensity in Japanese Ministry of the Environment database	236,002	production sites on a non-consolidated bases
2 Capital goods	Calculated by multiplying the acquisition price of the fixed asset by the emissions intensity in Japanese Ministry of the Environment database	31,345	consolidated basis, including overseas subsidiaries
3 Fuel- and energy-related activities not included in Scope 1 or Scope 2	Calculated by multiplying energy consumption by the emissions intensity in Japanese Ministry of the Environment database or Carbon Footprint database	9,822	non-consolidated basis
6 Business travel	Calculated by multiplying business travel expenses paid by the emissions intensity in Japanese Ministry of the Environment database	2,646	non-consolidated basis
11 Use of sold products	Calculated by multiplying HFC amount in pharmaceutical MDIs (metered dose inhalers) sold by GWP	5,731	non-consolidated basis
— Total of categories other than above (4,5,7,12 and 13)	—	4,295	non-consolidated basis

Japanese Ministry of the Environment database: The database on emissions unit values for accounting of greenhouse gas emissions, etc., by organizations throughout the supply chain (Ver. 2.6)
 Carbon Footprint Database: The Carbon Footprint Communication Program, basic database, Ver. 1.01

Independent Assurance Report



Independent Assurance Report

To the President and CEO of Sumitomo Dainippon Pharma Co., Ltd.

We were engaged by Sumitomo Dainippon Pharma Co., Ltd. (the “Company”) to undertake a limited assurance engagement of the environmental and social performance indicators marked with  (the “Indicators”) for the period from April 1, 2018 to March 31, 2019 included in its Integrated Report 2019 (the “Report”) for the fiscal year ended March 31, 2019.

The Company’s Responsibility

The Company is responsible for the preparation of the Indicators in accordance with its own reporting criteria (the “Company’s reporting criteria”), as described in the Report.

Our Responsibility

Our responsibility is to express a limited assurance conclusion on the Indicators based on the procedures we have performed. We conducted our engagement in accordance with the ‘International Standard on Assurance Engagements (ISAE) 3000, Assurance Engagements other than Audits or Reviews of Historical Financial Information’ and the ‘ISAE 3410, Assurance Engagements on Greenhouse Gas Statements’ issued by the International Auditing and Assurance Standards Board. The limited assurance engagement consisted of making inquiries, primarily of persons responsible for the preparation of information presented in the Report, and applying analytical and other procedures, and the procedures performed vary in nature from, and are less in extent than for, a reasonable assurance engagement. The level of assurance provided is thus not as high as that provided by a reasonable assurance engagement. Our assurance procedures included:

- Interviewing the Company’s responsible personnel to obtain an understanding of its policy for preparing the Report and reviewing the Company’s reporting criteria.
- Inquiring about the design of the systems and methods used to collect and process the Indicators.
- Performing analytical procedures on the Indicators.
- Examining, on a test basis, evidence supporting the generation, aggregation and reporting of the Indicators in conformity with the Company’s reporting criteria, and recalculating the Indicators.
- Visiting one of the Company’s factories selected on the basis of a risk analysis.
- Evaluating the overall presentation of the Indicators.

Conclusion

Based on the procedures performed, as described above, nothing has come to our attention that causes us to believe that the Indicators in the Report are not prepared, in all material respects, in accordance with the Company’s reporting criteria as described in the Report.

Our Independence and Quality Control

We have complied with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, which includes independence and other requirements founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior. In accordance with International Standard on Quality Control 1, we maintain a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

KPMG AZSA Sustainability Co., Ltd.

KPMG AZSA Sustainability Co., Ltd.
Osaka, Japan
September 17, 2019

Yutaka Atomi
Outside director

Hidehiko Sato
Outside director

Saeko Arai
Outside director

Outside Director Roundtable Discussion

Having a sense of decisive change and overcoming issues, based on Mid-term Business Plan 2022

Sumitomo Dainippon Pharma has three outside directors, who provide support to improve corporate value utilizing their respective expertise and experience. We asked all of the outside directors to discuss the formulation of the Mid-term Business Plan 2022 (fiscal 2018—2022) (“MTBP”), a major issue in fiscal 2018.

Note: Hidehiko Sato served as an Outside Audit & Supervisory Board Member for two years and as an Outside Director for six years, but retired effective June 2019.

— From the standpoint of an outside director, how did you participate in discussions during the formulation process for the MTBP announced in April?

Sato This MTBP is a five-year plan starting in fiscal 2018, so it was initially planned for release in March 2018. However, its start was delayed by about one year. This delay was due to Sumitomo Dainippon Pharma filing a patent infringement lawsuit against a number of generic drug manufacturers,

which had made applications for generic drugs to the U.S. Food and Drug Administration (FDA), on grounds of infringement of the LATUDA® use patent (the “ANDA lawsuit”).

Atomi As the management team considered and formulated the MTBP with a sense of decisive change about how to handle the next five years to develop a pillar of earnings following LATUDA® and achieve future sustained growth, the content may have been more fully refined.

Sato The MTBP was the subject of intense debate on multiple occasions at the Board of Directors as well. Sumitomo Dainippon Pharma established its vision for 15 years’ time and the first five-year period for achieving it to formulate the MTBP. Due to the speed of changes in the external environment, there may need to be minor adjustments to the content in the future, but I think that it is an appropriate period of time for clearly showing employees the direction to be aimed for. In fact, it was difficult to rethink strategy assuming various scenarios, but I feel that we have established an ambitious plan which is well-crafted down to the details whilst having a long-term perspective.

Arai In order to practice its corporate philosophy, Sumitomo Dainippon Pharma compiled material issues into a materiality map in 2018 with the aim of sustained growth and has been working on management with a focus on ESG. When formulating the MTBP, it was also considered that these efforts will lead to achieving the SDGs. As a long-term goal, Sumitomo Dainippon Pharma has set up a “Global Specialized Player” with ability to meet needs for healthcare, as a position we aspire to be in 2033. I think this is very good for indicating a future vision that will form a major guide for all employees.

Atomi In addition to pharmaceuticals, the traditional pillar of business, we have established the launch of the Frontier Business to be another pillar as a long-term target. Initially, I pointed out that this area is fiercely competitive and it will be difficult to develop with a half-hearted approach. As a result, there was considerable discussion about what kind of action is required to develop it into a pillar of business.

Arai In this MTBP, I focused on what the position of Sumitomo Dainippon Pharma is in the changing environment surrounding the pharmaceutical industry. There were many issues specific to the pharmaceutical industry and measures to counter them, and the preliminary explanations by relevant departments were extremely helpful. I think that the careful explanations deepened understanding, allowing us to have profound discussions on the content of the MTBP at the Board of Directors. In the formulation process, I was able to participate in the discussion from the drafting stage in the sense that questions and statements from the preliminary explanations were invariably taken up in the subsequent examination and review.

Sato As the plan was put together with the outside directors asking various questions and expressing opinions, I believe that the final content is compelling from our perspective.

—What challenges are you aware of for achieving the MTBP?

Arai Nurturing the corporate culture and developing human resources will be important. I think that the explicit description of the vision for employees, including the desired employee profile, is really good.

Sato In this MTBP, we decided to build a flexible and efficient organizational foundation in which “CHANTO*” is instilled. At first, I was dubious about the wording of “CHANTO,” but by writing “CHANTO” I now think that it was effective in unifying the thinking of the group overall, including

overseas subsidiaries, as a global company.

Atomi From my standpoint as a medical doctor, I think that society’s greatest expectation of Sumitomo Dainippon Pharma is for it to keep creating outstanding new drugs that save people from disease. In other words, this is solving social issues through our core business. However, the probability of success in new drug development is low, and we need to value the various seeds of new drugs within the Company in order to increase the probability even by a little. Fortunately, there are many young researchers with unique ideas at Sumitomo Dainippon Pharma, and it is important to develop these human resources and bring out their potential.

Arai I agree. As future research and development will have a major impact on performance, I think there is a need to establish an environment in which innovative and adventurous researchers can play active rather than passive roles while also complying with the rules.

Sato It is as you say. One of the reasons why I rate this MTBP highly is that it clearly indicates the vision that the Company will aim for, at the same time, elaborating sufficiently on the systems and methods for achieving the target. The environment surrounding the pharmaceutical industry is extremely challenging, and there are many issues to be overcome, but these risks are properly analyzed in the MTBP.

Atomi In this MTBP, the issues and responses are presented clearly, which should make it compelling for investors as well.

Sato Sumitomo Dainippon Pharma is highly motivated to contribute to patients and healthcare facilities by providing even better pharmaceuticals, and I think that this translated into a coherent and clear business strategy. So long as the Company takes this approach, it should be able to solve issues despite the challenging environment.

Atomi To accomplish this, I hope that Sumitomo Dainippon Pharma will implement the plan with a sense of decisive change going forward.

* CHANTO: Capability to continuously foster and deliver innovation to patients and other customers, while transforming our organization in flexible ways to adapt to changes in the world

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

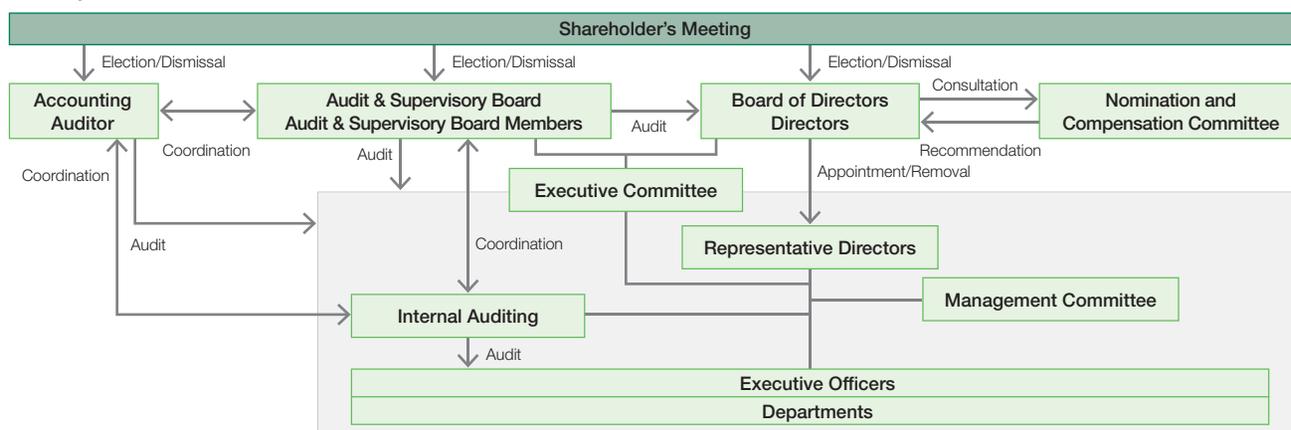
Mission. The Company posts on its website the summary for its basic concept and basic policy titled the “Basic Policy on Corporate Governance” (the “Basic Policy”).

Governance reform: progression of initiatives

(FY)

	2008–2010	2011	2012	2013	2014	2015	2016	2017	2018	
Outside Directors (number of Directors)				1 (8)	2 (8)			3 (8)		
Outside Audit & Supervisory Board Members (number of Audit & Supervisory Board Members)	3 (5)									
Supervisory function	Company with an Audit & Supervisory Board									
						Nomination and Compensation Committee				
Effectiveness						Evaluation of effectiveness of Board of Directors				
						Regular meetings of Outside Directors and Outside Audit & Supervisory Board Members				
Policy	Declaration of Conduct									
		Compliance Standards								
						Basic Policy on Corporate Governance				
						DSP Group Risk Management Policy				
Human Resource Development						DSP Academy, a selective training program that includes the Management Course to foster future managers, established				

Corporate Governance Structure



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.

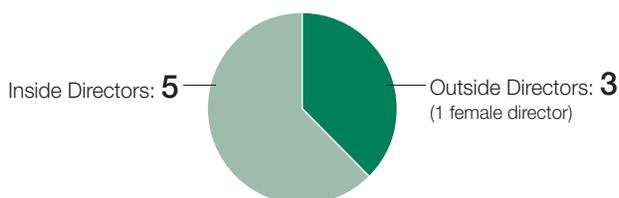
The Board of Directors consists of eight members, including three Independent Outside Directors (the chairperson: Chairman). The Board of Directors holds a meeting once a month, in principle, and resolves and reports on material business matters.

The Company has a Nomination and Compensation Committee,* which has Independent Outside Directors for a majority of its members and holds meetings as necessary, as a consultative body to the Board of Directors.

The Management Committee holds meetings twice a month, in principle, as a consultative body to the 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 the Audit & Supervisory Board Members, including the Outside Directors and the Outside Audit & Supervisory Board Members, as well as Executive Officers and other related persons, the status of the execution of business and material matters relating to the execution of business.

Ratio of Outside Directors (as of July 1, 2019)



* 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 the nomination of the candidates for Directors and Audit & Supervisory Board Members, and decision on compensation of Directors. The Nomination and Compensation Committee consists of the following four members, the majority (three members) of them being Independent Outside Directors, and the chairperson being appointed from among the Independent Outside Directors.

Composition of the Nomination and Compensation Committee

Chairman	Yutaka Atomi (Outside Director)
Members	Masayo Tada (Representative Director, Chairman) Saeko Arai (Outside Director) Nobuhiro Endo (Outside Director)

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, audit plans, 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 (FY2018)

	Amount to be paid (Millions of Yen)
Consideration to be paid for the services (audit attestation services) described in Paragraph 1 of Article 2 of the Certified Public Accountant Act (Act No. 103 of 1948)	99
Total amount of fees to be paid in cash or otherwise by the Company or Subsidiaries of the Company	103

- 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.
3. Significant subsidiaries located overseas were audited by auditing firms other than the Accounting Auditor of the Company.

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 sustained 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.

Principal areas of expertise and experience of Directors and Audit & Supervisory Board Members

Category	Position/Name	Corporate strategy	Human resources	Sales/ Marketing	Finance/ Accounting	Global	Research/ Development	Production/ Quality	Quality assurance
Directors	Representative Director, Chairman Masayo Tada	●		●		●			
	Representative Director, President and CEO Hiroshi Nomura	●	●	●	●	●	●		
	Executive Vice President Hitoshi Odagiri		●	●		●			
	Senior Executive Officer Toru Kimura	●					●		
	Senior Executive Officer Nobuhiko Tamura					●	●		●
Audit & Supervisory Board Members	Yoshinori Oh-e					●	●		●
	Takashi Kutsunai		●	●		●			

● indicates current positions and responsibilities held for at least the past two years

Status of Convocation of the Meeting of the Board of Directors (FY2018)

Organizational Body	Composition	Frequency of convocation	Purpose
The Board of Directors	The Directors 8 members, (including three Outside Directors)	Once a month as a rule	Resolving and reporting important management matters The Board of Directors Met 18 times in fiscal 2018
The Audit & Supervisory Board	The Audit & Supervisory Board 5 members, (including three outside Audit & Supervisory Board members)	Once a month as a rule	Discussing and resolving important audit-related matters Met 16 times in fiscal 2018
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 Met 7 times in fiscal 2018
Management Committee	The members of the Board of Directors, and Executive Officers 13 members	Twice a month as a rule	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 26 times in fiscal 2018
Executive Committee	Executives, including the members of the Board of Directors, the Audit & Supervisory Board, and Executive Officers 25 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 2018

Reasons for appointment and principal areas of expertise of Outside Directors and Outside Audit & Supervisory Board Members

Category	Name	Reasons for Appointment	Principal Areas of Expertise
Director	Yutaka Atomi	Yutaka Atomi has extensive 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 Group using his experience and expertise.	Medical science
	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 Group using her experience and expertise.	Accounting and management
	Nobuhiro Endo	Nobuhiro Endo has a wide range of knowledge and extensive experience which he has acquired in the course of his long career as a corporate executive at a company conducting ICT business, etc. at a global level. He has been appointed as an Outside Director in the hope that he will be able to contribute to the management of the Group using his knowledge and experience.	Management
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.	Tax affairs and finance
	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.	Management
	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 expertise and experience.	Law

The Principal Activities of the Outside Directors and Outside Audit & Supervisory Board Members (FY2018)

Category	Name	Name Principal Activities	Attendance
Outside Director	Hidehiko Sato	Of the eighteen (18) meetings during the fiscal year under review, he attended fifteen (15) 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.	15 times
	Yutaka Atomi	He attended all eighteen (18) meetings held by the Board of Directors during the fiscal year under review. He made statements at those meetings as necessary, primarily from the professional standpoint of a medical doctor.	18 times
	Saeko Arai	Out of the eighteen (18) meetings held by the Board of Directors during the fiscal year under review, she attended fourteen (14) of the fifteen (15) meetings held following her appointment as a Director. She made statements at those meetings as necessary, primarily based on her extensive experience as a corporate executive and from the professional standpoint of a certified public accountant.	14 times
Outside Audit & Supervisory Board Members	Kazuto Nishikawa	He attended all eighteen (18) meetings held by the Board of Directors and all sixteen (16) 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.	Board of Directors 18 times Audit & Supervisory Board 16 times
	Junsuke Fujii	He attended all eighteen (18) meetings held by the Board of Directors and fifteen (15) of the sixteen (16) Audit & Supervisory Board meetings. He made statements at those meetings, primarily based on his extensive experience and broad perspective as a corporate executive.	Board of Directors 18 times Audit & Supervisory Board 15 times
	Yoshio Iteya	Out of the eighteen (18) meeting held by the Board of Directors and the sixteen (16) meetings held by the Audit & Supervisory Board during the fiscal year under review, he attended fourteen (14) of the fifteen (15) meetings held by the Board of Directors and ten (10) of the eleven (11) meetings held by the Audit & Supervisory Board following his appointment as an Audit & Supervisory Board Member. He made statements, primarily from the professional standpoint of an attorney.	Board of Directors 14 times Audit & Supervisory Board 10 times

Message from a New Outside Director

I am Nobuhiro Endo from NEC Corporation, and I was appointed as an Outside Director at the Annual Shareholders' Meeting in 2019. I have been responsible for ICT*-related development work at NEC Corporation for approximately 30 years, and I have 13 years of experience as an executive officer. ICT has evolved considerably in recent years, and we are now moving from an information-driven society to a data-driven society with the source of value shifting from information to data. In conjunction with this, methods of creating value are on the brink of transformation, and ICT use in the medical field is increasingly being stepped up. I look forward to having useful and positive discussions that will help with the Company's business expansion, primarily in this field of medical ICT usage. In addition, based on my experience of corporate management, I believe that corporate culture is the very foundation of value creation and corporate sustainability, and I hope that I will also be able to provide positive support from this angle.



Nobuhiro Endo

*ICT: Information and Communications Technology

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 three 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.

Executive remuneration

The Company manages its compensation for Directors and the Audit & Supervisory Board Members in accordance with the following policies, etc.

(a) Procedures for determining compensation, etc.

The Company has the Nomination and Compensation Committee, which holds a meeting as necessary, as the consultative body to the Board of Directors for enhancing the objectivity and independence of the functions of the Board of Directors relating to matters such as the nomination of candidates for Directors and Audit & Supervisory Board Members and decisions regarding compensation of Directors.

The compensation of the Directors and Audit & Supervisory Board Members and other related matters are determined by the Board of Directors based on the recommendation from the Nomination and Compensation Committee after the Board of Directors seeks such recommendation and the Nomination and Compensation Committee deliberates the relevant matters.

In fiscal 2018, the Nomination and Compensation Committee deliberated compensation and the like for the Directors and Outside Directors several times and made recommendations to the Board of Directors.

(b) System and the total amount of compensation, etc.

Compensation for the Directors consists of base compensation and performance-linked compensation (bonuses), and this system is designed to serve as an incentive for achieving sustained growth and enhancing the corporate value of the Group. In order to promote value sharing with shareholders, 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 continue to hold the shares they acquire during their term of office and for one year after their retirement.

Compensation for the Outside Directors consists of base compensation and bonuses, and the Company adopts a compensation system where the business performance of the Company is not linked thereto, for the purpose of securing the supervisory function and independence of the Outside Directors. Compensation for the Audit & Supervisory Board Members consists only of the base compensation.

The total amount of the compensation and the like for the Directors and Audit & Supervisory Board Members was resolved at the annual shareholders' meeting held in June 2005 to be not more than 400 million yen annually for the Directors and not more than 100 million yen annually for the Audit & Supervisory Board Members. The numbers of the Directors and Audit & Supervisory Board Members with respect to the said resolution were 10 and four, respectively. Individual amounts for the Directors are determined in accordance with the procedures described in the above (a) at a meeting of the Board of Directors, and the individual amounts for the Audit & Supervisory Board Members are determined by the Audit & Supervisory Board.

(c) Calculation method for compensation, etc.

Of the compensation for the Directors, the base amount is set with respect to the base compensation according to each position, such as Representative Director. The amount of the performance-linked compensation (bonuses) is calculated by reflecting performance-linked elements and individual performance, to the base amount which is set according to each position, such as Representative Director.

The performance-linked elements are evaluated by the Nomination and Compensation Committee, using as an indicator the degree of achievement of forecasts by the consolidated financial results which indicate the operating results of the Company. As for the individual performance, the degree of achievement of performance targets of each Director is evaluated by the Nomination and Compensation Committee. As targets to be achieved, the consolidated financial

forecasts publicized in the announcement of the consolidated financial results for the previous fiscal year are used.

■ Amount of executive remuneration (FY2018)

Category	Number	Amount of Remuneration (Millions of Yen)
Directors	9	368
Audit & Supervisory Board Members	7	88

- Notes: 1. The above includes the amount of remuneration and the like for Outside Directors and Outside Audit & Supervisory Board Members, eight persons in total, which is 72 million yen in total.
 2. The above includes one Director and two Audit & Supervisory Board members who reached the end of their tenure at the conclusion of the 198th Ordinary General Meeting of Shareholders held on June 19, 2018.
 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 remuneration and the like for Directors includes 29 million yen in bonuses for Directors relating to fiscal 2018.

Analysis and evaluation of the effectiveness of the Board of Directors

The Company has evaluated the effectiveness of the Board of Directors annually since fiscal 2015. As the Company conducted such evaluation for the fourth time in fiscal 2018, the Company asked outside legal counsel to review the method of evaluation of the effectiveness of the Board of Directors of the Company and the evaluation results.

1) Purpose and method of evaluation of effectiveness

The Company has evaluated the effectiveness of the Board of Directors with the aim of improving the effectiveness of the Board of Directors for enhancing corporate governance of the Company: specifically, recognizing 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; regularly and repeatedly engaging in agenda-finding and improvement activities; and thereby continuously improving the functions of the Board of Directors. In fiscal 2018, the Company conducted a questionnaire on all the Directors and Audit & Supervisory Board Members during the period from February 2019 to March 2019. Based on the results of analysis of the answers to the questionnaire, opinions were exchanged at the meeting of the Board of Directors held in April 2019.

2) Survey Categories

The Company partially revised topics of the questionnaire in

fiscal 2018 based on the advice of outside legal counsel. The major topics of the questionnaire for fiscal 2018 were as follows:

- 1) Composition of the Board of Directors
- 2) Roles and duties of the Board of Directors
- 3) Status of the operations of the Board of Directors
- 4) 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

3) Improvement from the previous fiscal year

Based on the report of the answers to the questionnaire (quantitative evaluation by four grade scales and the entry of opinions in free space) and analysis thereof (such as the comparative analysis of the numerical values of the evaluation results for each topic for fiscal 2018 and those in the past), all the Directors and Audit & Supervisory Board Members exchanged opinions at the meeting of the Board of Directors in April 2019. As a result, it was confirmed that there is no major problem to be pointed out with respect to the operation of the Board of Directors in fiscal 2018 and the effectiveness of the Board of Directors of the Company has been ensured in general. In addition, it was agreed that appropriate progress was seen as to the handling of the agenda identified in fiscal 2017.

4) External evaluation

At a meeting of the Board of Directors held in May 2019, the Company received a report on external evaluation results from outside legal counsel on the process of evaluation of the effectiveness of the Board of Directors and the evaluation results of the Company for fiscal 2018. Based on the analysis and examination of the topics to be considered in the questionnaire and answers to such topics for fiscal 2018, results of the analysis of answers to the questionnaire conducted in the past fiscal year, examination of the minutes of meetings of the Board of Directors, report materials and other related documents for fiscal 2018, and observation of the circumstances of the opinion exchange at the meeting of the Board of Directors in April 2019, the Company received evaluation results from outside legal counsel to the effect that the process of evaluation of the effectiveness of the Board of Directors of the Company is appropriate,

and the evaluation results of the Company that the effectiveness of the Board of Directors has been ensured in general is appropriate. The Company also received from the outside legal counsel suggestions, etc. regarding matters that are found desirable to be examined for further improvement of the effectiveness.

5) Major matters to be addressed in fiscal 2019

Based on the results of the external evaluation and suggestions, etc., the following agendas have been identified as major matters to be addressed in fiscal 2019 as a result of the evaluation of the effectiveness of the Board of Directors for fiscal 2018.

- Further stimulation of deliberation by the Board of Directors;
- Enhancement of follow-up activities after resolutions are made by the Board of Directors;

and

- Enhancement of reports to the Board of Directors regarding opinions, etc. from shareholders, investors and other related persons.

The Board of Directors of the Company is determined to further enhance its functions, while addressing these agendas.

Factors That Could Significantly Influence Corporate Governance

Sumitomo Chemical Co., Ltd. is the parent company holding 51.78% (as of March 31, 2019) of the voting rights of the Company.

In the case where the Company conducts transactions with the parent company, appropriate supervision is given in light of the importance of the transactions, and in accordance with relevant procedures such as a requirement of approval at meetings 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 of the Company.

The Company conducts transactions with the parent company, such as leasing lands and procuring raw materials from the parent company. In these transactions, the prices were reasonably determined through negotiations between the two companies, taking into account the general market conditions. The contractual agreements resulting from these negotiations include the clause that the prices may be adjusted when relevant market conditions change. In addition, the Company has made a short-term loan to the parent company. The Company has set the relevant

terms and conditions for the loan so that the interests of the Company will not be harmed. For example, a reasonable rate for the interest rate was set while taking the market interest rate into account.

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. In addition to this policy, the Board of Directors annually evaluates whether it is reasonable to continue each respective strategic shareholding based on points such as the purpose of such shareholding, as well as the transaction status and unrealized profit and loss thereof. As a result of such evaluation, while the Company embarked on selling shares for which continued shareholding was found unreasonable, and the number of listed companies whose shares are held by the company is 26 as of May 31, 2019.

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. To be specific, it was decided that decisions regarding some proposals such as M&A related proposals and all the proposals at the Shareholders' Meeting held for the first time after any major scandal has occurred should be made with special care.

Efforts to Facilitate the Exercise of Voting Rights

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

The Company has implemented initiatives to invigorate the annual shareholders' meeting such as presenting the

business report with the use of video and narration. In addition, details of the results of resolutions on proposals at the annual shareholders' meeting are submitted in an extraordinary report and disclosed on our website. The business report and the presentation by the President at the annual shareholders' meeting are also posted on our website.

Communication with Shareholders and Investors

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

Sumitomo Dainippon Pharma regularly holds meetings with analysts and institutional investors from Japan and from abroad. In Japan, meetings are held to coincide with financial results announcements at the end of the second and fourth quarters, while conference calls are carried out for announcements of financial results of the first and third quarters. In addition, meetings focused on specific topics are held as appropriate. In November 2018, Sumitomo Dainippon Pharma held an ESG meeting.

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 2018 held six 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, Fact Books and notices of convocation for the annual shareholders' meetings, among others.

Moreover, since fiscal 2018, feedback from shareholders and investors has been reported to the Directors and Executive Officers each quarter in a report format as well as being reported to the Board of Directors semi-annually since fiscal 2019.

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 in English.

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 March of the fiscal year and the basic policies are revised as necessary to improve the internal control 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

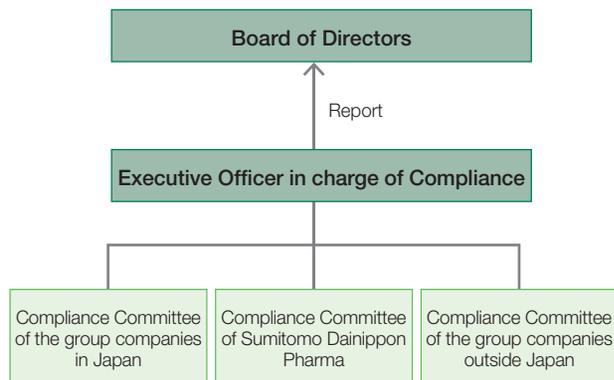
Compliance

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 2018, each compliance committee held meeting 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

■ Framework for compliance implementation



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.

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 (group-wide risks), and those requiring specific approaches by each company (business activity risks). 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.

Response to Guidelines on Ethical Drug Detailing Activities

Sumitomo Dainippon Pharma has responded appropriately to Guidelines on Ethical Drug Detailing Activities issued by the Ministry of Health, Labour and Welfare in September 2018. In order to promote even more appropriate detailing activities, we established the Rules on Detailing Activities as in-house rules effective April 1, 2019, and we have ensured there is thorough awareness of the guidelines within the Company.

We are also working to establish internal monitoring systems for detailing activities ahead of the full-scale commencement of the guidelines in October 2019.

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, the Company has prepared manuals that cover such issues as the set up and operational procedures of a headquarters for countermeasures to respond to a major disaster.

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, etc. to minimize risks. We also provide ongoing education and training for officers and employees.

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.

Information Security

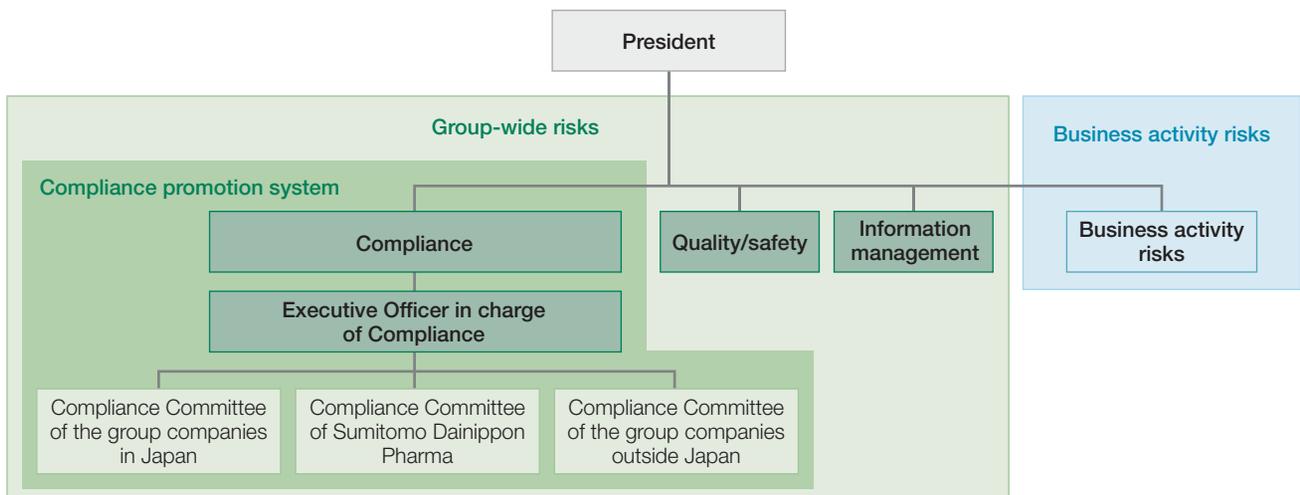
With respect to our information security efforts, we continue to update technical measures, rules and procedures according to change of social environment or progress of information technology and monitor compliance. We also strive to strengthen information security in our group companies. In addition, we hold periodic information security training for officers and employees to raise awareness.

Moreover, in addition to creating a system that prevents and detects unauthorized access and responds rapidly when an incident occurs (Computer Security Incident Response Team: CSIRT), we continue to implement efforts to prevent information security incidents.

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.

Risk Management System





Directors

1 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 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, Chairman of the Company (to the present)

2 Hiroshi Nomura Representative Director, President and Chief Executive Officer

1981: Joined Sumitomo Chemical Co., Ltd.
2008: Joined the Company
2008: Executive Officer of the Company
2012: Member of the Board of Directors of the Company
2014: Member of the Board of Directors and Senior Executive Officer of the Company
2016: Member of the Board of Directors and Executive Vice President of the Company
2017: Representative Director and Executive Vice President of the Company
2018: Representative Director, President and Chief Executive Officer of the Company (to the present)

3 Hitoshi Odagiri Member, Board of Directors, Executive Vice President Executive Director

1979: Joined Inabata & Co., Ltd.
1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2009: Senior Vice President of Dainippon Sumitomo Pharma America, Inc. (currently, Sunovion Pharmaceuticals Inc.)
2012: Executive Officer of the Company, Senior Director of Human Resources
2016: Senior Executive Officer of the Company
2016: Member of the Board of Directors and Senior Executive Officer of the Company
2018: Executive Director of Sales & Marketing Division and Head of Japan Business Unit of the Company (to the present)
2019: Member of the Board of Directors and Executive Vice President of the Company (to the present)

4 Toru Kimura Member, Board of Directors, Senior Executive Officer

1989: Joined Sumitomo Chemical Co., Ltd.
1992: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2009: Senior Director of Genomic Science Laboratories of the Company
2010: Senior Director of Research Planning & Management of the Company
2012: Senior Director of Global Strategy of the Company
2013: Senior Director of the Regenerative & Cellular Medicine Office of the Company
2015: Executive Officer of the Company
2016: Member of the Board of Directors and Executive Officer of the Company, Senior Director of Global Corporate Strategy

2019: Member of the Board of Directors and Senior Executive Officer of the Company and Senior Executive Research Director of Drug Research Division, and in charge of Regenerative & Cellular Medicine Office, Regenerative & Cellular Medicine Kobe Center and Regenerative & Cellular Medicine Manufacturing Plant, and Chief Research Officer of the Company (to the present)

5 Nobuhiko Tamura Member, Board of Directors, Senior Executive Officer

1982: Joined Sumitomo Chemical Co., Ltd.
1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2007: President of Dainippon Sumitomo Pharma America, Inc. (currently, Sunovion Pharmaceuticals Inc.)
2009: Executive Officer of the Company
2012: Executive Director of the Drug Development Division of the Company
2013: Senior Executive Officer of the Company
2016: Chair and President of Sunovion Pharmaceuticals Inc.
2019: Member of the Board of Directors and Senior Executive Officer of the Company and Executive Director of Corporate Regulatory Compliance & Quality Assurance Division, and in charge of Regulatory Affairs, Medical Information, Medical Affairs and Drug Development Division, and Deputy Head of Japan Business Unit of the Company (to the present)

6 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 Company
2017: Outside Member of the Board of Directors of the Company (to the present)
2018: President Emeritus of Kyorin University (to the present)
2018: President of the Pancreas Research Foundation of Japan (to the present)

7 Saeko Arai
Member, Board of Directors (Outside)

1987: Joined Eiva 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 teamS Inc. (to the present)
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
2018: Outside Member of the Board of Directors of Tokyu Fudosan Holdings Corporation (to the present)
2018: Outside Member of the Board of Directors of the Company (to the present)
2019: Professor at the Faculty of Business Administration of Hakuoh University (to the present)

8 Nobuhiro Endo
Member, Board of Directors (Outside)

1981: Joined NEC Corporation
2006: Senior Vice President and Executive General Manager of the Mobile Network Operations Unit of NEC Corporation
2009: Executive Vice President of NEC Corporation
2009: Executive Vice President and Member of the Board of NEC Corporation
2010: President (Representative Director) of NEC Corporation
2016: Chairman of the Board (Representative Director) of NEC Corporation
2016: Outside Director of JAPAN POST INSURANCE Co., Ltd.
2017: Outside Director of Seiko Holdings Corporation
2018: Outside Director of Japan Exchange Group, Inc. (to the present)
2019: Outside Member of the Board of Directors of the Company (to the present)
Director and Chairman of the Board of NEC Corporation (to the present)
Outside director of Tokio Marine Holdings, Inc. (to the present)

Audit & Supervisory Board Members

9 Yoshinori Oh-e
Audit & Supervisory Board Member

1982: Joined the Company
2007: Senior Director of Development Planning & Management
2009: Senior Director of Pharmaceutical Strategy
2010: Executive Officer of the Company, Senior Director Business Development
2014: Senior Executive Officer of the Company, Executive Director of Corporate Regulatory Compliance & Quality Assurance Division
2017: Audit & Supervisory Board Member of the Company (to the present)

10 Takashi Kutsunai
Audit & Supervisory Board Member

1981: Joined Sumitomo Chemical Co., Ltd.
1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2005: Senior Director of Personnel of the Company
2008: Senior Director of Strategic Marketing & Planning (Asia), International Business Management of the Company
2009: Senior Director of International Business Strategic Marketing and Planning of the Company
2010: Senior Director of Global Sales and Marketing of the Company
2012: Senior Director of Internal Auditing of the Company
2018: Audit & Supervisory Board Member of the Company (to the present)

11 Kazuto Nishikawa
Audit & Supervisory Board Member (Outside)

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

12 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
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
2017: Outside Audit & Supervisory Board Member of the Company (to the present)

13 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

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
Senior Executive Officer

Global Corporate Strategy; IT Management & Digital Transformation; Frontier Business Office

Hideyuki Harada
Executive Officer

Executive Research Director, Drug Research Division

Atsuko Higuchi
Executive Officer

Corporate Communications; Human Resources

Shigeyuki Nishinaka
Executive Officer

Global Business Development; International Business Management

Kazuhiro Takada
Executive Officer

Corporate Governance; Legal Affairs; Intellectual Property

Takuya Taguchi
Executive Officer

Deputy Executive Director, Sales & Marketing Division; Senior Director, Sales & Marketing Management

Shinichiro Katayanagi
Executive Officer

Executive Vice President and Chief Corporate Strategy Officer, Sunovion Pharmaceuticals Inc.

Antony Loebel
Executive Officer

President and Chief Executive Officer, Sunovion Pharmaceuticals Inc.

Patricia S. Andrews
Executive Officer

Chief Executive Officer, Boston Biomedical, Inc.

Ten-Year Summary of Selected Financial Data

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

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

3. 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.

4. 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 software.

5. ROIC: (core operating profit - income taxes) / (capital + interest-bearing liabilities)

Millions of yen

	2016	2017	2018
	¥403,206	¥411,639	¥477,966
	215,055	227,495	290,321
	53.3%	55.3%	60.7%
	104,471	100,071	119,852
	261,805	259,066	292,291
	82,034	80,819	91,397
	20.3%	19.6%	19.1%
	36,930	52,501	65,823
	9.2%	12.8%	13.8%
	24,697	28,733	37,525
	¥707,717	¥783,640	¥801,425
	446,473	460,389	483,050
	¥9,785	¥10,619	¥10,060
	20,267	18,649	19,909
Yen			
¥	62.16	72.32	94.45
	1,123.76	1,158.80	1,215.84
	18.00	20.00	28.00
	5.5%	6.3%	8.0%
	3.5%	3.9%	4.7%
	63.1%	58.8%	60.3%
	29.0%	27.7%	29.6%

Millions of yen

IFRS (Core Basis)	2017	2018	2019
RESULTS OF OPERATIONS:			
Revenue	¥408,357	¥466,838	¥459,267
Overseas sales revenue	224,234	281,434	293,325
Ratio to revenue	54.9%	60.3%	63.9%
Cost of sales	94,523	112,345	113,109
Selling, general and administrative expenses	171,385	186,176	186,143
Research and development expenses	81,373	86,881	82,891
Ratio of R&D expenses to revenue	19.9%	18.6%	18.0%
Core operating profit	64,372	90,604	77,299
Ratio of core operating profit to revenue	15.8%	19.4%	16.8%
Net profit attributable to owners of the parent	31,316	53,448	48,627
FINANCIAL POSITION:			
Total assets	¥779,072	¥809,684	¥834,717
Total equity	412,268	452,723	498,138
OTHER STATISTICS:			
Capital expenditures	¥ 7,835	¥ 10,184	¥ 13,231
Depreciation and amortization	13,352	13,518	14,903
PER SHARE OF COMMON STOCK:			
	Yen		
Basic net profit	¥ 78.82	¥ 134.53	¥ 122.39
Equity attributable to owners of the parent	1,037.68	1,139.50	1,253.82
Cash dividends applicable to the year	20.00	28.00	28.00
FINANCIAL INDICATORS:			
ROIC	11.5%	12.1%	11.8%
ROE	7.8%	12.4%	10.2%
ROA	4.2%	6.7%	5.9%
Ratio of equity attributable to owners of the parent to total assets	52.9%	55.9%	59.7%
Dividend payout ratio	25.4%	20.8%	22.9%

Operating Results and Financial Condition

Overview of Overall Operating Results

During the fiscal year ended March 31, 2019, in the pharmaceutical sector, R&D expenses continue to rise and competition is intensifying, as 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. Meanwhile, this industrial sector is showing signs of change, such as a growing interest in preventive medicine and advancements in drug discovery utilizing digital technology.

Against this backdrop, in Japan the Group has focused its management resources to bolster sales of Trulicity®, TRERIEF®, and LONASEN®, to name but a few, while at the same time increasing efficiency in its business activities.

In North America, the Company's U.S. subsidiary Sunovion Pharmaceuticals Inc. poured its resources into maximizing the sales of global strategic product LATUDA® (atypical antipsychotic agent) and expanding the sales of other mainstay products.

In fiscal 2018, the Company and Sunovion were parties to (a) one (1) consolidated patent infringement lawsuit against 16 generic companies filed in February 2018 (the "Lawsuit"), and (b) three (3) additional patent infringement lawsuits against three (3) other generic companies (collectively, "Additional Lawsuits"). The Additional Lawsuits were filed during the period of August – October 2018. Both the Lawsuit and the Additional Lawsuits were filed in the U.S. District Court for the District of New Jersey (the "Court") and involved two U.S. patents protecting LATUDA®. With the assistance of the Court, the Company and Sunovion entered into settlement agreements with all of the defendants involved in the Lawsuit and the Additional Lawsuits except for one generic company. All of the defendants involved in the Lawsuit had entered into settlement agreements with the Company and Sunovion by December 3, 2018 and two of the defendants involved in the Additional Lawsuit had settled with the Company and Sunovion by March 31, 2019. Pursuant to the terms of the settlement agreements, the generic companies involved in the Lawsuit and the Additional Lawsuit will be permitted to distribute their generic versions of lurasidone HCL starting on February 20, 2023.

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

Operating Results

Revenue: ¥459.3 billion (down 1.6% year-on-year)

Sales grew in the North America segment primarily owing to increases in sales of LATUDA®, one of the primary revenue sources of the Group, as well as antiepileptic agent APTIOM®. Nevertheless, revenue for the Group slightly decreased as sales in the Japan segment showed a decrease owing primarily to the National Health Insurance (NHI) drug price revisions of April

2018 and declines in sales of long-listed drugs.

Core operating profit: ¥77.3 billion (down 14.7% year-on-year)

Core operating profit decreased as gross profit showed a decrease in the Japan segment chiefly attributable to NHI drug price revisions and the absence of one factor that existed in the previous fiscal year: other income as a result of divestiture of marketing rights.

Operating profit: ¥57.9 billion (down 34.4% year-on-year)

Operating profit decreased even further than core operating profit. This is primarily owing to impairment losses on intangible assets, including in-process research and development and marketing rights, and to business structure improvement expenses associated with the consolidation of production sites by the Company. This occurred despite an increase in reversal of expenses under changes in fair value of contingent consideration resulting chiefly from modifications of business plans, including a review of development plans.

Profit before taxes: ¥65.0 billion (down 23.4% year-on-year)

In addition to an increase in interest income, the Company reported foreign exchange gains on its financial assets denominated in foreign currencies at the end of the period under review as the yen depreciated against the U.S. dollar over the previous fiscal year-end. As a result, finance income increased substantially.

Net profit attributable to owners of the parent: ¥ 48.6 billion (down 9.0% year-on-year)

The ratio of net profit attributable to owners of the parent to revenue was 10.6%, which is down by 0.8 percentage points year-on-year.

Financial Condition

Summary of assets, liabilities, and net assets

-Assets

Non-current assets showed a slight increase from the previous fiscal year-end. This is because deferred tax assets increased and so did goodwill, owing to the impact of foreign currency translations, while intangible assets declined, owing primarily to the posting of impairment loss.

Current assets grew by 24.7 billion yen from the previous fiscal year-end, as cash and cash equivalents decreased while other financial assets increased significantly. Meanwhile, inventories and trade and other receivables showed an increase.

As a result, total assets increased by 25.0 billion yen from the previous fiscal year-end to 834.7 billion yen.

-Liabilities

Total liabilities decreased by 20.4 billion yen from the previous

fiscal year-end to 336.6 billion yen, as a result of a decrease in interest-bearing debts primarily attributable to redemption of bonds, decreases in trade and other payables and other financial liabilities, despite an increase in provisions.

-Equity

Equity increased by 45.4 billion yen from the previous fiscal year-end to 498.1 billion yen, owing primarily to increases in retained earnings and exchange differences in translation of foreign operations under other components of equity.

Status of cash flows

-Net cash provided by operating activities

Cash flows provided by operating activities decreased by 44.7 billion yen year-on-year to 48.7 billion yen, primarily owing to an increase in income taxes paid as well as to factors that contributed to a decrease in cash, including decreases in profit before taxes and trade and other payables.

-Net cash used in investing activities

Cash flows used in investing activities increased by 18.5 billion yen year-on-year to 35.0 billion yen, owing primarily to an increase in short-term loan receivables and the absence of proceeds from business transfer during the fiscal year under review, despite a decrease in purchase of intangible assets and investments.

-Net cash provided by financing activities

Cash flows used in financial activities edged down year-on-year to 28.6 billion yen, due primarily to a decrease in repayment of loans, while payment of dividends increased.

-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, 2019 was 137.3 billion yen, which represents a decrease of 10.5 billion yen from the end of the previous fiscal year.

Allocation of the Company's Profits

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

The Company's basic policy is to make 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.

The Company believes it important to distribute surplus in an appropriate manner reflecting any improvement in its performance. Accordingly, a performance-linked dividend hike will be considered in addition to consistent dividend payments. In a constant effort to further increase its

corporate value, the Company remains committed to establishing a solid management base and a strong financial position, while making proactive investments for sustainable business growth. In the Mid-term Business Plan covering the period from fiscal 2018 through 2022, the Company aims for a five-year average dividend payout ratio of 20% or higher during the period.

During the period under review, the Company reported core operating profit of 77.3 billion yen and net profit attributable to owners of the parent of 48.6 billion yen.

Given the dividend policy and earnings results of the fiscal year under review, the Company paid a year-end dividend of 19 yen per share, resulting in an annual dividend of 28 yen per share for fiscal 2018.

Forecasts for the Year Ending March 31, 2020 (July 2019 Revision of Initial Forecasts)

	Billions of yen	
	FY2018	FY2019 Forecasts
Revenue	459.3	475.0
Core operating profit	77.3	77.0
Operating profit	57.9	88.0
Net profit	48.6	36.0
Net profit attributable to owners of the parent	48.6	36.0

In Japan, despite the impact from the entry of generic drugs for LONASEN® oral medication and decline in sales of long-listed drugs, revenue is expected to increase due to expansion in sales of TRERIEF® and Trulicity®, the contribution of LONASEN® Tape and the commencement of the sales alliance with Novartis Pharma K.K. on Equa® and EquMet®. In North America, revenue is also expected to increase due to expansion in sales of LATUDA®, APTIOM®, and LONHALA® MAGNAIR®. Consolidated revenue is expected to reach 475.0 billion yen, up by 15.7 billion yen year-on-year.

Despite the increase in gross profit with the growth in revenue, core operating profit is expected to fall slightly year-on-year to 77.0 billion yen due to an increase in R&D expenses.

In fiscal 2018, the Group recorded impairment loss, and there will be a reversal of expenses resulting from changes in fair value of contingent consideration related to an acquisition in fiscal 2019. As a result, the Group expects operating profit of 88.0 billion yen, up by 30.1 billion yen year-on-year. Net profit attributable to owners of the parent is expected to be 36.0 billion yen, down 12.6 billion yen year-on-year, due to the impact from the reversal of deferred tax assets among other factors.

* Foreign currency exchange rates used for the forecasts are: 1 USD = 110 JPY (110.9 JPY in the fiscal year underreview), 1 RMB =16.5 JPY (16.5 JPY in the fiscal year under review).

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. The Group works to prevent these risks from occurring and will take appropriate measures if they occur.

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 40% of Sumitomo Dainippon Pharma's consolidated revenue. If LATUDA® revenue falls due to the emergence of other strong competing products, or through other unexpected events (including but not limited to the launch of competing products by manufacturers of branded prescription drugs as well as the sale of products that compete with LATUDA® by manufacturers of generic drugs), 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. Similarly, a variety of measures to curb the prices of pharmaceuticals aimed at reducing healthcare costs are being implemented overseas, primarily in Europe and the U.S. The direction that these healthcare system reforms might take could ultimately have a significant and negative impact on the Group's operating results and financial position.

Problems concerning adverse events

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

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

In February 2018, Sumitomo Dainippon Pharma filed a patent infringement lawsuits jointly with its U.S. subsidiary in the U.S. District Court of New Jersey against a total of 16 generic drug manufacturers on grounds of infringement of the method of use patent owned by Sumitomo Dainippon Pharma related to LATUDA®, the atypical antipsychotic which is one of the Company's mainstay products (the "preceding lawsuit"), as well as three patent infringement lawsuits against three manufacturers of generic drugs between August and October 2018 (the "additional lawsuits") in the same District Court. As a result of negotiations with the defendants for settlements with the involvement of the court, Sumitomo Dainippon Pharma and its subsidiary concluded the preceding lawsuit with all the defendants through settlements on or before December 3, 2018, and two of the three additional lawsuits were concluded through settlement before the end of fiscal 2018. Additionally, there is always the possibility that a lawsuit may be brought in connection with the adverse effect of a pharmaceutical product, product liability, labor issues, fair trade, etc., relating to the business activities of the Group. These patent infringement lawsuits and other potential lawsuits involve inherent uncertainties. Depending on the development thereof, such lawsuits 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 (in-process research and development, etc.), 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 research laboratories and plants, 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.

Note: Forward-looking statements in this discussion of the risks reflect the judgment of the Group as of March 31, 2019. There are risks other than those described above, and the risks listed here do not include all of the risks faced by the Group.

Consolidated Statement of Profit or Loss

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

		Millions of yen	
	Note	2018	2019
Revenue	4,5	¥ 466,838	¥ 459,267
Cost of sales		112,345	113,553
Gross profit		354,493	345,714
Selling, general and administrative expenses	6	183,651	180,439
Research and development expenses		86,928	102,364
Other income	7	9,417	885
Other expenses	8	5,158	5,912
Operating profit		88,173	57,884
Finance income	9	2,430	7,369
Finance costs	9	5,737	207
Profit before taxes		84,866	65,046
Income tax expenses	10	31,418	16,419
Net profit		53,448	48,627
Net profit attributable to:			
Owners of the parent		53,448	48,627
Net profit total		53,448	48,627
Earnings per share (yen)			
Basic earnings per share	11	134.53	122.39

Consolidated Statement of Comprehensive Income

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

		Millions of yen	
	Note	2018	2019
Net profit		¥ 53,448	¥ 48,627
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	12	8,527	876
Remeasurements of defined benefit liability (asset)	12	(2,824)	(2,089)
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	12	(10,748)	8,766
Cash flow hedges	12	(1)	15
Total other comprehensive income		(5,046)	7,568
Total comprehensive income		48,402	56,195
Total comprehensive income attributable to:			
Owners of the parent		48,402	56,195
Total comprehensive income		48,402	56,195

Consolidated Statement of Financial Position

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

Millions of yen

	Note	2018	2019
Assets			
Non-current assets			
Property, plant and equipment	13, 16	¥ 58,204	¥ 59,485
Goodwill	14	95,097	99,348
Intangible assets	15	189,681	171,390
Other financial assets	17, 27	70,993	74,668
Income taxes receivables		2,453	2,562
Other non-current assets		3,067	3,277
Deferred tax assets	10	41,608	50,719
Total non-current assets		461,103	461,449
Current assets			
Inventories	18	60,169	66,889
Trade and other receivables	19, 27	112,982	118,760
Other financial assets	17, 27	22,066	43,750
Income taxes receivables		419	483
Other current assets		5,170	6,090
Cash and cash equivalents	20	147,775	137,296
Total current assets		348,581	373,268
Total assets		809,684	834,717
Liabilities and equity			
Liabilities			
Non-current liabilities			
Bonds and borrowings	21, 27	30,940	27,980
Other financial liabilities	23, 27	88,427	80,387
Retirement benefit liabilities	25	20,700	23,613
Other non-current liabilities		6,551	6,425
Deferred tax liabilities	10	95	—
Total non-current liabilities		146,713	138,405
Current liabilities			
Bonds and borrowings	21, 27	16,460	2,960
Trade and other payables	22, 27	58,708	49,238
Other financial liabilities	23, 27	6,278	8,673
Income taxes payable		14,368	15,723
Provisions	24	84,433	92,176
Other current liabilities		30,001	29,404
Total current liabilities		210,248	198,174
Total liabilities		356,961	336,579
Equity			
Share capital	26	22,400	22,400
Capital surplus	26	15,860	15,861
Treasury shares	26	(669)	(674)
Retained earnings	26	396,037	431,799
Other components of equity	26	19,095	28,752
Equity attributable to owners of the parent		452,723	498,138
Total equity		452,723	498,138
Total liabilities and equity		¥ 809,684	¥ 834,717

Consolidated Statement of Changes in Equity

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

Millions of yen						
Equity attributable to owners of the parent						
Note	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					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, 2017	¥ 22,400	¥ 15,860	¥ (667)	¥ 357,769	¥ 18,797	¥ —
Net profit	—	—	—	53,448	—	—
Other comprehensive income	12	—	—	—	8,527	(2,824)
Total comprehensive income				53,448	8,527	(2,824)
Purchase of treasury shares	26	—	—	—	—	—
Dividends	26	—	—	(7,945)	—	—
Reclassification from other components of equity to retained earnings		—	—	(7,235)	4,411	2,824
Total transactions with owners				(15,180)	4,411	2,824
Balance as of March 31, 2018	22,400	15,860	(669)	396,037	31,735	—
Cumulative effects of changes in accounting policies	2	—	—	348	—	—
Restated balance	22,400	15,860	(669)	396,385	31,735	—
Net profit				48,627	—	—
Other comprehensive income	12	—	—	—	876	(2,089)
Total comprehensive income				48,627	876	(2,089)
Purchase of treasury shares	26	—	—	—	—	—
Disposal of treasury shares	26	—	1	—	—	—
Dividends	26	—	—	(11,124)	—	—
Reclassification from other components of equity to retained earnings		—	—	(2,089)	—	2,089
Total transactions with owners		1	(5)	(13,213)	—	2,089
Balance as of March 31, 2019	¥ 22,400	¥ 15,861	¥ (674)	¥ 431,799	¥ 32,611	¥ —

Millions of yen					
Equity attributable to owners of the parent					
Note	Other components of equity			Total	Total equity
	Exchange differences on translation of foreign operations	Cash flow hedges	Total		
Balance as of April 1, 2017	¥ (1,871)	¥ (20)	¥ 16,906	¥ 412,268	¥ 412,268
Net profit	—	—	—	53,448	53,448
Other comprehensive income	12	(10,748)	(1)	(5,046)	(5,046)
Total comprehensive income		(10,748)	(1)	48,402	48,402
Purchase of treasury shares	26	—	—	(2)	(2)
Dividends	26	—	—	(7,945)	(7,945)
Reclassification from other components of equity to retained earnings		—	—	7,235	—
Total transactions with owners		—	—	(7,947)	(7,947)
Balance as of March 31, 2018	(12,619)	(21)	19,095	452,723	452,723
Cumulative effects of changes in accounting policies	2	—	—	348	348
Restated balance	(12,619)	(21)	19,095	453,071	453,071
Net profit		—	—	48,627	48,627
Other comprehensive income	12	8,766	15	7,568	7,568
Total comprehensive income		8,766	15	56,195	56,195
Purchase of treasury shares	26	—	—	(6)	(6)
Disposal of treasury shares	26	—	—	2	2
Dividends	26	—	—	(11,124)	(11,124)
Reclassification from other components of equity to retained earnings		—	—	2,089	—
Total transactions with owners		—	—	(11,128)	(11,128)
Balance as of March 31, 2019	¥ (3,853)	¥ (6)	¥ 28,752	¥ 498,138	¥ 498,138

Consolidated Statement of Cash Flows

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

	Note	2018	2019
Millions of yen			
Cash flows from operating activities			
Net profit		¥ 53,448	¥ 48,627
Depreciation and amortization		12,887	13,976
Impairment losses		2,147	22,996
Changes in fair value of contingent consideration		(8,608)	(9,128)
Interest and dividend income		(2,430)	(3,702)
Interest expenses		394	178
Income tax expenses		31,418	16,419
(Increase) decrease in trade and other receivables		(2,934)	(3,630)
(Increase) decrease in inventories		(4,382)	(3,207)
Increase (decrease) in trade and other payables		10,493	(10,869)
Increase (decrease) in retirement benefits liabilities		276	(114)
Increase (decrease) in provisions		12,067	3,997
Others, net		442	(6,805)
Subtotal		105,218	68,738
Interest received		1,058	2,424
Dividends received		1,246	1,156
Interest paid		(338)	(144)
Income taxes paid		(13,764)	(23,463)
Net cash provided by operating activities		93,420	48,711
Cash flows from investing activities			
Purchase of property, plant and equipment		(5,129)	(9,265)
Proceeds from sales of property, plant and equipment		960	1,693
Purchase of intangible assets		(7,225)	(3,649)
Purchase of investments		(6,226)	(2,778)
Proceeds from sales and redemption of investments		31	—
Net decrease (increase) in short-term loan receivables		(5,468)	(21,050)
Proceeds from business transfer		9,423	—
Others, net		(2,889)	—
Net cash used in investing activities		(16,523)	(35,049)
Cash flows from financing activities			
Net increase (decrease) in short-term borrowings	21	(36,500)	(3,500)
Proceeds from long-term borrowings	21	35,300	—
Repayments of long-term borrowings	21	(9,400)	(2,960)
Redemption of bonds	21	(10,000)	(10,000)
Repayments of finance lease obligations	21	(1,064)	(1,059)
Dividends paid		(7,944)	(11,122)
Others, net		(2)	(4)
Net cash provided by financing activities		(29,610)	(28,645)
Net increase (decrease) in cash and cash equivalents		47,287	(14,983)
Cash and cash equivalents at beginning of year	20	105,603	147,775
Effect of exchange rate changes on cash and cash equivalents		(5,115)	4,504
Cash and cash equivalents at end of year	20	¥ 147,775	¥ 137,296

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

1. Reporting Entity

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, 2019. 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 <http://www.ds-pharma.com/>).

2. Basis of Preparation

(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 Group’s consolidated financial statements were approved on June 20, 2019 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 14 and 15)
- Estimated useful lives of intangible assets (Note 3)
- Recoverability of deferred tax assets (Note 10)
- Measurement of defined benefit obligations (Note 25)
- Fair value of financial assets (Note 27)
- Accounting treatment and measurement of provisions (Note 24)
- Fair value of contingent consideration related to business combination (Note 27)

(5) Changes in Significant Accounting Policies

The significant accounting policies applied to the Consolidated Financial Statements are same as those of prior fiscal year's consolidated financial statements, except for the accounting standards provided below.

IFRS		Overview of introduction or Revision
IFRS 15	Revenue from Contracts with Customers	New revenue recognition standards, replacing IAS 18, IAS 11, and related interpretations

The details of IFRS 15 Revenue from Contracts with Customers (issued in May 2014) and Clarifications to IFRS 15 (issued in April 2016) (collectively "IFRS 15") are presented in Note 3 Significant Accounting Policies (3) Revenue.

For the adoption of IFRS 15 Revenue from Contracts with Customers, the Group applied this Standard using the method, which is retrospectively with the cumulative effect of applying this Standard recognized at the date of initial application.

Compared with the application of the former accounting standards, the effect on the consolidated statement of profit or loss for the year ended March 31, 2019 and the consolidated statement of financial position as of March 31, 2019, is immaterial.

(6) 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 16	Leases	January 1, 2019	Fiscal year ending March 31, 2020	Revised accounting standards for recognition of leases

With the application of IFRS16 Leases, there is no distinction between previous operating leases and finance leases for lessee. In principle, the right-of-use assets and lease liabilities for the lease period are recognized for all leases on the consolidated statement of financial position at the commencement of the lease contracts. After recognition of right-of-use assets and lease liabilities, depreciation of right-of-use assets and interest on lease liabilities are recognized on the consolidated statement of profit or loss. In applying this Standard, a company can chose either the method of retrospectively applying to each of prior reporting periods to be presented in the consolidated financial statements and the method of recognizing the cumulative effect of adoption at the date of initial application. The Group uses the method of recognizing the cumulative effect of adoption at the date of initial application.

The major impact of these changes on the Group's financial position at the beginning of the fiscal year ending March 31, 2020 is expected to be the increases of total assets and total liabilities amounting to ¥14,566 million and ¥14,566 million, respectively, on the consolidated statement of financial position. The impact on the Group's consolidated statement of profit or loss is expected to be immaterial.

(7) Early application of the new standard

There are no Standards that were early applied by the Group.

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

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.

(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.

(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 transactions.

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.

(3) Revenue

The Group recognizes revenue based on the following five-step model:

Step 1: Identify the contract with a customer

Step 2: identify the performance obligations in the contract

Step 3: Determine the transaction price

Step 4: Allocate the transaction price to the performance obligations in the contract

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

The Group's revenue mainly consists of revenue from sales of products such as pharmaceuticals for medical treatments (sales of products), revenue from lump sum payments received arising from technology licensing-out agreements, milestone income and royalty income (revenue arising from intellectual property rights). The revenue recognition policies for each type of revenue are as follows.

1. Sales of products

For sales of products, the performance obligation is judged to have been satisfied and revenue is recognized upon delivery of the products, because the customer obtains control over the products upon delivery. Revenue is measured at the consideration promised in a contract with a customer, less product returns, discounts and rebates, to the extent that it is highly probable that a significant reversal will not occur.

2. Revenue arising from intellectual property rights

Lump sum payments received arising from agreements are recognized as revenue, after signing the technology licensing-out agreements and at a point in time that the development and marketing rights are granted to the third party.

Milestone income is recognized as revenue at a point in time of the achievement of a milestone defined in an agreement.

Royalty income is a consideration on the technology licensing-out agreement that is calculated based on the revenue of counterparty. It is recognized as revenue at the later of either when the revenue of counterparty is recognized or when the performance obligation is satisfied.

The Group's trade receivables are generally collected in one to three months after recognizing revenue on satisfying of performance obligations. In addition, the consideration for performance obligations does not include a significant financing component.

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(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
- Machinery and 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

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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

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 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 assets 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.

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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 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.

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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, 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.

1. Year ended March 31, 2018

	Millions of yen						
	2018						
	Reportable segments					Other Business (Note)	Total
	Pharmaceutical business						
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.

2. Year ended March 31, 2019

Millions of yen

2019							
	Reportable segments					Other Business (Note)	Total
	Pharmaceutical business						
	Japan	North America	China	Other Regions	Subtotal		
Revenues from external customers	¥ 129,287	¥ 252,542	¥ 24,749	¥ 14,287	¥ 420,865	¥ 38,402	¥ 459,267
Inter-segment revenues	71	—	—	—	71	35	106
Total	129,358	252,542	24,749	14,287	420,936	38,437	459,373
Segment profit (Core segment profit)	25,120	114,535	12,297	5,007	156,959	3,014	159,973
Other items							
Depreciation and amortization	2,509	7,086	527	685	10,807	88	10,895
Impairment losses	117	22,879	—	—	22,996	—	22,996

(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:

Revenue	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Total of reportable segments	¥ 424,103	¥ 420,936
Revenue of Other Business	42,878	38,437
Elimination of inter-segment revenue	(143)	(106)
Revenue on the consolidated financial statements	¥ 466,838	¥ 459,267

Profit	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Total of reportable segments	¥ 165,640	¥ 156,959
Segment profit of Other Business	2,650	3,014
Elimination of inter-segment profit	27	42
Research and development expenses (Note)	(86,881)	(82,891)
Gains on business transfers	9,178	148
Others	(10)	27
Core operating profit	90,604	77,299
Change in fair value of contingent consideration	6,371	9,128
Impairment losses	(2,147)	(22,996)
Litigation related expenses	(1,746)	—
Other income	249	710
Other expenses	(5,158)	(5,912)
Others	—	(345)
Operating profit in the consolidated financial statements	¥ 88,173	¥ 57,884

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

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Millions of yen

Other items	Total of reportable segments		Other Business		Adjustments		Amount in the consolidated financial statements	
	Year ended March 31, 2018	Year ended March 31, 2019	Year ended March 31, 2018	Year ended March 31, 2019	Year ended March 31, 2018	Year ended March 31, 2019	Year ended March 31, 2018	Year ended March 31, 2019
Depreciation and amortization	¥ 9,504	¥ 10,807	¥ 93	¥ 88	¥ 3,290	¥ 3,081	¥ 12,887	¥ 13,976

(4) Revenues

The details of revenues from external customers are as follows:

Millions of yen

	Year ended March 31, 2018	Year ended March 31, 2019
Sale of goods	¥ 462,117	¥ 454,088
Revenue arising from intellectual property rights	3,548	3,290
Other	1,173	1,889
Total	¥ 466,838	¥ 459,267

(5) Information by product and service

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

Millions of yen

	Year ended March 31, 2018	Year ended March 31, 2019
Pharmaceuticals	¥ 424,028	¥ 420,865
Others	42,810	38,402
Total	¥ 466,838	¥ 459,267

(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, 2018	Year ended March 31, 2019
Japan	¥ 188,806	¥ 170,916
North America	239,615	252,066
U.S.A. in North America	235,207	247,191
Others	38,417	36,285
Total	¥ 466,838	¥ 459,267

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

	As of March 31, 2018	As of March 31, 2019
Japan	¥ 74,221	¥ 75,973
North America	272,882	258,662
U.S.A. in North America	271,575	257,120
Others	1,399	1,427
Total	¥ 348,502	¥ 336,062

(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, 2018	Year ended March 31, 2019
McKesson Corporation	North America	¥ 82,506	¥ 84,453
Cardinal Health Inc.	North America	64,301	69,025
AmerisourceBergen Corporation	North America	59,783	66,692

5. Revenue

(1) Disaggregation of revenue and its relationship with reportable segments

The Group disaggregates revenue by type of goods and services. The relationship between disaggregated revenue and the reportable segments are as follows:

Year ended March 31, 2019

	Millions of yen						
	Reportable segments					Other Business (Note)	Total
	Pharmaceutical business				Subtotal		
	Japan	North America	China	Other Regions			
Sales of goods	¥ 127,117	¥ 251,321	¥ 24,668	¥ 12,581	¥ 415,687	¥ 38,401	¥ 454,088
Revenue arising from intellectual property rights	363	1,221	—	1,706	3,290	—	3,290
Other	1,807	—	81	—	1,888	1	1,889
Total	¥ 129,287	¥ 252,542	¥ 24,749	¥ 14,287	¥ 420,865	¥ 38,402	¥ 459,267

(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) Contract Balances

Contract balances of the Group mainly represent receivables (trade receivables and notes receivables) originating from contracts with customers, and are presented in Note 19 Trade and Other Receivables.

There was no revenue recognized during the year ended March 31, 2019 that was included in contract liability balance at the beginning of the current fiscal year. Also, there are no significant amounts of revenue recognized during the year ended March 31, 2019 from performance obligations satisfied (or partially satisfied) in the prior fiscal years.

(3) Assets recognized from the costs to obtain or fulfil a contract with a customer

There are no incremental costs of obtaining contracts or the costs incurred for fulfilling contracts that shall be recognized as assets.

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6. Selling, General and Administrative Expenses

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

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Salaries and bonuses	¥ 63,321	¥ 61,439
Retirement benefit expenses	4,740	5,107
Advertising and promotion expenses	38,212	37,975
Depreciation and amortization	6,538	7,858
Impairment losses	2,100	3,424
Change in fair value of contingent consideration (Note)	(6,371)	(9,128)
Others	75,111	73,764
Total	¥ 183,651	¥ 180,439

(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 27 Financial Instruments.

7. Other Income

The details of other operating income are as follows:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Gain on sale of property, plant and equipment	¥ 111	¥ 418
Gain on business transfers (Note)	8,895	—
Gain on sale of intangible assets	283	—
Others	128	467
Total	¥ 9,417	¥ 885

(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.

8. Other Expenses

The details of other operating expenses are as follows:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Donation	¥ 788	¥ 657
Business structure improvement expenses (Note)	3,723	3,806
Others	647	1,449
Total	¥ 5,158	¥ 5,912

(Note) Business structure improvement expenses are expenses for reformation of organizations and operations, including special retirement payments which were mainly incurred as a result of the Company's voluntary early retirement program, etc. for the years ended March 31, 2018 and 2019.

9. Finance Income and Finance Expenses

(1) Finance Income

The details of finance income are as follows:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Interest income		
Financial assets at amortized cost	¥ 1,184	¥ 2,546
Dividend income		
Financial asset at fair value through other comprehensive income	1,246	1,156
Exchange gain (net)	—	3,667
Total	¥ 2,430	¥ 7,369

(2) Finance costs

The details of finance costs are as follows:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Interest expenses		
Financial liabilities at amortized cost	¥ 394	¥ 178
Exchange loss (net)	5,207	—
Other	136	29
Total	¥ 5,737	¥ 207

10. Deferred Income Taxes and Income Tax Expenses

(1) Deferred Income Taxes

1. 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	
	As of March 31, 2018	As of March 31, 2019
Deferred tax assets	¥ 41,608	¥ 50,719
Deferred tax liabilities	95	—
Net deferred tax assets	¥ 41,513	¥ 50,719

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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:

Years ended March 31, 2018

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 profits 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.

Years ended March 31, 2019

Millions of yen					
	As of April 1, 2018	Recognized in profit or loss	Recognized in other comprehensive income	Others (Note)	As of March 31, 2019
Outsourced research expenses	¥ 11,099	¥ 1,113	¥ —	¥ (6)	¥ 12,206
Inventories	22,385	(5,389)	—	103	17,099
Property, plant and equipment	1,929	(22)	—	24	1,931
Intangible assets	(19,193)	3,265	—	(935)	(16,863)
Other financial assets	(12,654)	(3)	¥ (350)	(52)	(13,059)
Accrued expenses and provisions	13,551	(1,232)	—	441	12,760
Retirement benefits	7,158	—	918	3	8,079
Tax loss carryforwards	10,715	7,399	—	484	18,598
Tax credits	2,977	3,910	—	135	7,022
Undistributed earnings of foreign subsidiaries	(626)	2	—	—	(624)
Others	4,172	(763)	—	161	3,570
Total	¥ 41,513	¥ 8,280	¥ 568	¥ 358	¥ 50,719

(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		
	As of March 31, 2018	As of March 31, 2019
Tax loss carryforwards	¥ 1,478	¥ —
Tax credit carryforwards	5,089	5,389
Deductible temporary differences	91	11

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	
	As of March 31, 2018	As of March 31, 2019
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	1,478	—
Total	¥ 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	
	As of March 31, 2018	As of March 31, 2019
Not later than 1 year	¥ 274	¥ —
Later than 1 year and not later than 2 years	318	—
Later than 2 years and not later than 3 years	271	—
Later than 3 years and not later than 4 years	144	—
Later than 4 years	4,082	5,389
Total	¥ 5,089	¥ 5,389

5. Recoverability of deferred tax assets

Deferred tax assets as of March 31, 2019 was ¥91,451 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 March 31, 2018 and 2019.

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(2) Income Tax Expenses

1. Income tax expenses

The details of income tax expenses are as follows:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Current tax expenses	¥ 21,427	¥ 24,699
Deferred tax expense		
Origination and reversal of temporary differences	(3,586)	(8,280)
Change in income tax rate (Note)	13,577	—
Subtotal	9,991	(8,280)
Total	¥ 31,418	¥ 16,419

(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, 2018 and 2019. The normal statutory tax rate based on these taxes is 30.8% for the years ended March 31, 2018 and 30.6% for the years ended March 31, 2019. However, overseas subsidiaries are subject to income taxes in their respective countries of domicile.

	Year ended March 31, 2018	Year ended March 31, 2019
Normal statutory tax rate	30.8%	30.6%
Permanent non-deductible expenses such as entertainment expenses	2.4%	1.8%
Permanent non-taxable income such as dividend received	(0.1%)	(0.3%)
Tax credit for research and development expenses	(6.6%)	(6.5%)
Changes in unrecognized deferred tax assets	(0.9%)	(4.9%)
Difference of subsidiaries' applicable income tax rates	(2.5%)	7.5%
Changes in tax effect of undistributed earnings of subsidiaries	0.2%	— %
Effect of change in fair value of contingent consideration	(2.1%)	(3.6%)
Effect of change in tax rate	16.0%	— %
Others	(0.2%)	0.6%
Effective tax rate	37.0%	25.2%

11. Earnings per Share

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

	Year ended March 31, 2018	Year ended March 31, 2019
The basis for calculation of basic earnings per share		
Net profit attributable to owners of the parent (Millions of yen)	¥ 53,448	¥ 48,627
Amounts not attributable to ordinary shareholders of the parent (Millions of yen)	—	—
Net profit used to calculate basic earnings per share (Millions of yen)	53,448	48,627
Weighted average number of ordinary shares (Thousands of shares)	397,299	397,297
Earnings per share		
Basic earnings per share (Yen)	134.53	122.39

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

12. Other Comprehensive Income

The movement of other comprehensive income is as follows:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income		
Amounts arising during the year	¥ 12,186	¥ 1,217
Tax effect	(3,659)	(341)
Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income	8,527	876
Remeasurements of defined benefit liability (asset)		
Amounts arising during the year	(4,075)	(3,007)
Tax effect	1,251	918
Remeasurements of defined benefit liability (asset)	(2,824)	(2,089)
Exchange differences on translation of foreign operations		
Amounts arising during the year	(10,748)	8,766
Exchange differences on translation of foreign operations	(10,748)	8,766
Cash flow hedges		
Amounts arising during the year	(2)	24
Tax effect	1	(9)
Cash flow hedges	(1)	15
Total	¥ (5,046)	¥ 7,568

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13. 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 and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Total
Balance as of April 1, 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)	—
Sales and disposals	(519)	(3,473)	(4,525)	—	—	(8,517)
Foreign currency translation differences	(365)	(211)	(197)	(22)	(45)	(840)
Other	—	(296)	295	—	(16)	(17)
Balance as of March 31, 2018	96,974	84,001	30,056	6,306	2,708	220,045
Additions	399	1,068	765	—	8,094	10,326
Transfer from construction in progress	3,701	3,126	2,017	—	(8,844)	—
Sales and disposals	(5,377)	(4,849)	(2,489)	(1,235)	—	(13,950)
Foreign currency translation differences	302	169	158	18	34	681
Other	(15)	60	(120)	—	—	(75)
Balance as of March 31, 2019	¥ 95,984	¥ 83,575	¥ 30,387	¥ 5,089	¥ 1,992	¥ 217,027

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, 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)
Depreciation	(2,738)	(2,723)	(1,881)	—	—	(7,342)
Impairment losses	(375)	(60)	(57)	—	—	(492)
Sales and disposals	4,401	4,351	2,441	1,159	—	12,352
Foreign currency translation differences	(89)	(73)	(129)	—	—	(291)
Other	13	(56)	115	—	—	72
Balance as of March 31, 2019	¥ (59,111)	¥ (72,889)	¥ (25,451)	¥ (64)	¥ (27)	¥ (157,542)

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, 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
Balance as of March 31, 2019	36,873	10,686	4,936	5,025	1,965	59,485

(Note) 1. There is no capitalized borrowing cost for property, plant and equipment for the years ended March 31, 2018 and 2019.

2. Details of commitment in respect of acquisitions of property, plant and equipment are presented in Note 28. 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, 2017	¥ —	¥ 2,519	¥ —	¥ —	¥ 2,519
Balance as of March 31, 2018	—	2,225	—	—	2,225
Balance as of March 31, 2019	—	2,157	1	—	2,158

(3) Impairment losses

Impairment losses recognized for the year ended March 31, 2018 and 2019 were ¥2,147 million and ¥492 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, 2018 amounting to ¥2,147 million were mainly recognized in Selling, general and administrative expenses in the consolidated statement of profit or loss. Impairment losses were mainly caused 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.

Impairment losses recognized for the year ended March 31, 2019 amounting to ¥492 million yen were recorded in Cost of sales and research and development expenses in the consolidated statement of profit or loss by ¥99 million and ¥393 million, respectively. Impairment losses represented a reduction of carrying amount of buildings and structures, machinery and vehicles, and tools, furniture and fixtures to the recoverable amount, which is value in use, due to a decrease in the profitability in Japan segment and North America segment of pharmaceutical business.

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14. 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, 2018	Year ended March 31, 2019
Beginning balance	¥ 100,194	¥ 95,097
Foreign currency translation differences	(5,097)	4,251
Ending balance	¥ 95,097	¥ 99,348

2. Accumulated impairment losses

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Beginning balance	¥ —	¥ —
Impairment losses	—	—
Foreign currency translation differences	—	—
Ending balance	¥ —	¥ —

3. Carrying amount

	Millions of yen
Balance as of April 1, 2017	¥ 100,194
Balance as of March 31, 2018	95,097
Balance as of March 31, 2019	¥ 99,348

(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	
	As of March 31, 2018	As of March 31, 2019
Sunovion Pharmaceuticals Inc.	¥ 66,900	¥ 69,891
Tolero Pharmaceuticals, Inc.	¥ 21,010	¥ 21,949

(3) Impairment test of goodwill

In principle, the geographical business segment managed for internal reporting purposes is identified as a CGU used in the impairment test by the Group. Some business segments contain multiple CGUs. The North America segment of the pharmaceutical business are comprised of two individual CGUs, which are “excluding oncology area” and “oncology area”. All the goodwill recognized for the years ended March 31, 2018 and 2019 were attributed to the North America segment of the pharmaceutical business. The Group performs the impairment test of goodwill by the above two individual CGUs. The carrying amounts of goodwill attributable to the North America segment of the pharmaceutical business that were allocated to the two individual CGUs are as follows:

	Millions of yen	
	As of March 31, 2018	As of March 31, 2019
North America (excluding oncology area)	¥ 71,836	¥ 75,048
North America (oncology area)	23,261	24,300
Total	¥ 95,097	¥ 99,348

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

As the recoverable value of CGU is greater than the carrying amount as a result of the impairment tests as of March 31, 2018 and 2019, impairment losses are not recognized.

The discount rate used in the impairment test for goodwill is the weighted average cost of capital, etc. set by each CGU. The pre-tax discount rate used in the impairment test of goodwill were 9.0% - 17.0% and 9.5% -17.0% as of March 31, 2018 and 2019, 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 an impairment loss occurs low.

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15. 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, 2017	¥ 213,690	¥ 13,093	¥ 217	¥ 227,000
Individual acquisitions	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
Individual acquisition	334	2,905	10	3,249
Sales and disposals	(1)	(256)	—	(257)
Foreign currency translation differences	8,293	251	—	8,544
Other	566	4	—	570
Balance as of March 31, 2019	¥ 217,102	¥ 15,954	¥ 248	¥ 233,304

2. Accumulated amortization and accumulated impairment losses

Millions of yen

	Intangible assets related to products	Software	Other	Total
Balance as of April 1, 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)
Amortization	(4,734)	(1,890)	(10)	(6,634)
Impairment losses	(22,504)	—	—	(22,504)
Sales and disposals	1	213	—	214
Foreign currency translation differences	(688)	(210)	(1)	(899)
Other	(570)	(4)	—	(574)
Balance as of March 31, 2019	¥ (51,655)	¥ (10,085)	¥ (174)	¥ (61,914)

3. Carrying amount

Millions of yen

	Intangible assets related to products			Total
	Software	Other		
Balance as of April 1, 2017	¥ 191,941	¥ 5,098	¥ 75	¥ 197,114
Balance as of March 31, 2018	184,750	4,856	75	189,681
Balance as of March 31, 2019	165,447	5,869	74	171,390

- (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 March 31, 2018 and 2019 were ¥ 153,930 million, and ¥ 141,419 million, respectively.

(2) Significant intangible assets

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

Millions of yen

	As of March 31, 2018	As of March 31, 2019
Cynapsus Therapeutics Inc.		
APL-130277 (Apomorphine hydrochloride)	¥ 71,071	¥ 55,156
Tolero Pharmaceuticals, Inc.		
DSP-2033 (alvocidib)	25,500	26,640
TP-0903	16,150	16,872
Boston Biomedical, Inc.		
BBI608 (Napabucasin)	26,988	28,194

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 27.

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. In addition, there exist a risk of incurring impairment losses due to a decrease in the profitability associated with changes in market environment and other factors. 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.

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(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 exists, 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 unit. The pre-tax discount rate used in the impairment test of intangible assets were 6.0%-18.5% and 6.3%-17.0% as of March 31, 2018 and 2019, respectively.

As a result of impairment test, impairment losses amounting to ¥22,504 million were recognized for the year ended March 31, 2019. The impairment losses were recorded as Selling, general and administrative expenses and research and development expenses in the consolidated statement of profit or loss, and were ¥3,424 million and ¥19,080 million, respectively. There are no impairment losses recognized for the year ended March 31, 2018.

Impairment losses for the year ended March 31, 2019 amounting to ¥22,504 million were impairment loss on product marketing rights acquired from other companies in North America segment of pharmaceutical business amounting to ¥3,424 million, and impairment loss on in-progress research and development of sublingual film formulation of Apomorphine hydrochloride (Product code: APL-130277), which is aiming for a New Drug Application (NDA) to treat OFF episodes associated with Parkinson's disease, amounting to ¥19,080 million.

As for product marketing rights acquired from other companies, the total carrying amount is reduced, due to a decrease in the profitability.

As for in-progress research and development of Apomorphine hydrochloride (product code: APL-130277), the carrying amount was reduced to the extent of the recoverable amount of ¥55,156 million as the expected profitability would not be achieved. The recoverable amount is measured based on value in use, using the pre-tax discount rate of 10.0%-15.0%.

As for in-progress research and development excluding the above, the value in use is significantly greater than the carrying amount of that assets, even if key assumptions used in measuring the value in use change within a reasonable range, the Group considers the possibility of occurring an impairment loss low.

16. Lease

(1) Finance lease

The details of finance lease obligations are as follows:

	Millions of yen			
	Total minimum lease payments		Present value of total minimum lease payments	
	As of March 31, 2018	As of March 31, 2019	As of March 31, 2018	As of March 31, 2019
Within 1 year	¥ 726	¥ 765	¥ 702	¥ 737
Over 1 year, Within 5 years	1,467	1,330	1,445	1,306
Over 5 years	5	—	5	—
Total	¥ 2,198	¥ 2,095	¥ 2,152	¥ 2,043
Less: finance expenses	46	52		
Present value of total minimum lease payments	2,152	2,043		
Finance lease obligations (non-current)	1,450	1,306		
Finance lease obligations (current)	702	737		

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	
	As of March 31, 2018	As of March 31, 2019
Within 1 year	¥ 1,001	¥ 1,293
After 1 year, Within 5 years	2,586	4,284
After 5 years	3,022	3,966
Total	¥ 6,609	¥ 9,543

The Group uses many offices, warehouses, plants and equipment under operating lease contracts. 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 of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Total minimum lease payments	¥ 8,200	¥ 8,300

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17. Other Financial Assets

(1) Details of other financial assets

The details of other financial assets are as follows:

	Millions of yen	
	As of March 31, 2018	As of March 31, 2019
Financial assets at amortized cost		
Loan receivables	¥ 21,300	¥ 42,793
Others	2,716	2,917
Financial assets at fair value through profit or loss		
Derivative assets	79	—
Financial assets at fair value through other comprehensive income		
Equity securities, etc.	68,964	72,708
Total	¥ 93,059	¥ 118,418
Other financial assets (non-current)	70,993	74,668
Other financial assets (current)	22,066	43,750
Total	¥ 93,059	¥ 118,418

(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	
	As of March 31, 2018	As of March 31, 2019
Medipal Holdings Corporation	¥ 7,051	¥ 8,514
SanBio Company Limited	10,027	8,055
Suzuken Co., Ltd.	4,062	5,925
JCR Pharmaceuticals Co., Ltd.	5,160	5,542
Alfresa Holdings Corporation	3,886	5,170
BioElectron Technology Corporation	4,422	4,710
Ono Pharmaceutical Co., Ltd.	5,485	3,611
Mochida Pharmaceutical Co., Ltd.	2,026	3,076
HEALIOS K.K.	2,985	2,580
ANTEROGEN CO., LTD	2,462	1,978
Others	21,398	23,547
Total	¥ 68,964	¥ 72,708

2. Others

The dividend income derived from the financial assets measured at fair value through other comprehensive income held by the Group are ¥1,246 million and ¥1,156 million for the years ended March 31, 2018 and 2019, 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, 2018 and 2019 are as follows:

Millions of yen		
	Year ended March 31, 2018	Year ended March 31, 2019
Fair value at the time of disposal	¥ 31	¥ —
Accumulated gains (losses)	21	—
Dividend income	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 ¥15 million for the year ended March 31, 2018. There is no such reclassification for the year ended March 31, 2019.

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 ¥ (4,426) million for the year ended March 31, 2018, are reclassified from other components of equity to retained earnings. There is no such reclassification for the year ended March 31, 2019.

18. Inventories

The details of Inventories are as follows:

Millions of yen		
	As of March 31, 2018	As of March 31, 2019
Merchandise and finished goods	¥ 46,674	¥ 53,961
Work-in-process	3,345	1,098
Raw materials and supplies	10,150	11,830
Total	¥ 60,169	¥ 66,889

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 ¥863 million and ¥1,665 million for the years ended March 31, 2018 and 2019, respectively.

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19. Trade and Other Receivables

(1) Details of trade and other receivables

The details of trade and other receivables are as follows:

	Millions of yen	
	As of March 31, 2018	As of March 31, 2019
Financial assets measured at amortized cost		
Accounts receivable and notes receivable	¥ 110,583	¥ 115,250
Other receivables	2,400	2,701
Contract assets (Note)	—	810
Allowance for credit losses	(1)	(1)
Total	¥ 112,982	¥ 118,760
Trade and other receivables (non-current)	—	—
Trade and other receivables (current)	112,982	118,760
Total	¥ 112,982	¥ 118,760

(Note) Contract assets are variable consideration related to development milestones which is included in some technology licensing-out agreements. Variable consideration is recognized as revenue only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

(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 27. Financial Instruments.

20. Cash and Cash Equivalents

The details of cash and cash equivalents are as follows:

	Millions of yen	
	As of March 31, 2018	As of March 31, 2019
Financial assets measured at amortized cost		
Cash and deposits	¥ 113,428	¥ 96,342
Short-term investments (cash equivalents)	34,347	40,954
Total	¥ 147,775	¥ 137,296

21. Bonds and Borrowings

(1) Details of Bonds and borrowings

The details of Bonds and borrowings are as follows:

	Millions of yen			
	As of March 31, 2018	As of March 31, 2019	Average interest rate	Repayment due date
Bonds (other than current portion)	¥ —	¥ —	—	—
Current portion of bonds	10,000	—	—	—
Long-term borrowings (other than current portion)	30,940	27,980	0.18%	June 2020~ March 2023
Current portion of long-term borrowings	2,960	2,960	0.20%	—
Short-term borrowings	3,500	—	—	—
Total	¥ 47,400	¥ 30,940	—	—
Bonds and borrowings (non-current)	30,940	27,980	—	—
Bonds and borrowings (current)	16,460	2,960	—	—
Total	¥ 47,400	¥ 30,940	—	—

(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, 2019.

(2) Bond issuance conditions

The bond issuance conditions are summarized as follows:

Millions of yen							
Issuer	Bond name	Issuance date	As of March 31, 2018	As of March 31, 2019	Interest rate	Collateral	Maturity date
Sumitomo Dainippon Pharma Co., Ltd.	5th unsecured bonds	September 8, 2011	10,000	—	0.82%	No	September 7, 2018
Total	—	—	¥ 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, 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)
Balance as of March 31, 2018	3,500	33,900	10,006	2,152	49,558
Cash flows provided by financing activities	(3,500)	(2,960)	(10,000)	(1,059)	(17,519)
Other changes					
Additions due to acquisition of leased assets	—	—	—	886	886
Interest expenses	6	60	36	29	131
Payment of interests	(13)	(60)	(42)	(29)	(144)
Effect of foreign currency translation differences	7	—	—	64	71
Others	—	—	—	—	—
Balance as of March 31, 2019	—	¥ 30,940	—	¥ 2,043	¥ 32,983

22. Trade and Other Payables

The details of trade and other payables are as follows:

Millions of yen		
	As of March 31, 2018	As of March 31, 2019
Financial liabilities measured at amortized cost		
Accounts payable and notes payables	¥ 17,512	¥ 15,498
Other payables	41,196	33,740
Total	¥ 58,708	¥ 49,238
Trade and other payables (non-current)	—	—
Trade and other payables (current)	58,708	49,238
Total	¥ 58,708	¥ 49,238

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23. Other Financial Liabilities

The details of other financial liabilities are as follows:

	Millions of yen	
	As of March 31, 2018	As of March 31, 2019
Financial liabilities at amortized cost		
Deposit received	¥ 4,146	¥ 3,712
Others	1,758	1,854
Financial liabilities at fair value through profit or loss		
Contingent considerations	86,616	81,352
Others	33	99
Lease obligations	2,152	2,043
Total	¥ 94,705	¥ 89,060
Other financial liabilities (non-current)	88,427	80,387
Other financial liabilities (current)	6,278	8,673
Total	¥ 94,705	¥ 89,060

24. Provisions

(1) Movements of provisions

The movement of provisions is as follows:

Year ended March 31, 2019

	Millions of yen		
	Reserve for sales returns	Reserve for sales rebates	Total
Balance at the beginning of the year	¥ 12,570	¥ 71,863	¥ 84,433
Increase	3,773	82,521	86,294
Decrease (utilization)	(2,165)	(74,997)	(77,162)
Decrease (reversal)	(5,134)	—	(5,134)
Foreign currency translation differences	560	3,185	3,745
Balance at the end of the year	9,604	82,572	92,176
Provision (non-current)	—	—	—
Provision (current)	9,604	82,572	92,176
Total	¥ 9,604	¥ 82,572	¥ 92,176

(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.

25. 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	
	As of March 31, 2018	As of March 31, 2019
Present value of defined benefit obligations	¥ 101,380	¥ 102,007
Fair value of the plan assets (including retirement benefit trusts)	80,680	78,394
Net defined benefit (assets) liabilities	20,700	23,613
Retirement benefit liabilities	20,700	23,613
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, 2018	Year ended March 31, 2019
Balance at beginning of the year	¥ 95,378	¥ 101,380
Current service cost	3,352	3,406
Interest expense	725	727
Remeasurement of net defined benefit liability (asset)		
Changes in demographic assumptions	4,344	(38)
Changes in financial assumptions	1,406	2,255
Experience adjustments	102	(371)
Benefits paid	(3,929)	(5,777)
Foreign currency translation differences	(25)	20
Others	27	405
Balance at end of the year	¥ 101,380	¥ 102,007

(Note) The weighted average number of payment years of defined benefit obligations are 16.3 years and 16.7 years as of March 31, 2018 and 2019, respectively.

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3. Plan assets

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

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Balance at beginning of the year	¥ 79,004	¥ 80,680
Interest income	723	587
Benefits paid	(2,889)	(4,182)
Contributions by the employer	2,044	2,470
Remeasurement of defined benefit plans		
Return on plan assets	1,777	(1,161)
Others	21	—
Balance at end of the year	¥ 80,680	¥ 78,394

(Note) The Group is expected to pay contributions amounting to ¥ 2,382 million in the year ending March 31, 2020.

4. Components of plan assets

The details of plan assets by category are as follows:

	Millions of yen					
	As of March 31, 2018			As of March 31, 2019		
	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	¥ 14,988	¥ —	¥ 14,988	¥ 13,233	¥ —	¥ 13,233
Debt securities	39,667	—	39,667	40,777	—	40,777
General accounts of life insurance companies	—	8,740	8,740	—	8,852	8,852
Cash and cash equivalents	3,827	—	3,827	2,220	—	2,220
Others	—	13,458	13,458	—	13,312	13,312
Total	¥ 58,482	¥ 22,198	¥ 80,680	¥ 56,230	¥ 22,164	¥ 78,394

(Note) The retirement benefit trusts set for defined benefit pension plans consist of 8.1% and 7.5% in the total plan assets as of March 31, 2018 and 2019 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:

	As of March 31, 2018	As of March 31, 2019
Discount rate (%)	0.7	0.6

6. Sensitivity analysis

The effects of changes in the significant actuarial assumptions on the defined benefit obligations as of March 31, 2018 and 2019 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 of yen	
	As of March 31, 2018	As of March 31, 2019
In case that the discount rate increases by 0.5%	¥ (6,890)	¥ (7,225)
In case that the discount rate decreases by 0.5%	¥ 6,740	¥ 6,934

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 ¥2,213 million and ¥2,373 million for the years ended March 31, 2018 and 2019, respectively.

(4) Other Employee benefit expenses

The employee benefit expenses for the years ended March 31, 2018 and 2019 are as follows:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Salaries	¥ 67,419	¥ 65,670
Bonuses	21,852	20,283
Retirement benefit expenses	7,416	7,005
Business structure improvement expenses	3,686	3,007
Others	12,923	12,891
Total	¥ 113,296	¥ 108,856

26. Share Capital and Other Equity Items

(1) Share capital

The numbers of shares authorized and the changes in shares issued are as follows:

	Thousands of shares	
	Year ended March 31, 2018	Year ended March 31, 2019
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.

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(2) Treasury shares

The changes of number of treasury shares are as follows:

	Thousands of shares	
	Year ended March 31, 2018	Year ended March 31, 2019
Balance at the beginning of the year	600	601
Changes during the year	1	2
Balance at the end of the year	601	603

(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.

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, 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

(ii) For the year ended March 31, 2019

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
Meeting of the Board of directors (October 30, 2018)	Ordinary share	¥ 3,576	¥ 9.00	September 30, 2018	December 3, 2018

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, 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

(ii) For the year ended March 31, 2019

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 20, 2019)	Ordinary share	¥ 7,549	¥ 19.00	March 31, 2019	June 21, 2019

27. 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.

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

(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.

As there are no financial assets or credit-impaired financial assets of which significant credit risk has increased significantly after the initial recognition, the carrying amount by credit risk category of financial instruments at the end of each fiscal year is not presented.

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 of the Group are not presented, as they are immaterial

(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:

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	¥ —

As of March 31, 2019

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	¥ 30,940	¥ 31,099	¥ 3,015	¥ 3,007	¥ 5,000	¥ 20,077	¥ —	¥ —
Total	¥ 30,940	¥ 31,099	¥ 3,015	¥ 3,007	¥ 5,000	¥ 20,077	¥ —	¥ —

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, 2018	As of March 31, 2019
Receivables	\$ 1,133,520	\$ 1,475,530
Payables	97,338	102,848
Net exposures of the consolidated statement of financial position	1,036,182	1,372,682
Forward foreign exchange contracts	(100,757)	(70,520)
Net exposures	\$ 935,425	\$ 1,302,162

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, 2019.

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 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 ¥ 3,437 million and ¥ 5,016 million as of March 31, 2018 and 2019, 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

For financial instruments measured at fair value, the fair value developed observability of the inputs into the valuation techniques used in measurement are categorized within the following three levels.

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 quoted 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 yen			
	As of March 31, 2018		As of March 31, 2019	
	Carrying amount	Fair value	Carrying amount	Fair value
Financial liabilities at amortized cost				
Bonds	¥ 10,000	¥ 10,032	¥ —	¥ —
Borrowings	37,400	37,370	30,940	30,956
Total	¥ 47,400	¥ 47,402	¥ 30,940	¥ 30,956

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 quoted 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 March 31, 2018 and 2019.

(i) As of March 31, 2018

	Millions of yen			
	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

(ii) As of March 31, 2019

	Millions of yen			
	Level 1	Level 2	Level 3	Total
Financial assets at fair value through other comprehensive income				
Investment securities, etc.	55,766	—	16,942	72,708
Total	¥ 55,766	¥ —	¥ 16,942	¥ 72,708
Financial liabilities at fair value through profit or loss				
Contingent consideration	—	—	81,352	81,352
Others	—	99	—	99
Total	¥ —	¥ 99	¥ 81,352	¥ 81,451

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
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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, 2018	As of March 31, 2019
Balance at the beginning of the year	¥ 11,851	¥ 13,392
Purchase	6,205	2,501
Changes in financial assets at fair value through other comprehensive income	(4,633)	1,049
Sales/settlement	(31)	—
Balance at the end of the year	¥ 13,392	¥ 16,942

(ii) Financial liabilities

	Millions of yen	
	As of March 31, 2018	As of March 31, 2019
Balance at the beginning of the year	¥ 103,516	¥ 86,616
Changes in fair value of contingent consideration (Note)	(6,371)	(9,128)
Settlement	(5,543)	—
Foreign currency translation differences	(4,986)	3,864
Balance at the end of the year	¥ 86,616	¥ 81,352

(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. The discounted cash flow method is used to measure fair value, and the pre-tax discount rate of 16.0%-17.0% are applied. For unlisted securities for which fair value approximates their net asset value, the fair value is mainly calculated by valuation techniques based on the 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, 2019, and it is possible to pay a maximum amount of

USD 515 million (¥57,165 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 (¥209,790 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, 2019, and it is possible to pay a maximum amount of USD 210 million (¥23,310 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, 2019, and it is possible to pay a maximum amount of USD 430 million (¥47,730 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 (¥16,650 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 ¥342,661 million (undiscounted) and ¥354,645 million (undiscounted) as of March 31, 2018 and 2019, respectively. The amounts payable by due date of contingent consideration are not presented because of the uncertainty.

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, 2018	Year ended March 31, 2019
Revenue	Increase by 5%	¥ 2,445	¥ 2,553
	Decrease by 5%	(2,551)	(2,220)
Discount rate	Increase by 0.5%	(1,647)	(1,554)
	Decrease by 0.5%	1,753	1,665

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2019 and 2018

28. Capital Expenditure Commitments

Capital expenditure commitments of acquisition of assets are as follows:

	Millions of yen	
	As of March 31, 2018	As of March 31, 2019
Property, plant and equipment	¥ 7,073	¥ 3,930
Intangible assets	74,233	76,508
Total	¥ 81,306	¥ 80,438

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.

29. Subsidiaries and Associates

The significant subsidiaries and associates of the Group as of March 31, 2019 are as follows:
Major Consolidated Subsidiaries

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. (Other Business)	100%

30. 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:

Type	Company name	Description of transaction	Millions of yen			
			Year ended March 31, 2018		Year ended March 31, 2019	
			Transaction amount	Outstanding balance	Transaction amount	Outstanding balance
Parent company	Sumitomo Chemical Company, Limited	Lending and collection of funds	¥ 5,467	¥ 21,250	¥ 21,050	¥ 42,750

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:

	Millions of yen	
	Year ended March 31, 2018	Year ended March 31, 2019
Basic remuneration and bonus	¥ 440	¥ 455

31. Subsequent Events

There are no significant subsequent events.

Independent Auditor's Report

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

We have audited the accompanying consolidated financial statements of Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated statement of profit or loss, statement of comprehensive income, statement of financial position, statement of changes in equity and statement of cash flows for the year then ended March 31, 2019, 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, 2019, and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

KPM G AZSA LLC

June 20, 2019
Osaka, Japan

Principal Shareholders

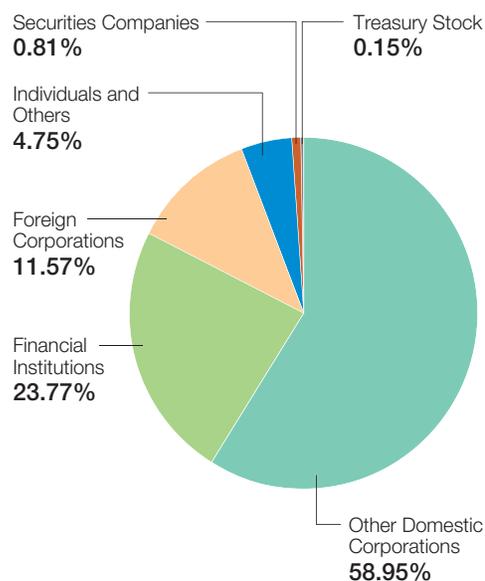
(As of March 31, 2019)

Name	No. of Shares Held (Thousands of Shares)	Percentage of Shareholding
Sumitomo Chemical Co., Ltd.	205,634	51.76
The Master Trust Bank of Japan, Ltd. (Trust account)	28,769	7.24
Inabata & Co., Ltd.	20,182	5.08
Japan Trustee Services Bank, Ltd. (Trust account)	12,756	3.21
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)	3,251	0.82
Japan Trustee Services Bank, Ltd. (Trust account 5)	2,908	0.73

Note: The 7,000,000 shares of the Company which are held by SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits) and which were contributed by Sumitomo Mitsui Banking Corporation, were placed in a retirement benefit trust account. After deducting the aforementioned shares that were contributed, Sumitomo Mitsui Banking Corporation holds 1,125,000 shares of the Company (shareholding ratio: 0.28%).

Composition of Shareholders

(As of March 31, 2019)



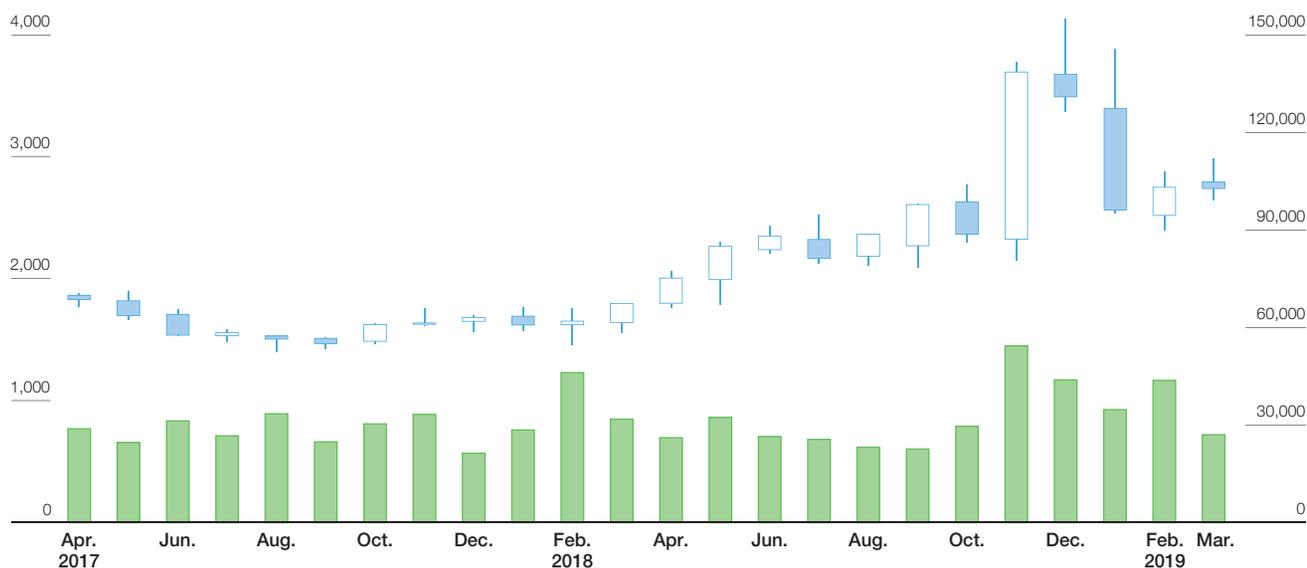
Share Price Range and Trading Volume

Share Price

(Yen)

Trading Volume

(Thousands of shares)





Corporate Data As of April 1, 2019

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, 2 Plants (Mie, Oita), 2 Research Laboratories (Osaka), 2 Distribution Centers (Hyogo, Saitama)
Major Consolidated Subsidiaries	DSP Gokyo Food & Chemical Co., Ltd. DS Pharma Animal Health Co., Ltd. DS Pharma Promo Co., Ltd. Sunovion Pharmaceuticals Inc. (U.S.) Boston Biomedical, Inc. (U.S.) Tolero Pharmaceuticals, Inc. (U.S.) Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (China)



IR Site
<https://www.ds-pharma.com/ir/>



CSR Site
<https://www.ds-pharma.com/csr/>

